BONE CARE INTERNATIONAL INC
Form 10-Q
May 14, 2004

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2004

OR

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

From the transition period from to

Commission File Number: 0-27854

BONE CARE INTERNATIONAL, INC.

(Exact name of registrant as specified in its charter)

Wisconsin	39-1527471
(State of Incorporation)	(IRS Employer Identification No.)

1600 Aspen Commons, Suite 300
Middleton, Wisconsin 53562
(Address 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 April 23, 2004, there were 14,339,535 shares of the registrant s common stock issued and outstanding.

BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended March 31, 2004

TABLE OF CONTENTS

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.

Table of Contents

BONE CARE INTERNATIONAL, INC.

Condensed Balance Sheets
(unaudited)

	March 31, 2004	June 30, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,240,744	$ 3,065,218
Marketable securities	7,700,000	13,624,826
Accounts receivable, net	4,200,259	2,814,753
Inventory purchased from related party	2,917,236	305,688
Inventory purchased from others	2,180,582	1,774,916
Other current assets	1,075,328	778,725
Total current assets	22,314,149	22,364,126
Long-term securities	909,632	913,401
Property, plant and equipment, net	1,677,664	1,889,000
Patent fees, net	1,671,490	1,322,670
Goodwill	359,165	359,165
	$ 26,932,100	$ 26,848,362
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,879,287	$ 2,684,838
Accrued compensation payable	1,686,050	2,028,783
Accrued clinical study and research costs	1,101,667	603,048
Other accrued liabilities	205,671	102,601
Allowance for sales returns	150,000	336,620
Total current liabilities	8,022,675	5,755,890
Long-term liabilities	77,011	649,880
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 14,339,485 and 14,218,522 shares as of March 31, 2004 and June 30, 2003, respectively	74,308,568	73,640,801
Accumulated deficit	(55,476,154)	(53,198,209)

Total shareholders equity	18,832,414	20,442,592
	$ 26,932,100	$ 26,848,362

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

Table of Contents

BONE CARE INTERNATIONAL, INC.

Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2004	2003	2004	2003
Product Sales	$11,617,323	$ 3,078,022	$28,857,850	$ 12,238,435
Cost and expenses				
Cost of product sales from related party	1,798,626	427,230	4,652,891	427,230
Cost of product sales from others	1,130,148	1,099,944	3,124,635	4,069,388
Research and development	2,610,139	1,712,899	6,056,527	5,083,414
Selling, general and administrative	5,803,602	4,575,697	17,431,151	13,522,074
	11,342,515	7,815,770	31,265,204	23,102,106
Income / (loss) from operations	274,808	(4,737,748)	(2,407,354)	(10,863,671)
Interest income, net	27,324	112,989	129,409	480,079
Net income / (loss)	$ 302,132	$ (4,624,759)	$ (2,277,945)	$(10,383,592)
Net income / (loss) per common share				
Basic	$ 0.02	$ (0.33)	$ (0.16)	$ (0.73)
Diluted	$ 0.02	$ (0.33)	$ (0.16)	$ (0.73)
Shares used in computing net income/ (loss) per common share				
Basic	14,329,963	14,168,652	14,290,162	14,160,893
Diluted	16,555,748	14,168,652	14,290,162	14,160,893

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

Table of Contents

BONE CARE INTERNATIONAL, INC.

Condensed Statements of Cash Flows
(Unaudited)

	Nine Months Ended March 31,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$(2,277,945)	$(10,383,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acceleration of stock option vesting	227,500	
Depreciation of fixed assets	592,437	545,779
Amortization of patents	128,988	115,805
Gain on disposal of fixed assets	(2,665)	
Loss on write-off of patents		47,853
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(1,385,506)	1,817,294
(Increase) decrease in inventory	(3,017,214)	60,121
Increase in other current assets	(296,603)	(204,574)
Increase in other long-term assets		(110,300)
Increase in accounts payable	2,194,449	696,191
Increase in accrued liabilities	151,618	1,167,065
(Decrease) increase in long-term liabilities	(649,880)	676,868
(Decrease) increase in allowance for sales returns	(186,620)	73,420
Net cash used in operating activities	(4,521,441)	(5,498,070)
Cash flows from investing activities:		
Maturities of marketable securities, net	5,928,595	6,009,130
Proceeds from the sale of property, plant and equipment	22,312	
Purchase of property, plant and equipment	(400,748)	(660,517)
Patent fees	(477,808)	(233,796)
Net cash provided by investing activities	5,072,351	5,114,817
Cash flow from financing activities:		
Proceeds from the sale of property, plant and equipment related to sale lease back	184,349	
Proceeds from exercise of stock options	440,267	123,646

Net cash provided by financing activities	624,616	123,646
Net increase (decrease) in cash and cash equivalents	1,175,526	(259,607)
Cash and Cash Equivalents at beginning of period	3,065,218	2,023,969
Cash and Cash Equivalents at end of period	$ 4,240,744	$ 1,764,362

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

Table of Contents

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 an emerging 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 2.5 mcg Hectorol® 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 0.5 mcg Hectorol® 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, 2003 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® 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 return policy. In accordance with Statement of Financial Accounting Standard (SFAS) No. 48, Revenue Recognition When Right of Return Exists , our March 31, 2004 and June 30, 2003 balance sheets include an accrual of $150,000 and $336,620, respectively, for the estimated amount of future returns, based on historical experience related to Hectorol® Capsules and Hectorol® Injection.

Segments

Our current commercial 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. We currently derive our revenues from two products, Hectorol® Injection and 2.5 mcg Hectorol® Capsules. 0.5 mcg Hectorol® Capsules were approved by the FDA in April 2004 and no product sales have been recorded.

Revenue performance by product is as follows:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2004	**2003**	**2004**	**2003**
Hectorol® Injection	$10,344,778	$1,930,391	$25,278,125	$ 8,882,119
Hectorol® Capsules	1,272,545	1,147,631	3,579,725	3,356,316
	$11,617,323	$3,078,022	$28,857,850	$12,238,435

Table of Contents

Accounts Receivable

Accounts receivable is stated net of allowance for doubtful accounts of $63,900 and $111,200 at March 31, 2004 and June 30, 2003, respectively.

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:

	March 31, 2004	June 30, 2003
Raw materials	$1,414,926	$1,293,329
Work in process	437,625	182,998
Finished goods purchased from related party	2,917,236	305,688
Finished goods purchased from others	328,031	298,589
	$5,097,818	$2,080,604

Property, Plant and Equipment

We periodically evaluate the carrying value of property and equipment in accordance with 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:

	March 31, 2004	June 30, 2003
Leasehold Improvements	$ 588,632	$ 588,632
Furniture and Fixtures	516,359	545,547
Machinery and Other Equipment	3,449,128	3,100,108
	4,554,119	4,234,287
Less: Accumulated Depreciation	(2,876,455)	(2,345,287)

	$ 1,677,664	$ 1,889,000

Marketable Securities

Securities classified as Held-to-Maturity include the following:

	March 31, 2004		June 30, 2003	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Corporate bonds	$909,632	$972,477	$4,688,227	$4,793,306

Securities classified as Available-for-Sale include the following:

	March 31, 2004		June 30, 2003	
	Cost	Fair Value	Cost	Fair Value
Municipal bonds	6,700,000	6,700,000	7,850,000	7,850,000
Corporate bonds	1,000,000	1,000,000	2,000,000	2,000,000
Total	$7,700,000	$7,700,000	$9,850,000	$9,850,000

Table of Contents

Scheduled maturities of marketable securities at March 31, 2004:

	Available-For-Sale		Held-To-Maturity	
	Cost	Fair Value	Amortized Cost	Fair Value
Fiscal Year				
2004	$7,770,000	$7,770,000	$ 0	$ 0
2005				
2006			909,632	972,477
Total	$7,770,000	$7,770,000	$909,632	$972,477

Patent Fees

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 $1,260,940 and $1,131,952 at March 31, 2004 and June 30, 2003, respectively.

Stock Based Compensation

Our 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. Pro forma net loss and net income/loss per share had we elected to adopt the fair-value based method of SFAS No. 123 are as follows:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2004	2003	2004	2003
Net Income/ (loss) as reported	$ 302,132	$(4,624,759)	$(2,277,945)	$(10,383,592)
Compensation expense recognized			227,500	
Less pro forma compensation expense	(929,073)	(441,877)	(2,594,913)	(1,150,738)

Pro forma net loss	$(626,941)	$(5,066,636)	$(4,645,358)	$(11,534,330)
Net income/ (loss) per share basic and diluted				
As reported	$ 0.02	$ (0.33)	$ (0.16)	$ (0.73)
Pro forma	$ (0.04)	$ (0.36)	$ (0.33)	$ (0.81)

Reclassifications

Certain prior period amounts in the condensed financial statements and the notes have been reclassified to conform to the fiscal 2004 presentation.

Table of Contents

(2) Commitments and Contingencies

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of March 31, 2004:

	Total	Less Than 1 Year	1-3 Years
Operating Lease Obligations (1)	$1,670,585	$ 856,856	$813,729
Capital Lease Obligations (2)	151,989	53,733	98,256
Purchase Commitment (3)	1,836,523	1,759,425	77,098
Total	$3,659,097	$2,670,014	$989,083

(1) Represents office and laboratory facilities in Middleton, WI and fleet vehicles used by field personnel.

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

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

(3) Net Income (Loss) Per Share

Basic earnings (loss) per share and diluted 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. 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 1,842,033 for the quarter ended March 31, 2003. The excluded options totaled 2,225,785 and 1,842,033 for the nine months ended March 31, 2004 and 2003, respectively.

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2004	2003	2004	2003
Net Income/ (loss) as reported (numerator)	$ 302,132	$ (4,624,759)	$ (2,277,945)	$(10,383,592)
Shares (denominator):				
Weighted-average shares for basic EPS	14,329,963	14,168,652	14,290,162	14,160,893
Effect of diluted securities	2,113,785			

Adjusted weighted-average shares for dilutive EPS	16,443,748	14,168,652	14,290,162	14,160,893
Earnings (loss) per share:				
Basic	$ 0.02	$ (0.33)	$ (0.16)	$ (0.73)
Diluted	$ 0.02	$ (0.33)	$ (0.16)	$ (0.73)

(4) Comprehensive Income (loss)

Total comprehensive income (loss) was $302,132 and $(4,642,745) for the quarters ended March 31, 2004 and 2003, respectively. Total comprehensive loss was $2,277,945 and $10,437,549 for the nine months ended March 31, 2004 and 2003, respectively. Comprehensive income (loss) is comprised of net income (loss) and changes in unrealized gains and losses on available-for-sale securities.

Table of Contents

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, 2003.

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

Bone Care International, Inc. (Bone Care, we, or the Company) is an emerging 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 2.5 mcg Hectorol® 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 0.5 mcg Hectorol® Capsules for the treatment of secondary hyperparathyroidism in moderate to severe chronic kidney disease.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 1 to the Notes to the Financial Statements in the Company s Form 10-K for the year ended June 30, 2003. These condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, we evaluate our estimates, including those related to our provision for sales returns and allowances, allowance for doubtful accounts, and our estimate of excess and obsolete inventory. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of judgments regarding the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Table of Contents

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.

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.

Results of Operations

Three months ended March 31, 2004 compared with three months ended March 31, 2003

Product sales of Hectorol® were $11,617,323 for the quarter ended March 31, 2004, an increase of $8,539,301, or 277%, from the quarter ended March 31, 2003. Sales of Hectorol® Injection were $10,344,778 for the quarter ended March 31, 2004, an increase of $8,414,387, or 436%, from the same period in 2003. The increase in sales of 2.5 mcg Hectorol® Injection in the third fiscal quarter of 2004 versus the same period in 2003 was primarily the result of volume increases of $6.4 million due in part to the efforts of our experienced sales and marketing organization and to manufacturing constraints in the prior year. The positive impact of price increases implemented in July 2003 also resulted in higher Hectorol® Injection revenues of approximately $2.0 million of the increase in the third quarter of 2004 compared to the same period in 2003. Sales of 2.5 mcg Hectorol® Capsules were $1,272,545 for the quarter ended March 31, 2004, an increase of $124,914, or 11%, from the same period in 2003 due primarily to a decrease in product returns, the positive impact of a price increase implemented in July 2003 and prescription growth as a result of our sales and marketing efforts.

Cost of product sales was $2,928,774 and $1,527,174 for the quarters ended March 31, 2004 and 2003, respectively, representing approximately 25% and 50%, respectively, of product sales. The increase in cost of product sales of $1,401,600 in the third quarter of 2004 versus the same period in 2003 was due to the higher sales volumes in 2004 offset partially by manufacturing validation expenses in the third quarter of 2003 for Hectorol® of $437,000, primarily related to Hectorol® Injection, and an increase in the royalty paid on Hectorol® of $254,000 based on the

higher sales volumes. The cost of manufacturing validation expenses for the quarter ended March 31, 2003 was approximately $437,000 or 14% of product sales.

Research and development (R&D) expense was $2,610,139 in the quarter ended March 31, 2004, an increase of $897,240, or 52%, from the same quarter in 2003. The increase in R&D expense was primarily due to a one-time charge for the purchase of LR-103 active pharmaceutical ingredient for clinical trial research, personnel expenses for senior R&D management, and additions in personnel in our regulatory and clinical support groups.

Table of Contents

Selling, general and administrative (SG&A) expense was $5,803,602 in the quarter ended March 31, 2004, an increase of $1,227,905, or 27%, from the same quarter in 2003. The increase in SG&A expense was primarily due to marketing promotional programs to provide support for our sales organization representing approximately $437,000, vacancies filled in our field sales organization representing approximately $418,000, an increase in incentive compensation of $257,000, consulting expenses related to strategic business activities of approximately $167,000, and board recruitment fees of approximately $83,000, offset partially by a reduction in legal expense of approximately $100,000.

Nine months ended March 31, 2004 compared with nine months ended March 31, 2003

Product sales of Hectorol® were $28,857,850 for the nine months ended March 31, 2004, an increase of $16,619,415, or 136%, from the nine months ended March 31, 2003. Sales of Hectorol® Injection were $25,278,125 for the nine months ended March 31, 2004, an increase of $16,396,006, or 185%, from the same period in 2003. The increase in sales of Hectorol® Injection in the first nine months of 2004 was primarily the result of volume increases of approximately $12.2 million due in part to the efforts of our experienced sales and marketing organization and manufacturing constraints in the prior year. The positive impact of price increases implemented in July 2003 also resulted in higher Hectorol® Injection revenues of approximately $4.2 million of the increase for the nine months ended March 31, 2004 compared to the same period in 2003. Sales of 2.5 mcg Hectorol® Capsules were $3,579,725 for the nine months ended March 31, 2004, an increase of $223,409, or 7%, from the same period in 2003 due to a price increase implemented in July 2003 and prescription growth as a result of our sales and marketing efforts.

Cost of product sales was $7,777,526 and $4,496,618 for the nine months ended March 31, 2004 and 2003, respectively, representing approximately 27% and 37%, respectively, of product sales. The increase of cost of product sales of $3,280,908 in the first nine months of 2004 versus the same period in 2003 was due to the higher sales volumes in 2004 offset partially by higher manufacturing validation expenses in 2003 of $791,000.

R&D expense was $6,056,527 for the nine months ended March 31, 2004, an increase of $973,113, or 19%, from the same period in 2003. The increase in R&D expense was primarily due to a one-time charge for the purchase of LR-103 active pharmaceutical ingredient for clinical trial research, higher personnel expenses for senior R&D management, and additions in personnel in our regulatory and clinical support groups.

SG&A expense was $17,431,151 for the nine months ended March 31, 2004, an increase of $3,909,077, or 29%, from the nine months ended March 31, 2003. The increase in SG&A expense was primarily due to marketing promotional programs representing approximately $1,173,000, vacancies filled in our sales organization representing approximately $877,000, consulting and research expenses related to strategic business activities of approximately $600,000, severance expenses for the former Vice President of Finance of approximately $393,000, an increase in incentive compensation of approximately $275,000, expenses associated with the recruitment, hiring, and relocation of the new Vice President of Finance of approximately $213,000, board recruitment fees of approximately $140,000, and professional legal fees of approximately $120,000 principally related to an increase in contractual, personnel and corporate governance activity.

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 and nine months ended March 31, 2004, we have spent $2,610,139 and $6,056,527, respectively, on

R&D expenses. The major portion of these expenses were for personnel in research, clinical development, clinical support and regulatory compliance. In addition, we made a one-time purchase of LR-103 in the third quarter of 2004 for use in clinical trials.

The expense of research and clinical trial projects has not, on a project basis, been significant to date for 2004. 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. We plan to make a one-time purchase of active pharmaceutical ingredient for a LR-103 reference standard in the fourth quarter of 2004 for use in pre-clinical trials at an approximate expense of $350,000.

Table of Contents

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 securities balances as of March 31, 2004 were $4,240,744, $7,700,000 and $909,632, respectively, totaling $12,850,376, a reduction in total of $4,753,069 from the June 30, 2003 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 $4,521,441 for the nine months ended March 31, 2004 primarily to fund the net operating loss of $2,277,945, for inventory purchases in anticipation of increased future demand for our products and to pay for accrued liabilities, principally management bonus compensation related to fiscal year end June 30, 2003.

We used $400,748 in cash for the purchase of capital assets, primarily computer and laboratory equipment. Our cash position was enhanced by $440,267 and $22,312 from stock option and vehicle and equipment sale proceeds, respectively, in the nine months ended March 31, 2004, and by $184,349 for vehicle sales that were leased back in the quarter ended March 31, 2004.

Our cash and investments to-date have been used to fund our operations and capital needs. We anticipate that annual expenditures for growth of our sales force, which is currently planned to occur in the fourth quarter of fiscal 2004 and the second quarter of fiscal 2005, expansion of our marketing programs, purchase of active pharmaceutical ingredients, contract manufacturing, research projects, development of our current and planned products, regulatory activity, and the development of the infrastructures to accommodate the planned growth and development of our organization, will increase in future years. Profits from product sales, if any, may not be sufficient to support these activities. In the quarter ended March 31, 2004, for the first time, we generated a net profit of $302,000. There can be no assurance that we will be able to maintain profitability or positive cash flow from operations. We anticipate that we may require additional financing in the future to finance our anticipated growth and development largely through equity or debt financing and/or strategic or corporate alliances. We believe that, without the proceeds of the offering described below, our existing cash position as of March 31, 2004 is adequate to fund our operations at least until our third quarter of fiscal year 2005. However, if such offering is not completed, there can be no assurance that we will not require additional capital prior to that time. There can be no assurance that additional equity or debt financing or corporate collaborations will be available on terms acceptable to us, if at all. The failure of the Company to maintain profitability or to raise capital on acceptable terms if and when needed would have a material adverse effect on our business, financial condition and results of operations. On May 13, 2004, the Company announced the pricing of its public offering of 5.0 million shares (4.5 million of which are being offered by the Company) at a price of $21.75 per share. Net proceeds to the Company after expenses are expected to be approximately $91 million. The Company has also granted an option to the underwriters to purchase an additional 750,000 shares of common stock at a price of $21.75 per share. The Company intends to use the proceeds from the sale of securities for general corporate purposes.

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.

At June 30, 2003, we had state tax net operating loss carryforwards of approximately $44,337,000 and state research and development tax credit carryforwards of approximately $621,000, which will begin expiring in 2006 and 2011, respectively. We also had federal net operating loss carryforwards of approximately $48,770,000 and research and development tax credit carryforwards of approximately $2,040,000, which will begin expiring in 2011 and 2012, respectively.

Table of Contents

Commitments

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of March 31, 2004:

	Total	Less Than 1 Year	1-3 Years
Operating Lease Obligations (1)	$1,670,585	$ 856,856	$813,729
Capital Lease Obligations (2)	151,989	53,733	98,256
Purchase Commitment (3)	1,836,523	1,759,425	77,098
Total	$3,659,097	$2,670,014	$989,083

(1) Represents office and laboratory facilities in Middleton, WI and fleet vehicles used by field personnel.

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

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

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 March 31, 2004, we held $7,700,000 and $909,632 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

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 March 31, 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 March 31, 2004 were identified that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(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

(b) Reports on Form 8-K

On January 29, 2004, we filed a Form 8-K under items 7 and 12 relating to our January 28, 2004 press release announcing our financial results for the quarter ended December 31, 2003.

On February 17, 2004, we filed a Form 8-K under items 5 and 7 relating to our February 17, 2004 press release announcing the appointment of Herbert J. Conrad as Chairman of our Board of Directors.

Table of Contents

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 13, 2004 /s/ Paul L. Berns

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

Date: May 13, 2004 /s/ Brian J. Hayden

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

Table of Contents

BONE CARE INTERNATIONAL, INC.

INDEX TO EXHIBITS

For the Quarterly Period Ended March 31, 2004

No.	Description	Page
31.1	Rule 13a-14(a) certification of President and Chief Executive Officer	18
31.2	Rule 13a-14(a) certification of Vice President and Chief Financial Officer	19
32.1	Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code	20
32.2	Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code	21