BONE CARE INTERNATIONAL INC
Form 10-Q
February 09, 2005

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended December 31, 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 900
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 þ No o

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

Yes þ No o

As of February 1, 2005, there were 19,957,168 shares of the registrant s common stock issued and outstanding.

BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended December 31, 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)

	December 31, 2004	June 30, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,383,268	$ 45,325,671
Marketable securities	55,512,823	68,776,698
Accounts receivable, net	6,153,100	4,732,698
Inventory	6,255,493	6,785,288
Other current assets	4,174,736	2,336,362
Total current assets	133,479,420	127,956,717
Marketable securities, non-current	905,863	908,376
Property, plant and equipment, net	1,799,115	1,526,638
Patent fees, net	1,898,704	1,785,045
Goodwill	359,165	359,165
	$ 138,442,267	$ 132,535,941
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 8,092,375	$ 6,490,488
Accrued compensation payable	1,224,101	2,890,728
Accrued clinical study and research costs	525,799	1,001,818
Deferred revenues	696,024	
Other accrued liabilities	188,171	214,010
Allowance for sales returns	45,794	100,000
Total current liabilities	10,772,264	10,697,044
Long-term liabilities	74,241	100,388
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 19,796,719 and 19,395,585 shares as of December 31, 2004 and June 30, 2004, respectively	181,285,270	178,868,933
Unearned compensation	(2,006,254)	(2,411,054)
Accumulated other comprehensive loss	(10,368)	
Accumulated deficit	(51,672,886)	(54,719,370)
Total shareholders equity	127,595,762	121,738,509

$ 138,442,267	$ 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 December 31,		Six Months Ended December 31,	
	2004	2003	2004	2003
Product Sales	$ 19,593,812	$ 9,115,485	$ 36,966,856	$ 17,240,527
Cost and expenses:				
Cost of product sales	4,531,669	2,267,957	8,705,138	4,482,922
Research and development	3,229,259	1,816,379	5,768,660	3,812,218
Selling, general and administrative	10,599,901	5,546,350	20,500,151	11,627,549
	18,360,829	9,630,686	34,973,949	19,922,689
Income / (loss) from operations	1,232,983	(515,201)	1,992,907	(2,682,162)
Interest income, net	571,432	37,176	1,053,577	102,085
Net income / (loss)	$ 1,804,415	$ (478,025)	$ 3,046,484	$ (2,580,077)
Net income / (loss) per common share				
Basic	$ 0.09	$ (0.03)	$ 0.16	$ (0.18)
Diluted	$ 0.09	$ (0.03)	$ 0.15	$ (0.18)
Shares used in computing basic and diluted net income / (loss) per common share				
Basic	19,456,149	14,300,232	19,433,284	14,270,479
Diluted	20,852,072	14,300,232	20,844,719	14,270,479

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)

	Six Months Ended December 31,	
	2004	2003
Cash flows from operating activities:		
Net income/ (loss)	$ 3,046,484	$ (2,580,077)
Adjustments to reconcile net income / (loss) to net cash provided (used) in operating activities:		
Equity-based compensation expense	404,800	227,500
Depreciation of fixed assets	452,417	383,529
Amortization of patents	110,120	81,893
(Gain) / loss on disposal of fixed assets	160,315	(7,876)
Inventory write-off	22,730	
Loss on write-off of patents	5,297	
Changes in assets and liabilities:		
Increase in accounts receivable	(1,420,402)	(444,723)
(Increase) decrease in inventory	507,065	(3,101,160)
Increase in other current assets	(1,838,374)	(531,466)
Increase in accounts payable	1,601,887	2,034,168
Decrease in accrued liabilities	(2,139,770)	(924,895)
Decrease in long-term liabilities	(26,147)	(649,880)
Increase in deferred revenues	696,024	
Decrease in allowance for sales returns	(54,206)	(186,620)
Net cash provided (used) in operating activities	1,528,240	(5,699,607)
Cash flows from investing activities:		
Maturities of marketable securities	57,949,965	11,802,339
Purchases of marketable securities	(44,693,945)	(6,825,000)
Proceeds from the sale of property, plant and equipment	94,833	17,753
Purchases of property, plant and equipment	(980,042)	(151,764)
Patent fees	(229,076)	(245,085)
Net cash provided by investing activities	12,141,735	4,598,243
Cash flows from financing activities:		
Proceeds from exercise of stock options	2,416,337	364,512
Repayment of capital lease obligation	(28,715)	
Net cash provided by financing activities	2,387,622	364,512
Net increase (decrease) in cash and cash equivalents	16,057,597	(736,852)

Cash and Cash Equivalents at beginning of period	45,325,671	3,065,218
Cash and Cash Equivalents at end of period	$ 61,383,268	$ 2,328,366

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® (doxercalciferol), 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 hormone 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, both 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 pre-dialysis.

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.

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.

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 December 31, 2004 and June 30, 2004 balance sheets include accruals of $45,794 and $100,000, respectively, for an estimated amount of future returns, based on historical experience related to Hectorol® Capsules and Hectorol® Injection. In August 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 third-party data points for purposes of recognizing revenue and for estimating returned goods reserves. The third-party data points included prescription information and wholesaler inventory levels. For the three and six months ended December 31, 2004, we have recognized $741,355 and $992,375, respectively, of revenue

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related to Hectorol® 0.5 mcg Capsules. As of December 31, 2004, we have recorded $696,024 in our balance sheet as deferred revenue representing the difference between shipments to customers and data points previously described. If current demand of Hectorol® 0.5 mcg Capsules continues to increase, the Company may be in a position to recognize revenue based on shipments to customers by the end of the 2005 fiscal year.

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 December 31		Six Months Ended December 31	
	2004	2003	2004	2003
Hectorol® Injection	$ 17,208,586	$ 7,897,288	$ 33,008,563	$ 14,933,347
Hectorol® 2.5 mcg Capsules	1,643,871	1,218,197	2,965,918	2,307,180
Hectorol® 0.5 mcg Capsules	741,355		992,375	
	$ 19,593,812	$ 9,115,485	$ 36,966,856	$ 17,240,527

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.

Marketable Securities

Securities as of December 31 2004 included the following:

	Amortized Cost	Unrecognized Gains	Unrecognized Losses	Fair Value
Held-to-Maturity				
Commercial paper	$ 50,514,206	$	$ (6,633)	$ 50,507,573
Corporate bonds	905,863	22,118		927,981
	$ 51,420,069	$ 22,118	$ (6,633)	51,435,554

	Carrying Value	Unrealized Gains	Unrealized Losses	Fair Value

Available-for-Sale				
Municipal bonds	$ 26,550,000	$	$	$ 26,550,000
Corporate bonds	2,500,000			2,500,000
Mutual funds	10,079,320			10,079,320
	$ 39,129,320			$ 39,129,320
Total marketable securities	$ 90,549,389	$ 22,118	$ (6,633)	$ 90,564,874

Held-to-Maturity securities included $34,130,701 of commercial paper classified as cash equivalents in the balance sheet at December 31, 2004 as these securities are highly liquid with maturity dates of ninety days or less at the balance sheet date.

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Securities as of June 30, 2004 included the following:

	Amortized Cost	Unrecognized Gain	Unrecognized Loss	Fair Value
Held-to-Maturity				
Commercial paper	$ 60,257,989	$	$ (38,594)	$ 60,219,395
Corporate bonds	1,908,376	35,463		1,943,839
	62,166,365	35,463	(38,594)	62,163,234

	Cost	Unrealized Gain	Unrealized Loss	Fair Value
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	$ 89,916,365	$ 35,463	$ (38,594)	$ 89,913,234

Held-to-Maturity securities included $20,231,291 of commercial paper classified as cash equivalents in the balance sheet at June 30, 2004 as these securities are highly liquid with maturity dates of ninety days or less at the balance sheet date.

Scheduled maturities of Marketable Securities at December 31, 2004:

	Available-For-Sale		Held-To-Maturity	
	Cost	Fair Value	Amortized Cost	Fair Value
Fiscal Year				
2005	$ 39,139,688	$ 39,129,320	$ 50,514,206	$ 50,507,573
2006			905,863	927,981
Total	$ 39,139,688	$ 39,129,320	$ 51,420,069	$ 51,435,554

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 was 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 (FSP) 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. The delay of the effective date for paragraphs 10 20 will be superseded

concurrent with the final issuance of proposed FSP EITF Issue 03-1-a, Implication Guidance for the Application of Paragraph 16 of EITF Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments. The disclosures continue to be effective in annual financial statements for fiscal years ending after December 15, 2003, for investments accounted for under SFAS Nos. 115 and 124. For all other investments within the scope of EITF Issue No. 03-1, the disclosures continue to be effective in annual financial statements for fiscal years ending after June 15, 2004. The additional disclosures for cost method investments continue to be effective for fiscal years ending after June 15, 2004. Upon final issuance, 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.

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.

At December 31, 2004, the unrealized losses on mutual funds were included in accumulated other comprehensive income within the equity section of the balance sheet. The unrecognized losses on commercial paper represent losses on fixed

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income securities, which 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.

Accounts Receivable

Accounts receivable is stated net of allowance for doubtful accounts of $30,940 and $72,070 at December 31, 2004 and June 30, 2004, respectively.

Inventory

Inventory is stated at the lower of cost or market; cost is determined in a manner which approximates the first-in, first-out (FIFO) method. Inventory consisted of the following:

	December 31, 2004	June 30, 2004
Raw materials	$ 1,485,006	$ 1,659,734
Work in process	1,187,598	89,388
Finished goods	3,582,889	5,036,166
	$ 6,255,493	$ 6,785,288

Finished goods inventory at December 31, 2004 included $19,808 of our Hectorol® 0.5 mcg Capsules owned by our wholesale customers for which we have not yet recognized revenue.

Property, Plant and Equipment

Property, plant and equipment is carried at cost and depreciation expense is calculated using the straight-line method. For the three and six months ended December 31, 2004, the Company recognized depreciation expense of $260,560 and $452,417, respectively. Included in depreciation expense is amortization related to our sales-leaseback transaction of fleet vehicles.

On December 13, 2004, the Company relocated its principal office, which resulted in the write off of certain leasehold improvements, furniture and fixtures representing $120,794 as reflected in our statement of operations.

We continue to 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:

June 30,

	December 31, 2004	2004
Leasehold Improvements	$ 164,481	$ 588,632
Furniture and Fixtures	705,007	524,455
Machinery and Other Equipment	3,545,177	3,502,221
	4,414,665	4,615,308
Less: Accumulated Depreciation	(2,615,550)	(3,088,670)
	$ 1,799,115	$ 1,526,638

Intangibles

Legal costs incurred to register patents are amortized on a straight-line basis over the life of the patent (weighted average amortization period of 10 years at December 31, 2004). Patent fees are stated net of accumulated amortization of

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$1,421,382 and $1,131,427 at December 31, 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 and other intangible assets on at least 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.

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 six months ended December 31, 2004, we have incurred $3,229,259 and $5,768,660, respectively, of research and development expenses. The major portion of these expenses were for personnel in research, clinical development, clinical support and regulatory compliance.

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 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 No. 123, are as follows:

	Three Months Ended December 31,		Six Months Ended December 31,	
	2004	2003	2004	2003
Net income/ (loss)	$ 1,804,415	$ (478,025)	$ 3,046,484	$ (2,580,077)
Compensation expense recognized	202,399		404,800	227,500
Less pro forma compensation expense	(1,630,052)	(779,844)	(3,143,303)	(1,665,840)
Pro forma income/ (loss)	$ 376,762	$ (1,257,869)	$ 307,981	$ (4,018,417)
Net income/ (loss) per share basic				
As reported	$ 0.09	$ (0.03)	$ 0.16	$ (0.18)
Pro forma	$ 0.02	$ (0.09)	$ 0.02	$ (0.28)
Net income/ (loss) per share diluted				
As reported	$ 0.09	$ (0.03)	$ 0.15	$ (0.18)

Pro forma	$ 0.02	$ (0.09)	$ 0.01	$ (0.28)

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which will be effective in our first quarter of fiscal 2006. SFAS 123R will result in our recognition of compensation expense relating to our stock option plan. Under the new rules, we are required to adopt a fair-value-based method for measuring the compensation expense related to our employee and non-employee director stock awards, which will result in non-cash compensation expense which will have an adverse effect on our reported results of operations.

Income Taxes

As of June 30, 2004, we had 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 had state net

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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 three consecutive fiscal years, management may have a sufficient basis to conclude that some or all of the valuation allowance may be reduced.

Advertising Expenses

We expense advertising costs as incurred. Advertising expenses were $290,397 and $1,184,114 for the three and six months ended December 31, 2004, respectively, compared to $154,862 and $462,783 for the three and six months ended December 31, 2003, respectively.

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 or our method of manufacture may 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 99% of the net accounts receivable balance as of December 31, 2004. These same five wholesale distributors represented 95% of our product sales for the six months ended December 31, 2004, with the largest of the five wholesale distributors representing 31% of product sales. As of June 30, 2004 five individual customers comprised 97% of the net accounts receivable balance. These same five customers represented 95% of our product sales for the year ended June 30, 2004, with the largest of the five companies representing 39% of product sales.

As of December 31, 2004, we maintained cash and cash equivalent balances of $61.4 million. Although deposits are held at multiple financial institutions, balances exceed federally insured amounts.

(2) Contingencies

In the ordinary course of business, the Company is involved in legal proceedings and other matters. While it is not possible to accurately predict or determine the eventual outcome of these items, we do not believe any such items currently pending will have a material adverse effect on our annual financial statements, although an adverse resolution in any matter could have a material impact on the results of operations for that period.

(3) Net Income (Loss) Per Share

Basic and diluted net income (loss) per share is based upon the weighted-average number of common shares outstanding. Diluted net income per share is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. For the three and six months ended December 31, 2004, stock options to

purchase 40,000 and 200,000 shares of common stock were outstanding, respectively, but not included in the computation of diluted net income 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 and six months ended December 31, 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 2,078,935.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2004	2003	2004	2003
Net income/ (loss) as reported	$ 1,804,415	$ (478,025)	$ 3,046,484	$ (2,580,077)
Shares:				
Basic weighted average shares outstanding	19,456,149	14,300,232	19,433,284	14,270,479
Dilutive effect of stock options	1,395,923		1,411,435	
Dilutive weighted average shares outstanding	20,852,072	14,300,232	20,844,719	14,270,479
Net income (loss) per share:				
Basic	$ 0.09	$ (0.03)	$ 0.16	$ (0.18)
Diluted	$ 0.09	$ (0.03)	$ 0.15	$ (0.18)

(4) Comprehensive Income (loss)

Total comprehensive income was $1,783,738 and $3,036,116, respectively, for the three and six months ended December 31, 2004 and total comprehensive loss was $478,025 and $2,580,777, respectively, for the three and six months ended December 31, 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 with Cardinal Health PTS, LLC for the launch and commercialization of Hectorol^{Ò} 0.5 mcg Capsules with nephrologists in pre-dialysis Stages 3 and 4 chronic kidney disease. Under the terms of the agreement, Cardinal Health provides contract sales force and medical communication services to support a specified level of promotion. We sell Hectorol^{Ò} 0.5 mcg Capsules through Cardinal Health s distribution network and support the promotional effort through Cardinal Health s nephrology focused sales force with an additional specified level of investment. For its efforts, Cardinal Health receives a variable co-promotion fee based on the net sales of Hectorol^{Ò} 0.5 mcg Capsules. The fee as a percentage of net sales of Hectorol^{Ò} 0.5 mcg Capsules declines gradually over the term of the agreement. Initial sales of Hectorol^{Ò} 0.5 mcg Capsules were recognized in the quarter ended September 30, 2004. Refer to Note 1 above.

(6) New Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities an interpretation of Accounting Research Bulletin (ARB) No. 51, which provides guidance on the identification of and reporting for variable interest entities. In December 2003, the FASB issued a revised Interpretation No. 46, which expands the criteria for consideration in determining whether a variable interest entity should be consolidated. Interpretation No. 46 became effective for us in the second quarter of fiscal 2004. Our adoption of Interpretation No. 46 did not have an impact on our results of operations or financial position.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. Financial instruments that are within the scope of the

statement, which previously were often classified as equity, must now be classified as liabilities. In November 2003, FASB Staff Position No. SFAS 150-3 deferred indefinitely the effective date of SFAS No. 150 for applying the provisions of the Statement for certain mandatorily redeemable non-controlling interests. However, expanded disclosures are required during the deferral period. The Company does not have financial instruments with mandatorily redeemable non-controlling interests.

In December 2003, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB)

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No. 104, Revenue Recognition, which supercedes SAB 101, Revenue Recognition in Financial Statements. SAB 104 s primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superceded as a result of the issuance of EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. Additionally, SAB 104 rescinds the SEC s Revenue Recognition in Financial Statements Frequently Asked Questions and Answers issued with SAB 101 that had been codified in SEC Topic 13, Revenue Recognition. The adoption of the bulletin did not have an impact on our results of operations or financial position.

In December 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment ARB No. 43, Chapter 4, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material. This statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, this statement requires that allocation of fixed production overheads to the costs of conversions be based on the normal capacity of the production facilities. The adoption of this statement did not have an impact on our results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Non-monetary Assets, an amendment of APB Opinion No. 29. This Statement addresses the measurement of exchanges of non-monetary assets. The Company has not entered into any non-monetary exchanges; thus adoption of this Statement did not have an impact on our results from operations or financial position.

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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 in this Form 10-Q 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_2 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 hormone 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: Hectorol® Injection and Hectorol® Capsules. Hectorol® Injection is approved for the treatment of secondary hyperparathyroidism in end-stage renal. Hectorol® 2.5 mcg Capsules and 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 2004 there were approximately 330,000 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 Hectorol® 0.5 mcg Capsules in the U.S. in July 2004 with our co-promotion partner Cardinal Health PTS, LLC. 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 2004 there were approximately 8,100,000 Stage 3 patients, 425,000 Stage 4 patients and 330,000 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

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practice, together with our recently approved expanded indication for Hectorol® Capsules, could expand the potential use of 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 provides contract sales force and medical communication services to support a specified level of promotion. We 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 receives 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 our first 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. Since receipt of the subpoena we have been cooperating with the request of the Justice Department. Compliance with the subpoena has required additional management attention and legal costs.

On November 3, 2004, pursuant to final rules issued by the Centers for Medicare and Medicaid Services, Medicare reimbursement for Hectorol® Injection used in dialysis clinics calendar year 2005 will be changed to a rate based upon average acquisition cost for calendar year 2003 as determined by the Office of the Inspector General and adjusted for price inflation based on the Producer Price Index for prescription preparation. We continue to analyze this change and its potential impact on our business and we plan to make any modifications to our programs to minimize any impact.

In December, 2004, the Company received notice of allowance from the U.S. Patent and Trademark Office for claims relating to stabilized hydroxyvitamin D_2 products and pharmaceutical compositions and medicaments including stabilized hydroxyvitamin D_2. The stabilized hydroxyl vitamin D_2 product for which a patent will be granted is characterized by a purity profile and level of impurities and residual solvents. 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, is covered by this new composition of matter patent that will expire in 2021.

Critical Accounting Policies and Estimates

Our accounting policies are disclosed in our 2004 Report on Form 10-K. During the three months ended December 31, 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 December 31, 2004 and June 30, 2004 balance sheets include accruals of $45,794 and $100,000, respectively, for an 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 third-party data points for purposes of

recognizing revenue and for estimating returned goods reserves. The third-party data points included prescription information and wholesaler inventory levels. For the three and six months ended December 31, 2004, we have recognized $741,355 and $992,375, respectively, of revenue related to Hectorol^{Ò} 0.5 mcg Capsules. As of December 31, 2004, we have recorded $696,024 in our balance sheet as deferred revenue representing the difference between shipments to customers and the data points previously described. If current demand of Hectorol® 0.5 mcg Capsules continues to increase, the Company may be in a position to recognize revenue based on shipments to customers by the end of the 2005 fiscal year.

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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 United States. Management 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 are 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 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. Management continues to monitor profitability and the realizability of deferred tax assets.

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Expensing of Stock Awards

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which will be effective in our first quarter of fiscal 2006. SFAS 123R will result in our recognition of compensation expense relating to our stock option plan. The Company currently uses the intrinsic value method to measure compensation expense for stock-based awards to its employees and non-employee directors. Under this standard, we generally do not recognize any compensation related to stock option grants we issue under our stock option plans. Under the new rules, we are required to adopt a fair-value-based method for measuring the compensation expense related to employee and non-employee director stock awards which will result in non-cash compensation expense which will have an adverse effect on our reported results of operations. Note 1 to our Consolidated Financial Statements provides our pro forma net income and earnings per share as if we had used a fair-value-based method similar to the methods required under SFAS 123R to measure the compensation expense for employee and non-employee director stock awards during fiscal years 2005 and 2004.

Results of Operations

Three months ended December 31, 2004 compared with three months ended December 31, 2003.

Total Hectorol^{Ò} sales were $19,593,812 for the quarter ended December 31, 2004, an increase of $10,478,327 or 115% from the quarter ended December 31, 2003. Hectorol^{Ò} Injection sales were $17,208,586 for the quarter ended December 31, 2004, an increase of $9,311,298 or 118%, from the quarter ended December 31, 2003. We have expanded our sales force from approximately thirty-four direct sales specialists in fiscal 2004 to approximately sixty-five direct sales specialists as of December 31, 2004. The increase in Hectorol^{Ò} Injection sales in the quarter ended December 31, 2004 versus the quarter ended December 31, 2003 was primarily the result of the efforts of an expanded and experienced sales force as well as contract initiatives with national dialysis providers. Hectorol^{Ò} 2.5 mcg Capsules sales were $1,643,871 for the quarter ended December 31, 2004, an increase of $425,674, or 35%, from the quarter ended December 31, 2003. The increase was primarily attributed to price increases and the efforts of our expanded sales force. Sales of Hectorol^{Ò} 0.5 mcg Capsules were $741,355 for the quarter ended December 31, 2004. Hectorol^{Ò} 0.5 mcg Capsules were approved by the FDA in April 2004 and we began recording sales in the quarter ended September 30, 2004.

Total Hectorol^{Ò} gross margin was $15,062,143, or 77% of product sales, for the quarter ended December 31, 2004, compared to $6,847,528, or 75% of product sales, for the quarter ended December 31, 2003. Hectorol^{Ò} Injection and Hectorol^{Ò} 2.5 mcg Capsule gross margins were 75% and 91%, respectively, for the quarter ended December 31, 2004 versus 74% and 86%, respectively, for the quarter ended December 31, 2004. Hectorol^{Ò} 0.5 mcg Capsule gross margin was 91% in its second quarter of product sales. The overall improvement in gross margin for the quarter ended December 31, 2004 compared with the quarter ended December 31, 2003 was primarily due to economies of higher sales volumes and change in product mix.

Research and development (R&D) expense was $3,229,529 in the quarter ended December 31, 2004, an increase of $1,412,880, or 78%, from the quarter ended December 31, 2003. The increase in R&D expense was primarily due to preclinical, clinical and bioanalytical research activities of approximately $800,000, an increase in our clinical support expenses of approximately $200,000, an increase in compensation expenses of approximately $200,000, and personnel recruitment expenses of approximately $100,000 due to hiring clinical personnel.

Selling, general and administrative (SG&A) expense was $10,599,901 in the quarter ended December 31, 2004, an increase of $5,053,551, or 91%, from the quarter ended December 31, 2003. The increase in SG&A expense was primarily due to the planned expansion of our sales and marketing organization representing approximately $2,300,000, and marketing promotional programs of approximately $600,000, legal expenses of approximately

$500,000 for intellectual property, general legal activities and the co-promotion expense for Hectorol® 0.5 mcg Capsule sales.

Six months ended December 31, 2004 compared with six months ended December 31, 2003.

Total Hectorol® sales were $36,966,856 for the six months ended December 31, 2004, an increase of $19,726,329, or 114%, from the same period ended December 31, 2003. Hectorol® Injection sales were $33,008,563 for the six months ended December 31, 2004, an increase of $18,075,216, or 121%, from the same period in fiscal 2004. We have expanded our sales force from approximately thirty-four direct sales specialists in fiscal 2004 to approximately sixty-five direct sales specialists

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as of December 31, 2004. Hectorol® 2.5 mcg Capsule sales were $2,965,918 for the six months ended December 31, 2004, an increase of $658,738, or 29%, from the six months ended December 31, 2003. Hectorol® 0.5 mcg Capsule sales were $992,375 for the six months ended December 31, 2004. Hectorol® 0.5 mcg Capsules were approved by the FDA in April 2004 and we began recording sales in the quarter ended September 30, 2004.

Total Hectoral® gross margin was $28,261,718, or 76% of product sales, for the six months ended December 31, 2004, compared to $12,757,605, or 74% of product sales, for the six months ended December 31, 2003. Hectorol® Injection and Hectorol® 2.5 mcg Capsule gross margin were 75% and 90%, respectively, for the six months ended December 31, 2004 versus 73% and 78%, respectively, for the same period in 2003. Hectorol® 0.5 mcg Capsule gross margin was 91% for the six months ended December 31, 2004. The overall improvement in gross margin for the six months ended December 31, 2004 compared to the six months ended December 31, 2003 was primarily due to economies of higher sales volumes and change in product mix.

R&D expense was $5,768,660 for the six months ended December 31, 2004, an increase of $1,956,442, or 51%, from the same period in 2003. The increase in R&D expense was primarily due to preclinical, clinical and bioanalytical research activities of approximately $1,100,000, an increase in our clinical support expenses of approximately $300,000, and an increase in compensation expenses of approximately $300,000.

SG&A expense was $20,500,151 in the six months ended December 31, 2004, an increase of $8,872,602, or 76%, from the six months ended December 31, 2003. The increase in SG&A expense was primarily due to the planned expansion of our sales and marketing organization representing approximately $4,300,000, marketing promotional programs of approximately $2,000,000, legal expenses of approximately $800,000 for intellectual property and general legal activities, consulting and market research expenses related to strategic business activities of approximately $200,000 and the co-promotion expense for Hectorol® 0.5 mcg Capsule sales.

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 six months ended December 31, 2004, we have incurred $3,229,259 and $5,768,660, respectively, of R&D expense. The major portion of this expense was 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 have used cash to fund our operations, for capital expenditures and for strategic investments. Our cash and cash equivalents, marketable securities and long-term investment balances as of December 31, 2004 were $61,383,268, $55,512,823 and $905,863, respectively, totaling $117,801,954, an increase in total of $2,791,209 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 provided by operating activities was $1,528,240 for the six months ended December 31, 2004 which resulted primarily from increased earnings.

Cash provided by investing activities was $12,141,735 for the six months ended December 31, 2004 primarily due to maturities of various held-to-maturity securities. Non-cash amortization of discounts and premiums related to investing activities was $157,338 and $121,224 for the six months ended December 31, 2004 and 2003, respectively.

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Cash provided by financing activities was $2,387,622 for the six months ended December 31, 2004 due to proceeds received from the exercise of stock options, offset by repayments of 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 FDA regulations for manufacturing facilities. We believe relationships with our suppliers are good.

As of June 30, 2004, we had 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 had state net operating loss carryforwards of $46,036,000 and R&D tax credit carryforwards of $756,000, which expire in 2006 through 2024.

Contingencies

In the ordinary course of business, the Company is involved in legal proceedings and other matters. While it is not possible to accurately predict or determine the eventual outcome of these items, the Company does not believe any such items currently pending will have a material adverse effect on its annual financial statements, although an adverse resolution in any matter could have a material impact on the results of operations for that period.

Additional factors that might affect future results include the following:

Our business is at an early stage of development and we do not have a significant history for you to evaluate us on.

Our business is at an early stage of commercialization and product development, and historically has not had significant revenues or positive cash flow. Even if we are able to achieve positive cash flow from operations, we will face many challenges as we strive to maintain profitability. Hectorol® Injection is approved for one indication and Hectorol® Capsules are approved for two indications. Our product candidates and any expansion of indications for our current products will require extensive research and development and clinical testing before we can submit a new drug application to the FDA. In addition, we have not commercialized Hectorol® in foreign markets. The successful commercialization of Hectorol® or any of our other product candidates will require significant further research, testing, development and regulatory approvals and additional investment. There can be no assurance that we will be successful in any of our commercialization efforts. Our experience with, and history in, conducting these activities has been limited. Any predictions you make about our future success or viability may not be as accurate as they would be if we had a longer operating history.

We have a history of losses and only recently achieved profitability.

Historically, we have incurred operating losses. Beginning in the quarter ended March 31, 2004 and for the three subsequent quarters, we have reported operating profits. As of December 31, 2004, our accumulated deficit was approximately $51.7 million. To date, we have primarily spent our funds on product development and more recently on sales, marketing and manufacturing expenses incurred to commercialize Hectorol^{Ò} Injection and Hectorol^{Ò}Capsules. In fiscal year 2005 and subsequent fiscal years, we plan to make large expenditures to manufacture, market and sell Hectorol^{Ò} and to develop other products, which may result in losses in future periods. These expenditures include costs associated with continuing our research and development, performing clinical trials for new products, expanding our patent portfolio and seeking U.S. and foreign regulatory approvals for Hectorol^{Ò}, and business development activities. The amount of these expenditures is difficult to forecast accurately. It is possible, depending on the rate at which our revenues increase and our marketing, research and development, and other business development activities expand that may generate losses from operations. Our ability to generate revenues in the near future will depend primarily on our ability to continue to obtain products manufactured by third parties and on our

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success in marketing and selling Hectorol® Injection and Hectorol® Capsules. We do not know whether we will sustain profitability for the fiscal year or future fiscal years.

We currently derive all of our revenue from Hectorol®, and may continue to do so for the foreseeable future. If sales of Hectorol® decrease, our results of operations will be significantly adversely affected.

We currently derive all of our revenue from the sale of Hectorol®. In June 1999, we received FDA approval to market Hectorol® 2.5 mcg Capsules in the U.S. to manage secondary hyperparathyroidism in kidney dialysis patients and began selling Hectorol® 2.5 mcg Capsules in October 1999. In April 2000, we received FDA approval to market Hectorol® Injection to manage secondary hyperparathyroidism in dialysis patients and began selling Hectorol® Injection in the U.S. in August 2000. In April 2004 we obtained FDA approval for Hectorol® 0.5 mcg Capsules to manage secondary hyperparathyroidism in pre-dialysis patients with moderate to severe chronic kidney disease and we began selling this product in the U.S. in July 2004. We believe that sales of Hectorol® Capsules and Hectorol® Injection will continue to constitute a significant portion of our total revenues for the foreseeable future. Accordingly, any factor adversely affecting sales of Hectorol®, such as the introduction by other companies of generic equivalents of Hectorol® or alternatives to Hectorol® or any delay in marketing for pre-dialysis, may have a material adverse effect on our results of operations. There can be no assurance that the vitamin D hormone market will not decline in the future.

We may not be able to commercialize our existing or new products if we do not enter into successful strategic alliances or other marketing arrangements.

As part of our business strategy, we plan to establish strategic partnerships, alliances and commercialization arrangements with partners who can penetrate geographic markets and compete in therapeutic areas where we have no current or planned sales presence. In addition, we may seek to enter into strategic alliances or collaborations in connection with the development or commercialization of new products. We have been in discussions with several potential collaborators but have not entered into any agreements other than with Cardinal Health for the promotion of Hectorol® 0.5 mcg Capsules to nephrologists. We may not be able to negotiate collaborative arrangements on acceptable terms, if at all. If we are not able to establish collaborative arrangements, we will have to either delay further development of some of our programs or increase our expenditures and undertake the development activities at our own expense. We may encounter significant delays in commercializing our products or find that the development, manufacture or sale of our products is hindered due to the absence of collaborative agreements.

We have limited experience establishing and maintaining collaborative agreements. Our agreement with Cardinal Health, and any other collaborative agreements we may enter into in the future, may pose additional risks, including the following:

- the terms of our contracts with our collaborators may not be favorable to us in the future;
- a collaborator with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of such products;
- disputes with our collaborators may arise, leading to delays in or termination of the development or commercialization of our products, or resulting in significant litigation or arbitration;
- contracts with our collaborators may fail to provide significant remedies if one or more of them fail to perform;
- our contracts with collaborators may be terminated and we may not be able to replace our collaborators;

in some circumstances, if a collaborator terminates an agreement, or if we are found to be in breach of our obligations, we may be unable to secure all of the necessary intellectual property rights and regulatory approval to continue developing the same compound or product; and

our collaborators could independently develop, or develop with third parties, products that compete with ours.

If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.

If appropriate opportunities become available, we may attempt to acquire licenses, technologies, products or companies that we believe fit strategically with our business. We currently have no understandings, commitments or arrangements with respect to any such acquisitions. If we do undertake any transaction of this sort, the process of integrating an acquired license, technology, product or company may result in operating difficulties and expenditures and may absorb significant management

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attention that would otherwise be available for our ongoing business development plans. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in in-process research and development expenses, potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or impairment of goodwill and amortization or impairment of other intangible assets, which could adversely affect our business, financial condition and results of operations.

We have limited experience commercializing our products and may not be able to successfully do so.

To date, our experience in commercializing our products has been primarily limited to marketing Hectorol® to treat patients with moderate to severe chronic kidney disease and end-stage renal disease. In order to successfully commercialize Hectorol® or any other products, we will need to have adequate sales, marketing and distribution capabilities in place. Our sales force has been limited in number, current product experience and training. We have recently expanded our sales force and marketing capabilities. We may not be able to continue to attract skilled sales/marketing personnel in a timely manner. In addition, we may not be able to maintain a commercial infrastructure with the technical expertise to support manufacturing oversight, product release and distribution capabilities. If we are unsuccessful in our commercialization efforts, our growth prospects will be diminished.

We lack sufficient long-term data regarding the safety and efficacy of Hectorol® and we could find that our long-term data do not support our current clinical findings which may limit our efforts to commercialize Hectorol®.

Hectorol® is supported by only five or less years of patient follow-up, and therefore, we could discover that our current clinical results cannot be supported by actual long-term clinical experience. If longer-term patient studies or clinical experience indicate that treatments with our products do not provide patients with sustained benefits, our sales could significantly decline. If longer-term patient studies or clinical experience indicate that our procedures cause tissue or muscle damage, motor impairment or other negative effects, we could be subject to significant liability. We are not certain how long it may take for patients to show significant increases in side effects. Further, because some of our data have been produced in studies that are not randomized and involved small patient groups, our data may not be reproduced in wider patient populations.

We have not conducted prospective clinical trials comparing Hectorol® and competitive vitamin D hormone therapies in moderate to chronic kidney disease and end-stage renal disease. We, and others not affiliated with us, have compared the toxicity and efficacy of Hectorol® to some other vitamin D hormone therapies (1-a-calcidol and calcitriol) in rats and mice. We cannot be sure, however, that the results of additional clinical trials will prove that our assumptions, based on animal studies, are correct as applied to humans. Hectorol® may not compare favorably to existing or new vitamin D hormone therapies. If Hectorol® or our future products do not prove to be superior to competing products, we may face severe difficulties and may incur greater marketing expenses. If additional clinical trials prove that Hectorol® is inferior to competitive vitamin D hormone therapies, we may be forced to suspend our efforts to commercialize Hectorol® and to delay or suspend our planned efforts to develop Hectorol® for additional indications.

If the medical community does not accept our products, our business will suffer.

The success of our products depends on acceptance of those products by the medical community, which is based on a number of factors including:

perceptions about the safety and efficacy of our products;

cost-effectiveness of our products relative to competing products;

availability of reimbursement for our products from government or third-party payors; and

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

If doctors and patients do not use our products, we may not become profitable. We cannot predict how quickly, if at all, the medical community will accept our products or the extent to which these products will be used. If we encounter difficulties introducing our products into our targeted markets, our operating results and business may be substantially impaired.

Failure to raise additional funds in the future may delay or eliminate some or all of our efforts to develop, manufacture and sell Hectorol® and any of our future products.

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In recent years we have significantly increased our sales and marketing expenditures and we continue to spend significant amounts on research and development. We cannot be sure that our estimates of capital expenditures for Hectorol® and the development of our other new products will be accurate. We could have significant cost overruns that could reduce our ability to commercialize new products.

Reimbursement for Hectorol® or any future products could be reduced or modified.

Sales of our products will depend, in part, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. These health care management organizations and third-party payors are increasingly challenging the prices charged for medical products and services and frequently require predetermined discounts from list prices. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been targeted in this effort. Our current and potential products may not be considered cost effective, and reimbursement to the consumer may not be available or sufficient to allow us to sell our products on a competitive basis. Legislation and regulations affecting reimbursement for our products have recently changed and may change at any time, including in ways that are adverse to us. Currently, only Hectorol® Injection is eligible to be reimbursed under Medicare but there is no guarantee as to the level of this reimbursement or whether it will continue at all. Any reduction in Medicare or other third-party payor reimbursements could have a negative effect on our operating results.

We currently have no manufacturing capabilities so we must rely exclusively on suppliers who are outside of our control to manufacture our products, including Hectorol®.

The manufacturing of pharmaceutical products requires significant expertise, oversight, and capital investment. We do not have the internal capability to manufacture pharmaceutical products, and we currently use others to formulate, manufacture and package Hectorol® and other drug candidates and manufacture our active pharmaceutical ingredient. Our manufacturers are required to adhere to current Good Manufacturing Practices regulations enforced by the FDA. Our dependence upon others to manufacture our active pharmaceutical ingredient and products may adversely affect our profit margins and our ability to develop and commercialize products on a timely and competitive basis. Delays or difficulties with contract manufacturers in manufacturing active pharmaceutical ingredient and producing, packaging or distributing our products would adversely affect the results of operations of Hectorol® or introduction of other products. If we were to need to seek alternative sources of supply, we may be unable to enter into alternative supply arrangements on commercially acceptable terms, if at all. Any disruption of these activities could impede our ability to sell our products, which would significantly reduce our results of operations.

We entered into a manufacturing agreement with Draxis Pharma Inc., a subsidiary of Draxis Health Inc., to serve as a manufacturer of Hectorol®Injection and began commercial distribution in March 2003. There is no assurance that Draxis will have sufficient production capacity to meet future demand or that Draxis will perform its contractual obligations.

We purchase our active pharmaceutical ingredient for Hectorol® from a sole supplier, located in the Middle East, a geographic location subject to increased political instability, which could disrupt or halt the operations of this supplier. We are currently in the process of obtaining regulatory approval for an additional active pharmaceutical ingredient supplier. We rely on one supplier to formulate Hectorol®Capsules and another supplier to package Hectorol Capsules®. Although we believe that other suppliers may be available, any change in suppliers or method of manufacture could cause an increase in cost, a delay in manufacturing, and a possible loss of sales, any of which would affect operating results adversely. All of our current suppliers are, and any future suppliers will be, subject to extensive government regulation by the FDA and other comparable foreign regulators.

While we currently do not intend to manufacture any products ourselves, we may choose to do so in the future. If we were to manufacture products ourselves, we would need additional funding and would have to hire and train additional personnel and comply with the extensive regulations applicable to the FDA regulations for manufacturing facilities and would be subject to risks associated with delays or difficulties encountered in manufacturing a regulated product. We may not be able to manufacture any products successfully or in a cost-effective manner.

If we are unable to satisfy the FDA with the results of our Phase IV commitment studies for Hectorol® Capsules or are otherwise required to meet any additional FDA obligation with respect to Hectorol® Injection, our operating results and business will be substantially impaired.

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After initial FDA or other health authority approval has been obtained, further studies, including Phase IV post-marketing studies, may be required to provide additional data on safety. The FDA or other regulatory authorities may also require post-marketing reporting to monitor the side effects of a drug. Results of post-marketing requirements may limit the marketing of such products.

The FDA allowed us to market Hectorol® 2.5 mcg Capsules to end-stage renal disease patients, but required us to complete post-approval Phase IV research and development pertaining to the analysis of this product and its active ingredients by July 2000. We have completed and submitted the results of our Phase IV commitments for Hectorol® 2.5 mcg Capsules to the FDA. In addition, in connection with our recent FDA approval of Hectorol® 0.5 mcg Capsules, the FDA required us to commit to complete, by April 2006, a post-marketing Phase IV study of Hectorol® 0.5 mcg Capsules in pediatric patients ages 5 through 18 with Stage 3 or 4 chronic kidney disease, pre-dialysis. We are also required to complete, by February 2007, a post-marketing Phase IV study of Hectorol® 0.5 mcg Capsules in adult vitamin D deficient patients with Stage 3 or 4 chronic kidney disease to address recommendations made in the K/DOQI guidelines. Lastly, we are required to complete, by June 2008, a post-marketing Phase IV carcinogenicity study in a single species. We do not know if we will be able to timely complete these studies, if the FDA will be satisfied with the results or if the FDA will require additional post-marketing commitments.

We cannot assure you that we will obtain regulatory approvals for Hectorol® or any of our future products.

Obtaining required regulatory approvals may take several years to complete and may consume substantial capital resources. There can be no assurance that the FDA or any other regulatory authority will act quickly or favorably on any of our current or future requests for product approval, or that the FDA or any other regulatory authority will not require us to provide additional data that we do not currently anticipate to obtain product approvals. We cannot apply for FDA approval to market our future products until we successfully complete pre-clinical and clinical trials. If we are not able to obtain regulatory approvals for use of our future products, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited.

We filed an investigational new drug application in September of 2003 for LR-103. Our investigational new drug will be initially tested in refractory cancer patients. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety problems develop, we or the FDA could stop our trials before completion.

We also plan to file an Investigational New Drug application (IND) for LR-103 in the third quarter of fiscal 2005 for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease (CKD) Stages 3 to 5 (moderate to end-stage CKD). The successful filing of this IND, the initial patient population, the duration and timing of the initial study (ies) will be dependent on pre-IND discussions planned with the FDA. As with the oncology program above, once a study (ies) is (are) initiated under this new IND, several factors could prevent successful completion or cause significant delays of these trials. These factors include an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety problems develop we, or the FDA, could stop our trials before completion.

Our failure to obtain regulatory approvals in foreign jurisdictions would prevent us from marketing our products abroad.

We may also market our products in international markets, including the European Union and Japan. In order to do so, we must obtain separate regulatory approvals from these other foreign jurisdictions. The regulatory approval processes differ among these jurisdictions. Approval in any one jurisdiction does not ensure approval in a different jurisdiction. Hectorol® has not been approved for marketing by any governmental entity outside of the U.S. except for

Hectorol® 2.5 mcg Capsules which are approved in Canada. We will require substantial additional funds to develop the product, conduct clinical trials and gain the necessary regulatory approvals for Hectorol® Injection, Hectorol® Capsules or other products in foreign countries. As a result, in order to commercialize our products outside the U.S. we will need to invest additional resources or enter into arrangements with partners.

Our success depends on our key personnel, the loss of whom could impair our business.

Our success depends upon our ability to attract and retain qualified personnel including our management, scientific, regulatory, sales, marketing and financial personnel. Pharmaceutical companies, academic and government organizations, research institutions and other entities compete for the services of qualified personnel. We may not be able to attract and retain

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such personnel. Furthermore, our anticipated growth and expansion into areas and activities requiring additional expertise will require additional personnel.

Our failure to expand our management systems and controls to support anticipated growth could harm our business.

Sustaining our growth has placed significant demands on management and our administrative, operational, information technology, financial and personnel resources. Accordingly, our future operating results will depend on the ability of our officers and other key employees to continue to implement and improve our operational, quality compliance, regulatory support and financial control systems, and effectively expand, train and manage our employee base. We may not be able to manage our growth successfully, which could seriously harm our operating results and business.

We have many competitors, several of which have significantly greater financial and other resources.

We face competition from several companies that are focused on developing vitamin D hormone therapies, particularly to treat secondary hyperparathyroidism and hyperproliferative diseases. We also compete with other companies that produce vitamin D hormones and vitamin D hormone analogs for international marketplaces where these treatments have already been approved for secondary hyperparathyroidism and hyperproliferative diseases. Competition may increase further as additional companies begin to enter our markets and/or modify their existing products to compete directly with ours. Companies also compete indirectly with us utilizing different therapeutic approaches. Many of our competitors have substantially greater financial, research and development and marketing resources than we do and may be better equipped to develop, manufacture and market products. Our competitors include companies that market products that compete with Hectorol® Injection and Hectorol® Capsules and may in the future include companies that are developing vitamin D hormone therapies to treat cancer or psoriasis.

Our competitors may have broad product lines which allow them to negotiate exclusive, long-term supply contracts and offer comprehensive pricing for their products. Broader product lines may also provide our competitors with a significant advantage in marketing competing products to group purchasing organizations and other managed care organizations that are increasingly seeking to reduce costs through centralized purchasing. Greater financial resources and product development capabilities may allow our competitors to respond more quickly to new or emerging technologies and changes in customer requirements that may render our products obsolete. These technological developments may result in Hectorol® becoming obsolete or non-competitive.

If our competitors develop more effective and/or affordable products, or achieve earlier patent protection or product commercialization than we do, our operations will likely be negatively affected.

We also face competition for marketing, distribution and collaborative development agreements, for establishing relationships with academic and research institutions, and for licenses to intellectual property. In addition, academic institutions, government agencies and other public and private research organizations also may conduct research, seek patent protection and establish collaborative arrangements for discovery, research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs.

Our products and development activities are subject to extensive government regulation, which could make it more expensive and time-consuming for us to conduct our business and could adversely affect the manufacturing and marketing of our products.

Any new drug product, including any new indication for Hectorol®, must undergo lengthy and rigorous clinical testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. We may elect to delay or cancel our anticipated regulatory submissions for new indications for Hectorol® or proposed new products for a number of reasons, including:

unanticipated clinical testing results;

lack of sufficient resources;

changes in, or adoption of, new FDA regulations;

unanticipated enforcement of existing regulations or guidelines;

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an inability to enroll the required number of patients in trials;

unexpected technological developments; and

developments by our competitors.

The FDA continues to review products even after they receive FDA approval. The manufacture, distribution and marketing of Hectorol® is subject to extensive ongoing regulation, including compliance with the FDA s current Good Manufacturing Practices, adverse event reporting requirements and the FDA s general prohibitions against promoting products for off-label uses, or uses not listed on the FDA-approved labeling. We and our manufacturers are also subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Failure to comply with these requirements could result in:

warning letters;

fines;

civil penalties;

injunctions;

recall or seizure of products;

total or partial suspension of production;

refusal of the government to grant approvals; or

withdrawal of existing approvals and criminal prosecution.

Any such enforcement action could adversely affect the manufacturing and marketing of our products.

We must also comply with numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, current Good Laboratory Practices, product distribution and the experimental use of animals. Additionally, products using inventions that are fully or partially funded by federal research grants are subject to government rights. We cannot predict the extent of government regulation or the impact of new governmental regulations which might have an adverse effect on the discovery, development, production, distribution and marketing of our products, and require us to incur significant costs to comply with the regulations.

Our distributor base is highly concentrated and if we lose any of our distributors our business could be materially harmed.

Five individual wholesale distributors comprised 99% of the net accounts receivable balance as of December 31, 2004. These same five wholesale distributors represented 95% of our product sales for the six months ended December 31, 2004, with the largest of the five wholesale distributors representing 31% of product sales. The loss or bankruptcy of any of these distributors could materially and adversely affect our results of operations and financial condition.

We are exposed to product liability risks which may exceed our existing coverage and could result in significant liabilities and costly litigation.

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. The use of our products in the marketplace and the use of our products and drug candidates in clinical trials may expose us to product liability claims. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management s time, attention and resources. We have obtained product liability insurance relating to clinical trials and our current products. We cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all. Claims or losses in excess of any product liability insurance coverage that we have or may obtain, or a series of unsuccessful claims against us, could have a material adverse effect on our business, financial condition and results of operations.

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Our use of hazardous materials exposes us to the risk of material environmental liabilities.

Because we use hazardous substances in our research and development activities, we are potentially subject to material liabilities related to personal injuries or property damages that may be caused by hazardous substance releases or exposures at or from our facility. Decontamination costs, other clean-up costs and related damages or liabilities could impair our business and operating results. We are required to comply with stringent laws and regulations governing environmental protection and workplace safety, including requirements governing the handling, storage and disposal of hazardous substances.

If we are unable to protect our patents, our competitiveness and business prospects may be materially damaged.

Our success will depend to a significant degree on our ability to obtain and enforce patents and licenses to patent rights, both in the U.S. and in other countries. The patent position, however, of pharmaceutical companies is often uncertain and involves complex legal and factual questions, not the least of which is that we cannot predict the breadth of patent claims in pharmaceutical patents. In addition, a substantial backlog of pharmaceutical patent applications exists at the U.S. Patent and Trademark Office. The backlog may delay review and potential issuance of patents. Further, patents once granted are subject to challenge and may, in litigation or administrative proceedings before the U.S. Patent and Trademark Office, be found invalid.

To date, in addition to a number of issued patents, we have filed a number of patent applications in the U.S. and other countries. We have filed a patent application directed toward the use of Hectorol® for the treatment of hyperparathyroidism associated with chronic kidney disease (Stages 1 through 4). Should this application not issue as a U.S. patent, our patent protection covering the treatment of hyperparathyroidism in patients with moderate to severe chronic kidney disease (Stages 1 through 4) would cease in 2008, although our patent protection for the use of Hectorol® for the treatment of hyperparathyroidism associated with end-stage renal disease (Stage 5), which begins to expire in 2014, would not be affected. However, in December 2004, the Company received notice of allowance from the U.S. Patent and Trademark Office for claims relating to stabilized hydroxyvitamin D_2 products and pharmaceutical compositions and medicaments including stabilized hydroxyvitamin D_2. The stabilized hydroxyl vitamin D_2 product for which a patent will be granted is characterized by a purity profile and level of impurities and residual solvents. Hectorol® is covered by this new composition of matter patent that will expire in 2021.

If we were to lose this patent protection relating to Stages 1 through 4, our future sales and results could be significantly adversely affected. In addition, except for the new composition of matter patent described in the preceding paragraph, our issued patents and pending patent applications relating to Hectorol® are method-of-use patents which cover only the use of certain compounds to treat specified conditions, rather than composition-of-matter patents which would cover the chemical composition of the active ingredient. Method-of-use patents provide less protection than composition-of-matter patents because of the possibility of off-label uses if other companies market or make the compound for other uses. We actively continue to file applications as appropriate for patents covering our products, uses and processes. We cannot guarantee that we will obtain patent protection for our products, uses or processes.

We also cannot guarantee that competitors will not successfully challenge our patents on the basis of validity and/or enforceability. Nor can we guarantee that they will not circumvent or design around our patent position. We could face increased competition as a result of the failure of patents to be issued on our pending applications or a finding of invalidity and/or unenforceability of one of our patents.

In the U.S., most patent applications are maintained in secrecy until a patent application publishes 18 months after filing or is issued. We cannot be certain that others have not filed unpublished patent applications for compounds, uses

or processes covered by our pending applications. We also cannot be certain that we were the first to invent or discover the compound, use or process that is the subject of our applications. Competitors may have filed applications for, or may have received patents and may obtain additional patents and proprietary rights relating to, compounds, uses or processes that block or compete with our patents and rights. We are aware of a significant number of patent applications relating to vitamin D hormones filed by, and patents issued to, third parties. If any of our competitors have filed patent applications in the U.S. that claim compounds, uses or processes also claimed by us, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention and the corresponding right to a patent for the compounds, uses or processes in the U.S. Any such proceeding could result in substantial cost to us even if the outcome is favorable.

We have not filed patent applications in every country. In certain countries, obtaining patents for our products, processes and uses may be difficult or impossible. Patents issued in countries and regions other than the U.S., Japan and Europe may be harder to enforce than, and may not provide the same protection as, patents obtained in the U.S., Europe and Japan.

In addition, litigation may be necessary to enforce our patents, if infringed, and in that connection to determine the scope and validity of the proprietary rights of third parties. Litigation could result in substantial cost to us. We cannot guarantee that our patents or those of licensors from whom we have licensed rights will not be challenged, invalidated, found unenforceable or circumvented. Nor can we guarantee that the rights granted under licenses will provide any proprietary protection or commercial advantage to us.

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If we are unable to protect our proprietary rights and trade secrets, our competitiveness and business prospects may be materially damaged.

Operation of our business also relies on our ability to protect proprietary information and trade secrets. We require our employees, consultants and advisors to execute confidentiality and invention assignment agreements upon commencement of employment or consulting relationships with us. We cannot guarantee, however, that these agreements will provide meaningful protection or adequate remedies for our proprietary information and trade secrets in the event of unauthorized use or disclosure of such information nor can we guarantee that the parties to the agreements will not breach their agreements. We also cannot guarantee that third parties will not know, discover or develop independently equivalent proprietary information or techniques, that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets.

We may be accused of infringing upon the patents or other proprietary rights of others and any related litigation could damage our business.

Our commercial success depends significantly on our ability to operate our business without infringing upon the patents and other proprietary rights of third parties. We cannot guarantee that our compounds, uses or processes do not and will not infringe upon the patents and proprietary rights of third parties. In the event of an infringement determination, we may be enjoined from research, development or commercialization of our products. We may also be required to enter into royalty or license arrangements with third parties claiming infringement or otherwise to design around their patents. Any required license, if available at all, may not be obtained on commercially reasonable terms. If we do not obtain the licenses or are unable to design around the patent, we may be delayed or prevented from pursuing the development of some of our product candidates.

We may lose the exclusive rights to market LR-103 if we are unable to commercialize it by December 31, 2006.

We and the U.S. Department of Agriculture jointly own rights to LR-103 under issued patents and a pending patent applications. The U.S. Department of Agriculture has granted to us a worldwide exclusive license under its rights in the jointly owned patents to make, use and sell products covered under their rights. This agreement calls for us to commercialize LR-103 by December 31, 2006, or the U.S. Department of Agriculture may modify or terminate the license. If the U.S. Department of Agriculture terminates the license, we would lose our exclusivity and the U.S. Department of Agriculture could license the right to make, use and sell the product to a third party or do it themselves.

Concentration of ownership in our company by a few shareholders and features of our corporate charter make it more difficult to replace or remove our current management and may have the effect of delaying, deferring or preventing takeover transactions.

Based on the number of shares outstanding at February 1, 2005, our executive officers, directors and major shareholders beneficially own approximately 34.3% of the outstanding shares of our common stock and, as a result, have significant control of us, which they could exert to make it more difficult to replace or remove our current management or could be used to delay, defer or prevent a change in control of the company.

In addition, certain provisions of our articles of incorporation may make it more difficult for a third party to acquire, or may discourage acquisition bids for, Bone Care and could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Such provisions, among other things, include:

We have a board of directors serving staggered three-year terms; and

We have a shareholders rights plan.

Our future operating results and the trading price of our common stock is likely to fluctuate substantially in the future

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Our stock price has fluctuated substantially since we became a public company in May 1996. Our stock price, like that of many other biotechnology and pharmaceutical companies, is likely to remain volatile. The trading price of our common stock may fluctuate widely as a result of a number of factors, some of which are not in our control, including:

- market perception and customer acceptance of our products;
- our efforts to increase sales of our Hectorol® products;
- quarter-to-quarter variations in our operating results;
- timely implementation of new and improved products;
- our level of investment in research and development;
- increased competition;
- our establishment of strategic alliances or acquisitions;
- changes in our relationships with suppliers;
- litigation concerning intellectual property rights in the industry;
- announcements regarding clinical activities or new products by us or our competitors;
- timing of regulatory actions, such as product approvals or recalls;
- costs we incur in anticipation of future sales, such as inventory purchases or expansion of manufacturing facilities;
- general and economic conditions in the biotechnology and pharmaceutical industry and the state of healthcare cost containment efforts, including reimbursement policies;
- limited research coverage by independent securities analysts; and
- changes in earnings estimates by analysts.

In addition, the market for our stock has experienced extreme price and volume fluctuations, which have often been unrelated to our operating performance. We believe that period-to-period comparisons of our historical and future results will not necessarily be meaningful and that investors and prospective investors in Bone Care should not rely on them as an indication of future performance. To the extent we experience the factors described above, our future operating results may not meet the expectations of securities analysts or investors from time to time, which may cause the market price of our common stock to decline or be volatile.

Substantial future sales of our common stock in the public market may depress our stock price.

Most of our outstanding shares of common stock are freely tradable. The market price of our common stock could drop due to sales of a large number of shares or the perception that such sales could occur, including sales or perceived sales by our directors, officers or principal shareholders. These factors also could make it more difficult to raise funds through future offerings of common stock.

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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 December 31, 2004, we held $55,512,823 and $905,863 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 December 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 December 31, 2004 were identified that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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. We have been cooperating with the request of the Justice Department since receipt of the subpoena.

In the ordinary course of business, the Company is involved in legal proceedings and other matters. While it is not possible to accurately predict or determine the eventual outcome of these items, the Company does not believe any such items currently pending will have a material adverse effect on its annual financial statements, although an adverse resolution in any matter could have a material impact on the results of operations for that period.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On November 23, 2004, at our annual meeting of shareholders, our shareholders voted on proposals to: (1) elect three directors to serve until the 2007 annual meeting; (2) approve an amendment to our 2003 Stock Incentive Plan; (3) approve an amendment to our Articles of Incorporation to increase the number of our authorized shares of common stock from 28 million to 75 million and to increase the number of our authorized shares of preferred stock from 2 million to 10 million; (4) approve an agreement and plan of merger of Bone Care International, Inc., a Wisconsin corporation, into Bone Care International, Inc., a Delaware corporation, to effect our reincorporation in Delaware and to increase the number of our authorized shares of common and preferred stock as provided in proposal (3) and; (5) ratify the selection of Deloitte & Touche LLP as our independent auditors for the fiscal year ended June 30, 2005. The results of the proposals voted upon at the annual meeting are as follows:

1. Three directors were elected for terms of three years each, as follows:

DIRECTOR	Votes FOR	Votes WITHHELD
Michael A. Appelbaum	17,288,387	1,280,589
Michael D. Casey	17,934,204	634,772
Herbert J. Conrad	18,172,924	396,052

2. The Amendment to the 2003 Stock Incentive Plan was approved, as follows:

Votes FOR	Votes AGAINST	Votes ABSTAIN	Broker NON-VOTE
12,323,258	2,571,211	74,480	3,600,027

3. The Amendment to the Articles of Incorporation to increase the authorized common and preferred Stock was approved, as follows:

Votes FOR	Votes AGAINST	Votes ABSTAIN	Broker NON-VOTE
9,679,609	5,186,227	103,113	3,600,027

4. The Agreement and Plan of Merger to effect the reorganization of the Company was approved, as follows:

Votes FOR	Votes AGAINST	Votes ABSTAIN	Broker NON-VOTE
14,227,831	698,817	42,301	3,600,027

5. The selection of Deloitte & Touche LLP as independent auditors for the Company for fiscal year ending June 30, 2005 was ratified, as follows:

Votes FOR	Votes AGAINST	Votes ABSTAIN	Broker NON-VOTE
17,832,785	731,457	4,734	

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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: February 9, 2005

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

Date: February 9, 2005

/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 December 31, 2004