BONE CARE INTERNATIONAL INC
Form 10-Q
November 08, 2004

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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 September 30, 2004

OR

o 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 of 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 o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes x No o

As of November 1, 2004, there were 19,420,935 shares of the registrant s common stock issued and outstanding.

BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended September 30, 2004

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Bone Care® is a registered trademark of Bone Care International, Inc. in the U.S. Hectorol® is a registered trademark of Bone Care International, Inc., in the U.S., the European Community, Japan and other selected countries. Hectorol® is Bone Care s brand name for the active drug substance, doxercalciferol. This filing may also include trademarks of other companies.

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BONE CARE INTERNATIONAL, INC.

Condensed Balance Sheets
(unaudited)

	September 30, 2004	June 30, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,533,847	$ 45,325,671
Marketable securities	48,777,170	68,776,698
Accounts receivable, net	7,471,918	4,732,698
Inventory	5,386,495	6,785,288
Other current assets	2,456,969	2,336,362
Total current assets	127,626,399	127,956,717
Long-term securities	907,119	908,376
Property, plant and equipment, net	1,513,431	1,526,638
Patent fees, net	1,854,394	1,785,045
Goodwill	359,165	359,165
	$132,260,508	$132,535,941
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,746,056	$ 6,490,488
Accrued compensation payable	1,053,280	2,890,728
Accrued clinical study and research costs	607,132	1,001,818
Other accrued liabilities	232,132	214,010
Deferred revenues	1,049,250	
Allowance for sales returns	183,804	100,000
Total current liabilities	8,871,654	10,697,044
Long-term liabilities	87,315	100,388
Commitments and contingencies (Note 2)		
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 19,415,938 and 19,395,585 shares as of September 30, 2004 and June 30, 2004, respectively	178,977,184	178,868,933

Unearned compensation	(2,208,653)	(2,411,054)
Accumulated other comprehensive income	10,309	
Accumulated deficit	(53,477,301)	(54,719,370)
Total shareholders equity	123,301,539	121,738,509
	$132,260,508	$132,535,941

The accompanying notes to the condensed financial statements are an integral part of these statements.

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BONE CARE INTERNATIONAL, INC.

Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,	
	2004	**2003**
Product Sales	$17,373,044	$ 8,125,042
Cost and expenses:		
Cost of product sales	4,398,366	2,417,644
Research and development	2,314,504	1,793,160
Selling, general and administrative	9,900,250	6,081,199
	16,613,120	10,292,003
Income / (loss) from operations	759,924	(2,166,961)
Interest income	482,145	64,909
Net income / (loss)	$ 1,242,069	$ (2,102,052)
Net income / (loss) per common share		
Basic	0.06	(0.15)
Diluted	0.06	(0.15)
Shares used in computing basic and diluted net income / (loss) per common share		
Basic	19,410,418	14,240,725
Diluted	20,796,740	14,240,725

The accompanying notes to the condensed financial statements are an integral part of these statements.

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BONE CARE INTERNATIONAL, INC.

Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended September 30,	
	2004	**2003**
Cash flows from operating activities:		
Net income/ (loss)	$ 1,242,069	$(2,102,052)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	202,401	227,500
Depreciation of fixed assets	195,061	185,764
Amortization of patents	53,920	39,372
(Gain) / loss on disposal of fixed assets	26,795	(7,876)
Inventory write-off	22,730	
Loss on write-off of patents	5,297	
Changes in assets and liabilities:		
Increase in accounts receivable	(2,739,220)	(528,879)
(Increase) decrease in inventory	1,376,063	(660,363)
Increase in other current assets	(120,607)	(187,967)
Increase (decrease) in accounts payable	(744,432)	1,845,283
Decrease in accrued liabilities	(2,199,654)	(1,476,881)
Decrease in long-term liabilities	(13,073)	(649,880)
Increase in deferred revenues	1,049,250	
Increase (decrease) in allowance for sales returns	83,804	(137,600)
Net cash used in operating activities	(1,559,596)	(3,453,579)
Cash flows from investing activities:		
Maturities of marketable securities	39,597,452	2,291,769
Purchases of marketable securities	(19,586,358)	
Proceeds from the sale of property, plant and equipment	76,131	17,753
Purchases of property, plant and equipment	(284,780)	(99,587)
Patent fees	(128,566)	(98,331)
Net cash provided by investing activities	19,673,879	2,111,604
Cash flows from financing activities:		
Proceeds from exercise of stock options	108,251	235,174
Repayment of capital lease obligation	(14,358)	

Net cash provided by financing activities	93,893	235,174
Net increase (decrease) in cash and cash equivalents	18,208,176	(1,106,801)
Cash and Cash Equivalents at beginning of period	45,325,671	3,065,218
Cash and Cash Equivalents at end of period	$ 63,533,847	$ 1,958,417

The accompanying notes to the condensed financial statements are an integral part of these statements.

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BONE CARE INTERNATIONAL, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

(1) Basis of Presentation and Summary of Significant Accounting Policies

Description of Business

Bone Care International, Inc. (Bone Care, we, or the Company) is a specialty pharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our current commercial and therapeutic focus is in nephrology utilizing Hectorol®, our novel vitamin D hormone therapy, to treat secondary hyperparathyroidism in patients with moderate to severe chronic kidney disease and end-stage renal disease. Vitamin D therapies are currently used to treat patients with a variety of diseases, including kidney disease, osteoporosis and psoriasis, and research has shown that they may be useful in treating certain cancers such as prostate, breast and colon. In June 1999, we received approval from the U.S. Food and Drug Administration for Hectorol® 2.5 mcg Capsules, and in April 2000 we received approval for Hectorol® Injection, for the treatment of secondary hyperparathyroidism in end-stage renal disease. In April 2004, we received approval from the U.S. Food and Drug Administration for Hectorol® 0.5 mcg Capsules for the treatment of secondary hyperparathyroidism in moderate to severe chronic kidney disease.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared from the books and records of Bone Care in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Interim results are not necessarily indicative of the results that may be expected for the year. These financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended June 30, 2004 included in the Company s Form 10-K as filed with the Securities and Exchange Commission.

Revenue Recognition Policy

We record sales and the related costs of Hectorol® 2.5 mcg Capsules and Hectorol® Injection based on shipments to customers reduced by the estimated future returns and allowances. Revenue is recognized at the time of shipment as risk of loss has transferred to the customer, delivery has occurred, and collectibility is reasonably certain. Customers have a right to return product in accordance with our returns policy. In accordance with Statement of Financial Accounting Standard (SFAS) No. 48, Revenue Recognition When Right of Return Exists , our September 30, 2004 and June 30, 2004 balance sheets include an accrual of $183,804 and 100,000 respectively, for the estimated amount of future returns, based on historical experience related to Hectorol® 2.5 mcg Capsules and Hectorol® Injection. In the quarter ended September 30, 2004, we began selling our newly approved product, Hectorol® 0.5 mcg Capsules. Due to insufficient historical data as it relates to Hectorol® 0.5 mcg Capsules and since this product is promoted in a new market segment, pre-dialysis chronic kidney disease, we utilized various data points for purposes of recognizing revenue and for estimating returned goods reserves. These data points included prescription information and wholesaler inventory levels. For the quarter ended September 30, 2004, we have recognized $251,020 of revenue related to Hectorol® 0.5 mcg Capsules and have recorded $1,049,250 in our balance sheet as deferred revenue.

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Segments

The Company operates in one segment with our current commercial focus in nephrology utilizing Hectorol®, our novel vitamin D hormone therapy, to treat secondary hyperparathyroidism in patients with moderate to severe chronic kidney disease, pre-dialysis and end-stage renal disease. We currently derive our revenues from three products, Hectorol® Injection, Hectorol® 2.5 mcg Capsules and Hectorol® 0.5 mcg Capsules. Revenue recognized by product is as follows:

	Three Months Ended September 30,	
	2004	**2003**
Hectorol® Injection	$15,799,977	$7,036,059
Hectorol® 2.5 mcg Capsules	1,322,047	1,088,983
Hectorol® 0.5 mcg Capsules	251,020	
	$17,373,044	$8,125,042

Cash and Cash Equivalents

Highly liquid investments with original maturities of ninety days or less at the time of purchase are considered to be cash equivalents. Other highly liquid marketable securities with remaining maturities of one year or less at the balance sheet date are classified as marketable securities. Bone Care classifies its investment securities as held to maturity when management has the positive intent and ability to hold the securities to maturity. All other investment securities are classified as available for sale. Those investments classified as available for sale are carried in the balance sheet at fair value, with unrealized gains and losses recorded within accumulated other comprehensive income, net of tax. Those investments classified as held to maturity are carried in the balance sheet at amortized cost, net of unamortized discounts or premiums. Dividends, interest income and amortization of discounts and premiums are recorded in current earnings.

Marketable Securities

Securities as of September 30, 2004 include the following:

	Amortized Cost	**Unrealized Gain**	**Unrealized Loss**	**Fair Value**
Held-to-Maturity				
Commercial paper	$31,004,571	$32,805	$(17,103)	$31,020,273
Available-for-Sale				
Municipal bonds	22,200,000			22,200,000
Corporate bonds	6,550,000			6,550,000

Mutual funds	10,027,170			10,027,170
	38,777,170			38,777,170
Total marketable securities	$69,781,741	$32,805	$(17,103)	$69,797,443

Held-to-Maturity securities include $20,097,452 of commercial paper classified as cash equivalents in the balance sheet at September 30, 2004 as the securities are highly liquid with maturity dates ninety days or less at the balance sheet date.

At September 30, 2004, the unrealized loss on commercial paper represents losses on fixed income securities and is primarily attributable to changes in market interest rates. We do not believe the unrealized loss on these securities represents an other-than temporary impairment based on the short-term duration of the securities, the issuers high credit quality and our ability and intent to hold the investments for the foreseeable future. The commercial paper has been in a loss position for less than twelve months.

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Securities as of June 30, 2004 included the following:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Held-to-Maturity				
Commercial paper	$40,026,698	$	$(38,594)	$39,988,104
Corporate bonds	1,908,376	35,463		1,943,839
	41,935,074	35,463	(38,594)	41,931,943
Available-for-Sale				
Municipal bonds	23,750,000			23,750,000
Corporate bonds	4,000,000			4,000,000
	27,750,000			27,750,000
Total marketable securities	$69,685,074	$35,463	$(38,594)	$69,681,943

Scheduled maturities of marketable securities at September 30, 2004:

	Available-For-Sale		Held-To-Maturity	
	Cost	Fair Value	Amortized Cost	Fair Value
Fiscal Year				
2005	$38,777,170	$38,777,170	$30,097,452	$30,080,349
2006			907,119	939,924
Total	$38,777,170	$38,777,170	$31,004,571	$31,020,273

Investments are considered to be impaired when a decline in fair value is judged to be other than temporary. If the cost of an investment exceeds its fair value, we evaluate, among other factors, general market conditions, the duration and extent to which fair value is less than cost, and our intent and ability to hold the investment. Once a decline in fair value is determined to be other than temporary, an impairment charge is recorded and a new cost basis in the investment is established.

In March 2004, the Financial Accounting Standards Board (FASB) ratified the recognition and measurement guidance and certain disclosure requirements for impaired securities as described in Emerging Issues Task Force (EITF) Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments. The recognition and measurement guidance will be applied to other-than-temporary impairment evaluations in reporting periods beginning with our first fiscal quarter 2005. In September 2004, the FASB Staff Position Board has directed the FASB to delay the effective date for the measurement and recognition guidance contained in paragraphs 10-20 of EITF Issue No. 03-1. We have not yet adopted the EITF No. 03-1; however, we believe the future adoption of the recognition and measurement guidance in EITF Issue No. 03-1 will not have a material impact on our financial statements.

Accounts Receivable

Accounts receivable is stated net of allowance for doubtful accounts of $65,842 and $72,070 at September 30, 2004 and June 30, 2004, respectively.

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Inventory

Inventory is stated at the lower of cost or market; cost is determined by the first-in, first-out method. Inventory consisted of the following:

	September 30, 2004	June 30, 2004
Raw materials	$1,728,123	$1,659,734
Work in process	294,385	89,388
Finished goods	3,363,987	5,036,166
	$5,386,495	$6,785,288

Finished goods inventory at September 30, 2004 includes $41,590 of our Hectorol® 0.5 mcg Capsules owned by our wholesale customers for which we have not yet recognized revenue.

Property, Plant and Equipment

We periodically evaluate the carrying value of property and equipment in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the expected future undiscounted cash flows are less than the carrying amount of the asset, a loss is recognized for the differences between the fair value and the carrying value of the asset. Property, plant and equipment consisted of the following:

	September 30, 2004	June 30, 2004
Leasehold Improvements	$ 588,632	$ 588,632
Furniture and Fixtures	524,455	524,455
Machinery and Other Equipment	3,536,653	3,502,221
	4,649,740	4,615,308
Less: Accumulated Depreciation	(3,136,309)	(3,088,670)
	$ 1,513,431	$ 1,526,638

Intangibles

Legal costs incurred to register patents are amortized on a straight-line basis over the life of the patent. We continuously evaluate whether events and circumstances have occurred that indicate the remaining estimated useful life of intangibles may warrant revision or that the remaining balance of intangibles may not be recoverable. When factors indicate that intangibles should be evaluated for possible impairment, we assess recoverability from expected future operations using undiscounted cash flows. Impairment would be recognized in operating results if the expected undiscounted cash flows were less than the carrying value of the asset. Impairment would be measured using fair value. Patent fees are stated net of accumulated amortization of $1,365,183 and $1,131,427 at September 30, 2004 and June 30, 2004, respectively.

The Company evaluates goodwill in accordance with SFAS No. 142, Goodwill and Other Intangible Assets. Under SFAS No. 142, an assessment of fair value is used to test for impairment of goodwill on an annual basis or when circumstances indicate a possible impairment. The Company s annual assessment will be performed during the quarter ended June 30, 2005. The Company does not expect any indicators of impairment.

Stock Based Compensation

Stock-based compensation related to employees and non-employee directors is recognized using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and thus there is no compensation expense for options granted with exercise prices equal to the fair value of our common stock on the date of the grant. Restricted stock awards are valued at the fair value of our common stock on the date of grant and reflected in the equity section as part of common stock. Compensation expense is recognized for restricted stock awards on a straight-line basis over the vesting period of the entire award with the balance of unearned compensation reflected in the equity section of the

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balance sheet.

Pro forma net income/(loss) per share had we elected to adopt the fair-value based method of SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of SFAS 123, are as follows:

	Three Months Ended September,	
	2004	2003
Net income/ (loss)	$ 1,242,069	$(2,102,052)
Compensation expense recognized	210,401	227,500
Less pro forma compensation expense	(1,521,251)	(885,996)
Pro forma loss	$ (68,781)	$(2,760,548)
Net income/ (loss) per share basic		
As reported	$ 0.06	$ (0.15)
Pro forma	$ 0.00	$ (0.19)
Net income/ (loss) per share diluted		
As reported	$ 0.06	$ (0.15)
Pro forma	$ 0.00	$ (0.19)

Income Taxes

As of June 30, 2004, we have federal net operating loss carryforwards of $50,872,000 and research and development tax credit carryforwards of $2,394,000, which expire in 2011 through 2024. As of June 30, 2004, we also have state net operating loss carryforwards of $46,036,000 and research and development tax credit carryforwards of $756,000, which expire in 2006 through 2024. Realization of deferred tax assets is dependent upon generating sufficient taxable income prior to the expiration of the related carryforward period. Because we have had cumulative losses in recent years, management has concluded that a valuation allowance is needed for net deferred tax assets. At the point in time in which we have realized a cumulative profit over a period of the three consecutive fiscal years, management may have a sufficient basis to conclude that some or all of the valuation allowance may be reduced.

Concentration of Risk

We currently have no internal manufacturing capabilities. We rely on third-party contractors to produce our active pharmaceutical ingredient and for the subsequent manufacturing and packaging of finished drug products.

We purchase our active pharmaceutical ingredient for Hectorol® from a sole supplier, although we are currently in the process of obtaining regulatory approval for an additional supplier. In addition, we rely on one manufacturer for Hectorol® Injection, one supplier to formulate Hectorol® Capsules and another supplier to package Hectorol® Capsules. Although, we believe that other manufacturers, suppliers, formulators, and vendors may be available to provide these goods and services to us, any change in suppliers could cause an increase in costs, a delay in manufacturing and a possible loss of sales, any of which would affect operating results adversely.

Our customers primarily consist of wholesale distributors of pharmaceutical products. We utilize these wholesale distributors as the principal means of distributing our products to clinics and hospitals. Five individual wholesale distributors comprised 91% of the net accounts receivable balance as of September 30, 2004. These same five wholesale distributors represented 91% of our product sales for the quarter ended September 30, 2004, with the largest of the five wholesale distributors representing 32% of product sales. As of June 30, 2004 five individual customers comprised 96% of the net accounts receivable balance. These same five customers represented 93% of our product sales for the quarter ended June 30, 2004, with the largest of the five companies representing 35% of product sales.

Advertising Expenses

We expense advertising costs as incurred. Advertising expenses were $893,717 and $307,921 for the quarters ended September 30, 2004 and 2003, respectively.

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Use of Estimates

In preparing the financial statements in accordance with accounting principles generally accepted in the U.S., management makes estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Reclassifications

Certain prior period amounts in the condensed financial statements and the notes have been reclassified to conform to the fiscal 2005 presentation.

(2) Commitments and Contingencies

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of September 30, 2004:

Payments due by Fiscal Period

	Total	Remaining in 2005	2006 2007	2008-2009	2010 and thereafter
Purchase Commitments (1)	$ 9,008,376	$9,008,376	$	$	$
Operating Lease Obligations (2)	4,731,369	760,712	2,103,499	1,602,494	264,664
Capital Lease Obligations (3)	108,591	40,469	68,122		
Total	$13,848,336	$9,809,557	$2,171,621	$1,602,494	$264,664

(1) Purchase commitment for active pharmaceutical ingredients used in Hectorol® production and pre-clinical research and prescriber data for market research.

(2) Represents primarily office and laboratory facilities in Middleton, WI and operating leases, primarily for fleet vehicles used by field personnel.

(3) Represents fleet vehicles used by field personnel that were sold and leased back.

(3) Net Income (Loss) Per Share

Basic and diluted earnings (loss) per share are based upon the weighted-average number of common shares outstanding. Diluted earnings per share are based upon the weighted-average number of common shares and dilutive potential common shares outstanding. For the three months ended September 30, 2004, stock options to purchase 69,890 shares of common stock were outstanding but not included in the computation of diluted earnings per share because the options exercise prices were greater than the average market price of the common shares and therefore

their effect would be anti-dilutive. For the three months ended September 30, 2003, options to purchase common stock have been excluded from the calculation of diluted loss per share, as the impact of these options on diluted loss per share would be anti-dilutive. The excluded options totaled 2,143,420.

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The following table sets forth the computation for basic and diluted earnings (loss) per share:

	Three Months Ended September 30,	
	2004	2003
Net income/ (loss) as reported	$ 1,242,069	$ (2,102,052)
Shares:		
Basic weighted average shares outstanding	19,410,418	14,240,725
Dilutive effect of stock options	1,386,322	
Dilutive weighted average shares outstanding	20,796,740	14,240,725
Earnings (loss) per share:		
Basic	$ 0.06	$ (0.15)
Diluted	$ 0.06	$ (0.15)

(4) Comprehensive Income (loss)

Total comprehensive income was $1,252,377 for the quarter ended September 30, 2004 and total comprehensive loss was $2,102,052 for the quarter ended September 30, 2003. Comprehensive income or loss is comprised of net income or loss and changes in unrealized gains and losses on available-for-sale securities.

(5) Co-promotion Agreement

On July 14, 2004, we entered into a multi-year co-promotion agreement for the launch and commercialization of Hectorol® 0.5 mcg Capsules with nephrologists in pre-dialysis Stages 3 and 4 chronic kidney disease. Under the terms of the agreement, Cardinal Health PTS, LLC will provide contract sales force and medical communication services to support a specified level of promotion. We will sell Hectorol® 0.5 mcg Capsules through its distribution network and support the promotional effort through its nephrology focused sales force with an additional specified level of investment. For its efforts, Cardinal Health will receive a variable co-promotion fee based on the performance of Hectorol® 0.5 mcg Capsule sales. The fee as a percentage of Hectorol® 0.5 mcg Capsule revenue declines gradually over the term of the agreement. Initial sales of Hectorol® 0.5 mcg Capsules were recognized in the current quarter ended September 30, 2004. Refer to Note 1 above.

(6) Subsequent Event

On October 27, 2004, we received a subpoena from the U.S. Department of Justice, Eastern District of New York. The subpoena requires production of a wide range of documents relating to the operations of the Company. We intend to meet with representatives from the Justice Department to discuss the scope of the subpoena and the production of responsive documents. We will cooperate with the request of the Justice Department.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our audited financial statements, including the related notes, presented in our Annual Report on Form 10-K for the year ended June 30, 2004.

Statements included in this Form 10-Q which do not relate solely to historical matters are intended to be, and are hereby identified as, forward looking statements for purposes of the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward looking statements may be identified by words including believe, may, will, estimate, continue, anticipate, intend, plan, expect and similar expressions. Forward looking statements, including without limitation those relating to our future business prospects, sales, cost of sales, profitability, financial resources or products and production schedules, are subject to risks and uncertainties that could cause actual results to differ materially from those indicated in the forward looking statements due to important risks and factors, including those identified herein or identified from time to time in our filings with the Securities and Exchange Commission. We disclaim any obligation to update any such risks or factors or to publicly announce any revisions to any of the forward-looking statements contained herein, unless otherwise required by law.

Overview

We are a specialty pharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our current commercial and therapeutic focus is in nephrology utilizing Hectorol®, our novel vitamin D hormone therapy, to treat secondary hyperparathyroidism in patients with moderate to severe chronic kidney disease and end-stage renal disease. Secondary hyperparathyroidism is a disease characterized by excessive secretion of parathyroid hormone which, if left untreated, can eventually result in cardiovascular disease, reduced immune system function, muscle weakness and bone disease, including mineral loss and fractures. Many patients with moderate to severe chronic kidney disease and most end-stage renal disease patients suffer from this disease. Hectorol®, a safe and effective vitamin D pro-hormone therapy in the management of secondary hyperparathyroidism in moderate to severe chronic kidney disease and end-stage renal disease, reduces elevated levels of parathyroid hormone while maintaining consistent levels of vitamin D with a low incidence of adverse events. Vitamin D therapies are currently used to treat patients with a variety of diseases, including kidney disease, osteoporosis and psoriasis, and research has shown that they may be useful in treating certain cancers such as prostate, breast and colon. Our principal clinical development programs focus on chronic kidney disease and hyperproliferative disorders such as cancer and psoriasis.

We have two products approved by the U.S. Food and Drug Administration (FDA): Hectorol® Injection and Hectorol® Capsules. Hectorol® Injection and Hectorol® 2.5 mcg Capsules are approved for the treatment of secondary hyperparathyroidism in end-stage renal disease. Hectorol® 0.5 mcg Capsules are approved for the treatment of secondary hyperparathyroidism in moderate to severe chronic kidney disease. We obtained FDA approval for Hectorol® 2.5 mcg Capsules in June 1999, and we began selling this orally administered product in the U.S. in October 1999. We obtained FDA approval for Hectorol® Injection in April 2000. We launched this intravenous product in the U.S. in August 2000 and we received a national Medicare reimbursement code for Hectorol® Injection in January 2002. The National Kidney Foundation estimates that as of 2003 there were approximately 300,000 end-stage renal disease patients in the U.S. and projects that this population will double by 2010. In April 2004 we obtained FDA approval for Hectorol® 0.5 mcg Capsules to treat secondary hyperparathyroidism in moderate to severe chronic kidney disease prior to end-stage renal disease, or pre-dialysis. We launched this product in the U.S. in July 2004. We are also developing Hectorol® and other vitamin D hormones for expanded indications.

In 2002, the National Kidney Foundation issued clinical practice guidelines for evaluating and classifying chronic kidney disease. These guidelines classify kidney disease into five stages based on kidney function as measured by glomerular filtration rate, a widely accepted overall measure of kidney function. In October 2003, the National Kidney Foundation published the Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. These guidelines, referred to as the K/DOQI guidelines, include recommendations for the treatment of bone disease and disorders of calcium and phosphorus metabolism which may encourage a shift in clinical practice to begin earlier treatment of patients with Stages 3 and 4 (moderate to severe) chronic kidney disease, in addition to Stage 5 (end-stage renal disease) chronic kidney disease. The National Kidney Foundation estimates that as of 2003 there were approximately 7,600,000 Stage 3 patients, 400,000 Stage 4 patients and 300,000 Stage 5 patients. According to the United States Renal Data System, approximately 65% of Stage 5 patients are treated with vitamin D hormone therapy. We believe that this potential shift in practice, together with our recently approved expanded indication for Hectorol® Capsules, could expand the potential use of

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Hectorol® to a broader range of chronic kidney disease patients.

On July 14, 2004, we entered into a multi-year co-promotion agreement for the launch and commercialization of Hectorol® 0.5 mcg Capsules with nephrologists in pre-dialysis Stages 3 and 4 chronic kidney disease. Under the terms of the agreement, Cardinal Health PTS, LLC will provide contract sales force and medical communication services to support a specified level of promotion. We will sell Hectorol® 0.5 mcg Capsules through its distribution network and support the promotional effort through its nephrology focused sales force with an additional specified level of investment. For its efforts, Cardinal Health will receive a variable co-promotion fee based on the performance of Hectorol® 0.5 mcg Capsule sales. The fee as a percentage of Hectorol® 0.5 mcg Capsule revenue declines gradually over the term of the agreement. Initial sales of Hectorol® 0.5 mcg Capsules were recognized in the current quarter ended September 30, 2004.

On October 27, 2004, we received a subpoena from the U.S. Department of Justice, Eastern District of New York. The subpoena requires production of a wide range of documents relating to the operations of the Company. We intend to meet with representatives from the Justice Department to discuss the scope of the subpoena and the production of responsive documents. We will cooperate with the request of the Justice Department.

Critical Accounting Policies and Estimates

Our accounting policies are disclosed in our 2004 Report on Form 10-K. During the three months ended September 30, 2004, there were no material changes to these policies. Our more critical accounting polices are as follows:

Revenue Recognition

We record sales and the related costs of Hectorol® 2.5 mcg Capsules and Hectorol® Injection based on shipments to customers reduced by the estimated future returns and allowances. Revenue is recognized at the time of shipment as risk of loss has transferred to the customer, delivery has occurred, and collectibility is reasonably certain. Customers have a right to return product in accordance with our returns policy. In accordance with Statement of Financial Accounting Standard (SFAS) No. 48, Revenue Recognition When Right of Return Exists , our September 30, 2004 and June 30, 2004 balance sheets include an accrual of $183,804 and 100,000 respectively, for the estimated amount of future returns, based on historical experience related to Hectorol® 2.5 mcg Capsules and Hectorol® Injection. In the quarter ended September 30, 2004, we began selling our newly approved product, Hectorol® 0.5 mcg Capsules. Due to insufficient historical data as it relates to Hectorol® 0.5 mcg Capsules and since this product is promoted in a new market segment, pre-dialysis chronic kidney disease, we utilized various data points for purposes of recognizing revenue and for estimating returned goods reserves. These data points included prescription information and wholesaler inventory levels. For the quarter ended September 30, 2004, we have recognized $251,020 of revenue related to Hectorol® 0.5 mcg Capsules and have recorded $1,049,250 in our balance sheet as deferred revenue.

Sales Returns and Allowances

When revenue is recognized, we simultaneously record an estimate of various costs, which reduce product sales. These costs include estimates for product returns, allowances or chargebacks, rebates, and discounts. Estimates are based on a variety of factors including historical return experience, rebate and chargeback agreements, inventory levels at our wholesale customers, and estimated sales by our wholesale customers to other third parties who have contracts with us. Actual experience associated with any of these items may differ materially from our estimates. Factors are reviewed that influence our estimates and, if necessary, adjustments are made when we believe that actual product returns, allowances or chargebacks, rebates, and discounts may differ from established reserves.

Allowance for Doubtful Accounts

An allowance is maintained for estimated losses resulting from the inability of customers to make required payments. Credit terms are extended on an uncollateralized basis primarily to wholesale drug distributors and independent dialysis clinics throughout the U.S. Management specifically analyzes accounts receivable, historical bad debts, customer credit-worthiness, percentage of accounts receivable by aging category, and changes if any, in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. If the financial condition of our customers were to deteriorate, resulting in impairment in their ability to make payments, additional allowances may be required. Our actual losses from uncollectible accounts have not been material to date.

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Excess and Obsolete Inventory

Inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out method. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, expiration dates, and the estimated time to sell such inventory. As appropriate, provisions are made to reduce inventories to their net realizable value. Cost of inventories that potentially may not sell prior to expiration or are deemed of no commercial value have been written-off when identified.

Cost of Inventory

Finished goods inventories are recorded at standard cost and reflect the average actual costs. Hectorol® Injection inventory is manufactured and purchased under a contract with calendar year terms that specifies base price per unit and the volume rebate scale. Based on annual forecasts and the contract terms, the average annual net cost per unit is calculated and recognized for finished goods inventory and cost of product sales. The actual rebate received may differ based upon differences between our forecasted purchases and actual purchases.

Income Taxes

We currently have significant deferred tax assets, resulting primarily from net operating loss carryforwards and tax credit carryforwards. These deferred tax assets may reduce taxable income in future periods. A valuation allowance is required when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Forming a conclusion that a valuation allowance is not needed is difficult when there are cumulative losses in recent years, as cumulative losses weigh heavily in the overall assessment of the need for a valuation allowance.

We expect to continue to maintain a full valuation allowance on future tax benefits until an appropriate level of profitability is sustained. Achieving sufficient profitability is dependent upon success in our commercial operations, including growth in sales of Hectorol® and our historical performance of achieving and sustaining profitability. At the point in which we would have realized a cumulative profit over a period of three consecutive fiscal years, we would expect to have a sufficient basis for concluding that some or all of the deferred tax assets would be realized and we may reduce some or all of the valuation allowance. We would report any reduction in the valuation allowance as an income tax benefit in our statement of operations.

During any period in which we continue to maintain a full valuation allowance against deferred tax assets, we would generally not report any income tax provision in our statement of operations during a profitable period and would not report any income tax benefit during a loss period. If we reach the point such that we no longer require a valuation allowance on future tax benefits, we would expect subsequent periods would reflect a tax provision in the statement of operations based on the statutory income tax rates.

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Results of Operations

Three months ended September 30, 2004 compared with three months ended September 30, 2003

Product sales of Hectorol® were $17,373,044 for the quarter ended September 30, 2004, an increase of $9,248,002, or 114%, from the quarter ended September 30, 2003. Sales of Hectorol® Injection were $15,799,977 for the quarter ended September 30, 2004, an increase of $8,763,919, or 125%, from the same period in 2003. During the quarter ended June 30, 2004, we expanded our sales force from approximately thirty-five direct sales specialists to approximately fifty-five direct sales specialists. The increase in sales of Hectorol® Injection in the first fiscal quarter of 2005 versus the same period in 2004 was primarily the result of the efforts of an expanded and experienced sales force as well as contract initiatives with national dialysis providers. Sales of Hectorol® 2.5 mcg Capsules were $1,322,047 for the first fiscal quarter of 2005, an increase of $233,064, or 21%, from the same period in 2004. The increase was attributed to the efforts of our expanded sales force in the first quarter of 2005 versus the same period in 2004. Sales of Hectorol® 0.5 mcg Capsules were $251,020 for the quarter ended September 30, 2004. Hectorol® 0.5 mcg Capsules were approved by the FDA in April 2004 and the Company began recording sales in the current quarter.

Gross margin on sales of Hectorol® was $12,974,678 or 75%, of product sales, for the quarter ended September 30, 2004, compared to $5,707,398, or 70% of product sales, for the quarter ended September 30, 2003. Gross margins for Hectorol® Injection and Hectorol® 2.5 mcg Capsules were 73% and 86%, respectively, for the first quarter of fiscal 2005 versus 71% and 67%, respectively, for the first quarter of fiscal 2004. The increase in gross margins was due to increased sales levels and reductions in manufacturing validation and quality assurance costs. Hectorol® 0.5 mcg Capsules achieved a 90% gross margin in its initial quarter of product sales.

Research and development (R&D) expense was $2,314,504 in the quarter ended September 30, 2004, an increase of $521,344, or 29%, from the quarter ended September 30, 2003. The increase in R&D expense was primarily due to preclinical, clinical and bioanalytical research activities of approximately $250,000, an increase of our clinical support expenses of approximately $180,000 and an increase in compensation expenses of approximately $100,000.

Selling, general and administrative (SG&A) expense was $9,900,250 in the quarter ended September 30, 2004, an increase of $3,819,051, or 63%, from the same quarter in 2003. The increase in SG&A expense was primarily due to the planned expansion of our sales organization, from approximately thirty-five direct sales specialists to approximately fifty-five direct sales specialists, representing $1.9 million and marketing promotional programs of $1.5 million. Additionally, we began paying a co-promotion fee to Cardinal Health related to the sales of Hectorol® 0.5 mcg Capsules in the quarter ended September 30, 2004. Consulting and market research expenses related to strategic business activities were also higher by approximately $0.2 million in the quarter ended September 30, 2004 versus the same period in 2003.

Research and Development

Research and development efforts are focused on developing and evaluating the clinical utility of Hectorol®, LR-103, and BCI-202 in secondary hyperparathyroidism and hyperproliferative diseases, as well as developing additional products and product candidates. All research and development costs are expensed as incurred, which include, but are not limited to, personnel, lab supplies, preclinical and clinical studies, active ingredients for use in clinical trial drugs, manufacturing costs, sponsored research at other labs, consulting, and research-related overhead. For the three months ended September 30, 2004, we have incurred $2,314,504 of R&D expenses. The major portion of these expenses were for personnel in research, clinical development, clinical support and regulatory compliance.

The expense of research and clinical trial projects has not, on a project basis, been significant to date for 2005. The addition of new projects and trials and the future development of LR-103 and BCI 202 may have a material impact on

our future operations, financial position, and liquidity. The impact of these projects, if any, are difficult to predict due to their early stage of progress and uncertainty.

Liquidity and Capital Resources

We require cash to fund our operations, make capital expenditures and for strategic investments. Our cash and cash equivalents, marketable securities and long-term security balances as of September 30, 2004 were $63,533,847, $48,777,170 and

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$907,119, respectively, totaling $113,218,136, a reduction in total of $1,792,609 from the June 30, 2004 balances. Our cash is invested in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

Cash used in operating activities was $1,559,596 for the three months ended September 30, 2004 primarily to fund operations, for inventory purchases in anticipation of increased future demand for our products and to pay for accrued liabilities, principally management bonuses related to fiscal year end June 30, 2004.

Cash provided by investing activities was $19,673,879 for the three months ended September 30, 2004 primarily due to maturities of various held-to-maturity securities. Non-cash amortization of discounts and premiums related to investing activities was $69,480 and $80,826 for the quarters ended September 30, 2004 and 2003, respectively.

Cash provided by financing activities was $93,893 for the three months ended September 30, 2004 due to proceeds received from stock option exercises, offset by repayments on our capital lease obligations.

We currently have no internal manufacturing capabilities. We rely on third party contractors to produce our active pharmaceutical ingredient (API) and for the subsequent manufacturing and packaging of finished injection and capsule products. We purchase our API from a sole supplier, although we are currently in the process of obtaining regulatory approval for an additional API supplier. In addition, we rely on one manufacturer for Hectorol® Injection and one supplier to formulate Hectorol® Capsules and another supplier to package Hectorol® Capsules. Changes in the manufacturing process or our suppliers could cause a delay in manufacturing and/or release of product and a possible loss of sales, which would affect operating results adversely. All of our suppliers have FDA-inspected facilities that are required to operate under current Good Manufacturing Practices regulations established by the FDA. These regulations govern all stages of the drug manufacturing process and are intended to assure that drugs produced will have the identity, strength, quality and purity represented in their labeling for all intended uses. If we were to establish a second source of manufacturing suppliers or our own manufacturing facility, we would need additional funds and would have to hire and train additional personnel and comply with the extensive regulations applicable to the facility. We believe relationships with our suppliers are good.

As of June 30, 2004, we have federal net operating loss carryforwards of $50,872,000 and R&D tax credit carryforwards of $2,394,000, which expire in 2011 through 2024. As of June 30, 2004, we also have state net operating loss carryforwards of $46,036,000 and R&D tax credit carryforwards of $756,000, which expire in 2006 through 2024.

Commitments

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of September 30, 2004:

Payments due by Fiscal Period

	Total	Remaining in 2005	2006 2007	2008 - 2009	2010 and thereafter
Purchase Commitments (1)	$ 9,008,376	$9,008,376	$	$	$
Operating Lease Obligations (2)	4,731,369	760,712	2,103,499	1,602,494	264,664

Capital Lease Obligations (3)	108,591	40,469	68,122		
Total	$13,848,336	$9,809,557	$2,171,621	$1,602,494	$264,664

(1) Purchase commitment for active pharmaceutical ingredients used in Hectorol® production and pre-clinical research and prescriber data for market research.

(2) Represents primarily office and laboratory facilities in Middleton, WI and operating leases, primarily for fleet vehicles used by field personnel.

(3) Represents fleet vehicles used by field personnel that were sold and leased back.

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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 may sell in foreign markets, including Europe and Asia. As our sales are made in U.S. dollars, a strengthening of the U.S. dollar at that time could make our products less competitive in foreign markets.

As of September 30, 2004, we held $68,874,622 and $907,119 in short-term and long-term marketable securities, respectively. The investments have been made for investment (as opposed to trading) purposes. Interest rate risk with respect to our investments is not significant as all such investments are:

short-term investments, which are by their nature less sensitive to interest rate movements, or

less than $1 million of our investment have maturities in excess of one year and are expected to be held to maturity, thereby eliminating the risks associated with interest rate changes.

ITEM 4. CONTROLS AND PROCEDURES

As of September 30, 2004, our management, including our Chief Executive Officer and Chief Financial Officer, have conducted an evaluation of the effectiveness of disclosure controls and procedures, pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in ensuring that all material information required to be filed in this report has been made known to them in a timely fashion.

In connection with the evaluation by our management, including our Chief Executive Officer and Chief Financial Officer, of our internal control over financial reporting, pursuant to Exchange Act Rule 13a-15(d), no changes during the quarter ended September 30, 2004 were identified that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On October 27, 2004, we received a subpoena from the U.S. Department of Justice, Eastern District of New York. The subpoena requires production of a wide range of documents relating to the operations of the Company. We intend to meet with representatives from the Justice Department to discuss the scope of the subpoena and the production of responsive documents. We will cooperate with the request of the Justice Department.

ITEM 6. EXHIBITS

(a) Exhibits furnished:

31.1 Rule 13a-14(a) certification of President and Chief Executive Officer

31.2 Rule 13a-14(a) certification of Vice President and Chief Financial Officer

32.1 Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

32.2 Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

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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 5, 2004 /s/ Paul L. Berns

Paul L. Berns
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2004 /s/ Brian J. Hayden

Brian J. Hayden
Vice President Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

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BONE CARE INTERNATIONAL, INC.

INDEX TO EXHIBITS

For the Quarterly Period Ended September 30, 2004