BONE CARE INTERNATIONAL INC
Form 10-K
September 13, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2004

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For 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 or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
1600 Aspen Commons **Middleton, Wisconsin**	**53562**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s Telephone Number, Including Area Code: **(608) 662-7800**

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, without par value
Preferred Stock Purchase Rights

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

Yes x No o

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $182,432,710 as of December 31, 2003, assuming solely for purposes of this calculation that all directors and executive officers of the registrant are affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of September 1, 2004, there were 19,410,157 shares of the Registrant s Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Bone Care International, Inc., Proxy Statement for its 2004 Shareholders Meeting (Part III).

BONE CARE INTERNATIONAL, INC.

INDEX TO
ANNUAL REPORT ON FORM 10-K
For the Year Ended June 30, 2004

In this Annual Report on Form 10-K, the Company , Bone Care, we, us and our refer to Bone Care Internatio Inc., unless the context suggests otherwise.

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

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated by reference into this Form 10-K contain forward-looking statements. Statements relating to future net sales, costs of sales, other expenses, profitability, financial resources, or products and production schedules, or statements that predict or indicate future events and trends and which do not relate solely to historical matters identify forward-looking statements. Forward-looking statements are made in reliance on the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are based on management s current plans and expectations as well as assumptions made by and information currently available to management. Accordingly, our actual results may differ materially from those expressed or implied in such forward-looking statements due to known and unknown risks and uncertainties that exist in our operations and business environment, including, among other factors:

- general economic and market conditions in the U.S., Europe and the rest of the world;
- our expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- the ability of us and each of our suppliers of doxercalciferol, Hectorol® Injection and Hectorol® Capsules to meet our anticipated production schedules;
- technical risks associated with the development of new products;
- regulatory policies in the U.S. and other countries;
- risks associated with our ability to avoid or minimize delays in/or interruption of the manufacture and supply of our products, including the approvals of regulatory authorities in connection therewith;
- reimbursement policies of public and private health care payors;
- introduction and acceptance of new drug therapies;
- competition from existing products and from new products or technologies;
- the failure by us to produce anticipated cost savings or improve productivity;
- the timing and magnitude of capital expenditures and acquisitions; and
- other risk factors set forth under Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations in this Annual Report on Form 10-K.

In addition, in this Annual Report, the words believe, may, will, estimate, continue, anticipate, intend, similar expressions, as they relate to us, our business or our management, are intended to identify forward-looking statements.

Unless otherwise required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this annual report. However, we acknowledge our obligation to disclose material developments related to previously disclosed information. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in the filing may not occur, and actual results could differ materially from those anticipated or implied in the forward-looking statements.

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PART I

ITEM 1. *BUSINESS*

Overview

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

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

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

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Business Strategy

Our strategy is to build a specialty pharmaceutical company with a strong distribution channel through research, development, commercialization and acquisition of key therapeutics. We plan to achieve these goals by:

Expanding our sales and marketing infrastructure. We plan to continue to develop our internal sales and marketing capabilities to compete in the $400 million vitamin D hormone market in the U.S. for end-stage renal disease, in the market for the estimated 8 million patient population with moderate to severe chronic kidney disease and in related markets for vitamin D hormone therapies that we believe could be effectively addressed with a highly focused sales and marketing effort.

Expanding the indications for Hectorol®. We plan to pursue new indications, new formulations and product life cycle management strategies for Hectorol®. The FDA recently approved the use of Hectorol® 0.5 mcg Capsules to treat secondary hyperparathyroidism in pre-dialysis.

Developing additional product offerings. We plan to leverage our vitamin D hormone platform and use our research and development, clinical and regulatory capabilities to seek to develop and improve products for targeted diseases such as secondary hyperparathyroidism, psoriasis and cancers.

Licensing and acquiring compounds that fit into our strategic plans. We are evaluating marketed products and compounds in development that fit into our strategic plans. In-licensing and acquisition targets may include products in the traditional nephrology therapeutic area, products that treat co-morbid conditions commonly seen in chronic kidney disease patients related to metabolic syndrome or other targeted specialty pharmaceutical markets.

Entering into strategic partnerships to globally commercialize our current products and assets or new products. We plan to establish mutually beneficial strategic partnerships, alliances and commercialization arrangements with partners who can penetrate geographic markets or compete in therapeutic areas where we have no current or planned sales presence. We also may seek to enter into strategic alliances to develop or commercialize new products.

Products for Secondary Hyperparathyroidism

Background

Vitamin D hormones are produced in the body from vitamin D precursors that are either ingested or activated in the skin from sunlight exposure. These hormones have essential roles in human health. Vitamin D hormones regulate (1) parathyroid hormone secretion by the parathyroid glands, (2) the absorption of calcium by the small intestine, (3) bone mineralization, (4) muscle function, and (5) the proliferation and maturation of several types of cells. Vitamin D hormone deficiency in chronic kidney disease occurs when the kidneys are unable to produce adequate active vitamin D hormones. Without sufficient active vitamin D hormone levels, parathyroid hormone secretion is increased and calcium absorption in the small intestine is reduced, leading to hypocalcemia, hyperparathyroidism, and eventually to bone disease.

Hyperparathyroidism is a disease characterized by excessive secretion of parathyroid hormone by the parathyroid glands. The medical community classifies hyperparathyroidism as either primary or secondary, depending on the underlying cause. Primary hyperparathyroidism is less common and is caused by a disorder in one or more of the parathyroid glands, usually a tumor. Surgical removal of the affected parathyroid glands is the only effective treatment. Secondary hyperparathyroidism is the more common type of hyperparathyroidism and is caused by diseases unrelated to the parathyroid glands, but which stimulates increased production of parathyroid hormone by the

parathyroid glands. It is seen in varying severity in the majority of patients with moderate to severe chronic kidney disease (Stages 3 and 4) and in most end-stage renal disease patients (Stage 5), in whom normal kidney function is lost and dialysis is required for survival. Secondary hyperparathyroidism in renal disease generally continues to worsen unless treated with vitamin D hormone therapy.

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The goals of vitamin D hormone therapy in this setting are to decrease blood parathyroid hormone levels and to normalize blood calcium, thereby treating or preventing bone disease, and other adverse effects of elevated parathyroid hormone. The challenge in administering vitamin D hormone therapy is to deliver a sufficient dose to be effective without causing adverse effects including:

Excessive phosphorus and/or calcium in the blood, which increases the risk that mineral deposits will develop in soft tissues, such as in the heart and arteries, contributing to cardiac disease, or in the kidneys, accelerating kidney failure in chronic kidney disease patients.

Excessive phosphorus in the blood, which stimulates secretion of parathyroid hormone by the parathyroid glands and exacerbates secondary hyperparathyroidism.

Excessive calcium in the urine, which increases the risk that calcium-rich deposits will develop in the kidneys and accelerate kidney failure in chronic kidney disease patients.

Due to the risks of these side effects, vitamin D hormones are customarily administered at low dosages. Starting dosages are increased cautiously, to minimize the chance of these adverse side effects and optimize therapeutic response. The pharmacokinetic profiles of intravenous calcitriol and paricalcitol, two key competing FDA approved vitamin D hormone products, typically demonstrate supraphysiological spikes occurring rapidly after administration, followed by trough levels at concentrations below the physiologic range of activated vitamin D prior to the next dose in hemodialysis patients. This is in contrast to the relatively constant blood levels of vitamin D hormones that are maintained in individuals with normal kidney function, yielding consistent, efficient regulation of parathyroid hormone secretion.

Products and Product Candidates

We have two FDA approved products, Hectorol® Injection and Hectorol® Capsules, and two products in development, LR-103 and BCI-202, for the treatment of secondary hyperparathyroidism.

Hectorol® offers:

Safe and Effective Treatment. Data obtained from our clinical trials have demonstrated that Hectorol® is a safe and effective therapy for treating secondary hyperparathyroidism in moderate to severe chronic kidney disease and in end-stage renal disease. In these trials, Hectorol® reduced blood levels of parathyroid hormone in more than 90% of the treated patients with minimal side effects. Based on these and other trials, we believe that Hectorol® compares favorably to competitive vitamin D hormones, including calcitriol and paricalcitol; however, we have not performed prospective comparative trials to demonstrate these conclusions.

Oral Delivery that Expands Market Opportunities. Hectorol® Capsules provide a safe, convenient and effective oral vitamin D therapy for the management of parathyroid hormone levels in patients with moderate to severe chronic kidney disease and end-stage renal disease. Intravenous vitamin D hormone products are generally used in hemodialysis patients and only under medical supervision. Competitive vitamin D hormones may be less well suited for oral delivery because they are fully active on delivery, which may cause certain cells lining the small intestine to absorb too much calcium and phosphorus, leading to side effects. Hectorol®, on the other hand, is an inactive pro-hormone that, after oral delivery, should not be immediately available to these intestinal cells.

A Pro-Hormone that Provides Consistent Levels of Natural Vitamin D Hormones. Hectorol® is a vitamin D pro-hormone, an inactive vitamin D analog that is metabolized by the liver into two active and naturally occurring vitamin D hormones. Activated Hectorol® is released into the bloodstream at a rate which appears to mimic the normal physiologic production of active vitamin D hormones by normal kidneys. Normal physiologic

blood levels of vitamin D hormones allow efficient regulation of parathyroid hormone secretion by the parathyroid glands with few side effects.

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A Potentially Wider Therapeutic Window. We believe that there is indirect evidence through animal studies that Hectorol® has a wider range, or therapeutic window, between a minimum effective dose and a dose with significant side effects, as compared to other vitamin D hormone therapies. Animal studies have demonstrated that Hectorol® has fewer side effects than calcitriol or alfacalcidol when delivered at doses of equivalent potency. No clinical trials have been conducted directly comparing Hectorol® to any other vitamin D hormone therapy in patients with moderate to severe chronic kidney disease or end-stage renal disease. We have not conducted any comparative trials of vitamin D hormones in any human subjects. A wider therapeutic window would improve safety and facilitate improved patient management.

Hectorol® Injection

End-Stage Renal Disease. Hectorol® Injection is approved for use in the approximately 300,000 end-stage renal disease patients in the U.S. We obtained FDA approval for Hectorol® Injection in April 2000. We began selling the product in August 2000. We received a national Medicare reimbursement code for Hectorol® Injection in January 2002, which has facilitated Medicare reimbursement.

Our FDA submission included data from two Phase III trials, which included a total of 70 patients and consisted of an eight-week monitoring period in which no vitamin D hormone therapies were given, followed by a 12-week period in which patients received open-label treatment with Hectorol® Injection at hemodialysis. The study endpoint for effectiveness was the observed reduction in blood parathyroid hormone levels, and the endpoints for safety were the observed rates of hypercalcemia and hyperphosphatemia. In both trials, after 12 weeks of open-label treatment, mean blood parathyroid hormone levels were reduced approximately 45%. These reductions were statistically significant ($p<0.01$). In both studies, blood parathyroid hormone reached a predetermined optimal range in more than 70% of treated patients. Hectorol® Injection maintained normal blood calcium with only infrequent episodes of hypercalcemia and hyperphosphatemia.

We believe that U.S. physicians and dialysis providers favor intravenous products because of several factors: (1) healthcare professionals can assure patient compliance with drug administration at the time of dialysis; (2) repeated oral delivery of active vitamin D hormones promotes their breakdown in the intestine, thereby increasing intestinal absorption of calcium and reducing the desired amount delivered to the parathyroid glands; and (3) Medicare reimbursement is only available for intravenous products.

Hectorol® Capsules

End-Stage Renal Disease. Hectorol® 2.5 mcg Capsules are approved for use in the approximately 300,000 end-stage renal disease patients in the U.S. The FDA approved Hectorol® 2.5 mcg Capsules for end-stage renal disease in June 1999 based on the results of two Phase III trials analyzing a total of 99 subjects, all of which were dosed with Hectorol® 2.5 mcg Capsules during the 16-week open-label period. Each trial consisted of an eight-week monitoring period in which no vitamin D hormone therapies were given, followed by a 16-week period in which patients received open-label treatment with Hectorol® 2.5 mcg Capsules at hemodialysis, and an eight-week period in which patients received, in a double-blinded randomized fashion, continuing treatment with either Hectorol® 2.5 mcg Capsules or a matching placebo. The study endpoint for effectiveness was the observed reduction in blood parathyroid hormone levels, and the endpoints for safety were the observed rates of hypercalcemia and hyperphosphatemia. In both trials, after 16 weeks of open-label treatment, mean blood parathyroid hormone levels were reduced more than 50%. These reductions were statistically significant ($p<0.001$). In addition, blood parathyroid hormone reached a pre-determined optimal range in 73% of the treated patients. At the end of the eight additional weeks of blinded treatment, mean blood parathyroid hormone levels increased toward baseline in patients receiving placebo; however, in patients receiving Hectorol®2.5 mcg Capsules parathyroid hormone levels remained approximately 50% below those receiving a matching placebo a clinically and statistically significant difference. Hectorol® 2.5 mcg Capsules maintained normal blood calcium levels with only infrequent episodes of hypercalcemia and hyperphosphatemia.

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Chronic Kidney Disease or Pre-Dialysis. Secondary hyperparathyroidism begins to develop in patients with modest reductions in kidney function and becomes more severe as chronic kidney disease progresses. Evidence from published clinical research suggests that early intervention with vitamin D hormone replacement therapy can slow the progression and enhance the treatment of secondary hyperparathyroidism in chronic kidney disease patients not yet on maintenance dialysis therapy. Calcitriol is approved in the U.S., and we believe oral alfacalcidol, which is not FDA approved, is used in certain foreign markets to treat chronic kidney disease patients. As with their use in dialysis patients, however, these competitive oral products may cause side effects.

In April 2004 the FDA approved Hectorol® 0.5 mcg Capsules for moderate to severe chronic kidney disease (Stages 3 and 4). The FDA approval was based on the results of two randomized, double-blind, placebo-controlled Phase III trials for Hectorol® 0.5 mcg Capsules to treat secondary hyperparathyroidism in patients with moderate to severe chronic kidney disease (Stages 3 and 4). The trials consisted of an eight-week monitoring period in which no vitamin D hormone therapies were given, followed by a 24-week period in which patients were treated with either Hectorol® 0.5 mcg Capsules or a matching placebo. The study endpoint for effectiveness was the observed reduction in blood parathyroid hormone levels, and the endpoints for safety were the observed rates of hypercalcemia, hyperphosphatemia and hypercalciuria, and significant decreases in kidney function. In both studies, Hectorol® significantly reduced blood parathyroid hormone levels by 46% at 24 weeks, a statistically significant result relative to a matching placebo ($p<0.01$). There were no significant differences in side effects or safety profiles. In two clinical studies, the incidences of hypercalcemia and hyperphosphatemia during therapy with 0.5 mcg Hectorol® Capsules were similar to placebo therapy, and no episodes of hypercalciuria were observed.

LR-103 and BCI-202

We have two product candidates, LR-103 and BCI-202, in development for the treatment of secondary hyperparathyroidism. We have synthesized and evaluated a series of compounds with chemical structures related to Hectorol®. From our research, we have determined that our current compound, Hectorol®, is activated in part to an active metabolite unlike the competing compounds calcitriol, paricalcitol and alfacalcidol which cannot be so activated. We have labeled this active metabolite as LR-103. We believe that LR-103 is as potent as calcitriol *in vitro,* but may be 30 times less likely than calcitriol to cause toxic side effects. We continue to study the pharmacological properties of LR-103 in biological models. In a mouse model for secondary hyperparathyroidism, LR-103 reduced parathyroid hormone levels without producing hypercalcemia. LR-103 is readily absorbed after oral delivery and circulates through the bloodstream to tissues which respond to vitamin D hormones. BCI-202 is a novel pro-hormone vitamin D analog in early pre-clinical development.

Product Candidates for Hyperproliferative Diseases

In addition to having a role in parathyroid function and calcium and phosphorus metabolism, vitamin D hormones may have an important role in regulating the growth and differentiation of skin, prostate, breast and colon cells. We are investigating the use of Hectorol® Capsules and other development stage vitamin D hormone therapies in diseases associated with hyperproliferative or neoplastic cell growth such as in cancers of the prostate and colon. Data from preclinical models indicate that vitamin D analogs inhibit the growth of cancer cells expressing the vitamin D receptor.

Prostate, Breast and Colon Cancers

We are evaluating Hectorol® and LR-103 in the treatment of cancers which have the potential to respond to vitamin D therapy, such as prostate, breast and colon cancers. We also intend to evaluate BCI-202 in this disease state as well. Pre-clinical models have demonstrated that vitamin D analogs inhibit the growth of prostate, breast and colon tumor cells. Oncologists consider vitamin D hormones to be a potentially promising treatment for cancers expressing

the vitamin D receptor. Our vitamin D compounds, with their safety profile, have the potential to benefit the treatment of cancer. Currently, no vitamin D hormone has received marketing approval for cancer anywhere in the world.

Prostate cancer has become the most commonly diagnosed tumor in American men. The American Cancer Society estimates that in the year 2003, approximately 221,000 men would have been diagnosed with, and approximately 29,000 men would have died from, prostate cancer. Breast cancer is the second leading cause of death among women in the U.S. The American Cancer Society estimates that in the year 2003, approximately 211,000 women would have been diagnosed with, and about 40,000 women would have died from, breast cancer. Colon cancer is also a common cancer in American men and women. The American Cancer Society estimates that in the year 2003, approximately 105,000 men and women would have been diagnosed with colon cancer.

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Hectorol®. We have completed a Phase I dose escalation trial of daily, Hectorol® Capsules in patients with hormone refractory prostate cancer. A total of 25 patients were enrolled in this study. Oral doses of Hectorol® ranging from 5 to 15 mcg/day were administered. Patients were closely followed for side effects in order to determine the maximum tolerated dose of daily, Hectorol® Capsules. Patients were monitored for response by objective imaging techniques. Two patients had radiographically confirmed partial responses while five other patients maintained stable disease for at least 6 months. The most common toxicity observed during this trial was reversible hypercalcemia. Based on the results of this study, a maximum daily dose of 12.5 mcg was recommended for further evaluation in Phase II clinical trials in cancer patients. The results of a Phase II Hectorol® monotherapy trial in patients with hormone refractory prostate cancer are being evaluated. A Phase II study of Hectorol® Capsules in combination with the chemotherapeutic agent Taxotere in the treatment of hormone refractory prostate cancer has also been initiated under an investigator sponsored investigational new drug application. We are collaborating with the University of Wisconsin and other institutions to further explore the use of Hectorol® in prostate cancer and other oncology settings.

LR-103. We initiated a Phase I study of LR-103 in cancer patients in February 2004 to assess safety and pharmacokinetic parameters. We have used LR-103, in animal models for cancer. LR-103 slowed tumor growth of breast cancer xenografts in mice without producing any apparent adverse effects on serum calcium. We have also observed that LR-103 inhibits growth of cancer cells *in vitro*. LR-103 has been shown *in vitro* to act synergistically with known chemotherapeutic agents to inhibit the proliferation of cultured breast and prostate cancer cell lines.

Psoriasis

We may seek to develop Hectorol®, LR-103 and BCI-202 as oral vitamin D hormone therapies for psoriasis. Preclinical data indicates that LR-103 is readily absorbed after oral delivery and circulates through the blood stream to tissues which respond to vitamin D hormones. We have observed that LR-103 inhibits growth of skin cells *in vitro.*

According to the National Psoriasis Foundation, psoriasis affects approximately 4.5 million individuals in the U.S. of which a physician is treating approximately 1.5 million. A similar prevalence rate is observed in Europe. Psoriasis affects people of all ages, with most exhibiting mild or moderate lesions. Psoriatic lesions are characterized by an abnormal thickening or growth of the skin, usually on the scalp, elbows, knees and shins. Microscopic examination of these lesions reveals an increased rate of skin cell division, together with a decrease in the time required for these cells to migrate to the skin surface, resulting in thickening or growth of the skin. No cure for psoriasis exists. Dovonex® (topical calcipotriol marketed by Bristol-Myers Squibb Company) is a synthetic vitamin D hormone analog of calcitriol and is approved to treat psoriasis in the U.S. Dovonex and tacalcitol, another vitamin D hormone analog, are approved to topically treat psoriasis in many countries outside of the U.S. Currently, no oral vitamin D hormones are approved to treat psoriasis in the U.S.

Research and Development

Research and development activities are essential to maintaining and enhancing our business. As of June 30, 2004, our research and development group consisted of 27 employees, including a Vice President/ Medical Director and 9 clinical support specialists. Our research and development expenses were approximately $9.1 million, $6.7 million and $6.8 million in the years ended June 30, 2004, 2003, and 2002, respectively. We intend to continue to focus our research and development activities 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.

Sales and Marketing

We commercially introduced Hectorol® 2.5 mcg Capsules in October 1999 and Hectorol®Injection in August 2000. Both products are currently marketed for end-stage renal disease patients in the U.S. by our direct sales force. In addition, we have commercially introduced the Hectorol® 0.5 mcg Capsules through a co-promotion partnership in July 2004 for patients in the U.S. with moderate to severe chronic kidney disease. We believe that the chronic kidney and end-stage renal disease markets in the U.S. are well defined, and are therefore suitable for a highly focused, direct sales and marketing effort. In addition, we believe that the clinical benefits of our products combined with competitive pricing allow us to offer a strong value proposition to patients and physicians.

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We are directing our marketing efforts to the following key decision makers:

Nephrologists. We estimate that in the U.S. there are approximately 4,800 office-based nephrologists. The nephrologist is the physician responsible for the care of patients diagnosed with chronic kidney and end-stage renal disease. This care includes delivering vitamin D hormone replacement therapy, which may be administered based on protocols developed in conjunction with the dialysis clinics.

Dialysis Clinics. The nephrologist is generally associated with a clinic that performs dialysis procedures. In the U.S., a limited number of large corporations control the majority of these clinics with the largest five corporations controlling approximately 46% of in-center dialysis facilities. Generally these clinics bill for services provided to end-stage renal disease patients, including vitamin D hormone therapy.

Third-Party Payors. Dialysis clinics that administer intravenous vitamin D hormones seek reimbursement from third-party payors who generally are either insurance companies or governmental agencies, including Medicare and Medicaid. These payors set reimbursement levels for products and services which the clinics provide to dialysis patients. Because dialysis patients all suffer from end-stage renal disease which qualifies all such patients for Medicare, dialysis clinics generally derive a high percentage of their revenues from the Medicare program. Pre-dialysis patients primarily seek reimbursement from third-party payors who generally are either insurance companies or governmental agencies, such as Medicaid.

As of June 30, 2004, our sales and marketing department consisted of 73 people, including a direct sales force of 62 people, of which four focus on national accounts and third-party payors including Medicare and Medicaid. Additionally, we may seek to establish mutually beneficial alliances or marketing agreements with partners who can access geographic markets and therapeutic areas where we have no current or planned sales presence.

Hectorol® is distributed to patients and dialysis centers through both direct and traditional wholesale and retail channels. A third party provides select administrative and distribution services for our wholesale and retail customers in the continental U.S., Hawaii and Puerto Rico.

Copromotion of Hectorol® 0.5 mcg Capsules

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

Intellectual Property

Our success will depend in part on our ability to continue to develop patentable products and technologies and obtain patent protection for our products and technologies both in the U.S. and other countries. We currently have over 150 issued patents and over 100 pending applications worldwide. We have several U.S. patents covering the use of Hectorol® for the prevention and treatment of hyperparathyroidism and metabolic bone disease, including renal osteodystrophy. Patents covering the treatment of hyperparathyroidism secondary to end stage renal disease with Hectorol® begin to expire in 2014. Patents covering treatment of hyperparathyroidism secondary to pre-dialysis chronic kidney disease begin to expire in 2008. We have filed a patent application directed toward the treatment of hyperparathyroidism associated with chronic kidney disease (Stages 1 through 4). Should the application issue as a

U.S. patent, it would expire in 2015. Patents covering metabolic bone disease begin to expire in 2009.

Corresponding patents for the use of Hectorol® to prevent and manage secondary hyperparathyroidism in kidney dialysis patients have been issued in Europe, Australia, Canada, Japan and Korea. All of these patents expire or would expire in 2016. A corresponding patent for the use of Hectorol® to prevent and treat metabolic bone disease has been issued by the European Patent Office and expires in 2009.

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We also own U.S. patents for the use of Hectorol® for treating prostate cancer that expire in 2013. We have filed counterpart patent applications in Europe and other geographic markets, including Japan, that would expire in 2017. We own U.S. and European patents for delayed sustained release formulations of Hectorol®, which expire in 2013. Foreign counterpart applications are also pending in Japan and other major markets.

The issued composition-of-matter patent covering Hectorol® has expired. We have filed applications directed toward a stabilized form of doxercalciferol (Hectorol®). Our issued patents relating to Hectorol® are method-of-use patents. A method-of-use patent encompasses the use of a compound or composition to treat a specified condition but does not encompass the compound itself, the active ingredient used in the composition or composition itself, or the method of making the composition or the compound used in the composition. Method-of-use patents provide less protection than composition-of-matter patents because of the possibility of the composition being used in ways that fall outside the scope of the claimed method-of-use and difficulties in detecting acts of infringement in particular due to off-label prescriptions if other companies market or make the composition for other uses.

We own issued patents and have pending patent applications in the U.S. and other countries relating to other vitamin D hormones. Our patents and pending applications include claims to compounds, compositions, methods of synthesizing the compounds and compositions, methods of use and methods of delivery of active vitamin D hormone and vitamin D hormone analogs.

In addition to patent protection, we also rely on proprietary information and trade secrets. We require our employees, consultants and advisors to execute confidentiality and invention assignment agreements upon commencement of an employment or a consulting relationship with us.

Licensing Agreements

We have a license from the Wisconsin Alumni Research Foundation to practice several of their process patents for the synthesis of Hectorol®. Under this license, which extends at least through July 2, 2013 and terminates upon the expiration of the last licensed patent, the Wisconsin Alumni Research Foundation has agreed not to license to other parties its patents to manufacture Hectorol® for use or sale anywhere in the world as long as the license agreement is in effect and we pay royalties based on Hectorol® sales.

We had initially granted Draxis Health Inc. a license to use and sell Hectorol® in Canada for secondary hyperparathyroidism, osteoporosis and other metabolic bone diseases. We also granted Draxis a license in Canada to all know-how developed by or on behalf of us relating to the use of Hectorol® for those indications. Draxis received marketing approval for Hectorol® 2.5 mcg Capsules in Canada in May 2001. Draxis sold its Canadian pharmaceutical business to Shire Pharmaceuticals Group in July 2003. In conjunction with that sale, we entered into a new manufacturing and supply agreement and patent and trademark license agreement with Shire that replaced and superceded all previous agreements with Draxis. The patent and trademark agreement transfers to Shire the exclusive right to use and sell Hectorol® previously granted to Draxis and requires a royalty for use of the Hectorol® trademark. The manufacturing and supply agreement provides for the sale of Hectorol® from us to Shire for distribution in Canada only.

We and the U.S. Department of Agriculture jointly own rights to LR-103 under issued patents and pending patent applications. The U.S. Department of Agriculture has granted to us an exclusive worldwide license 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. In any circumstance, however, because of our joint ownership of the licensed patents, we would retain non-exclusive marketing rights under these patents. The U.S. Department of Agriculture license terminates upon the expiration of the last licensed patent.

Manufacturing

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.

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Although we believe that other manufacturers, suppliers, formulators and vendors may be available to provide these goods and services to us, any change in suppliers could cause an increase in costs, a delay in manufacturing and a possible loss of sales, any of which would affect operating results adversely.

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 our own manufacturing facility, we would need substantial additional funds and would have to hire and train additional personnel and comply with the extensive regulations applicable to the facility. We believe our relationships with our suppliers are good.

Competition

We operate in a field in which new discoveries occur at a rapid pace. Competitors may succeed in developing technologies or products that are more effective than ours or in obtaining regulatory approvals for their drugs more rapidly than us, which could render our products obsolete or noncompetitive. Competition is significant and is expected to increase. Many competitors, including biotechnology and pharmaceutical companies, are actively engaged in the research and development of products in similar areas, including the fields of hyperparathyroidism, osteoporosis, psoriasis, and cancers of the prostate, breast and colon. Dialysis providers typically select which therapy a patient receives based on safety, efficacy, and cost. Abbott Laboratories, Inc. markets intravenous calcitriol (brand name Calcijex®) and intravenous paricalcitol (brand name Zemplar®) for end-stage renal disease patients and is developing oral paricalcitol for pre-dialysis and dialysis patients. Current intravenous versions of these drugs are approved to manage secondary hyperparathyroidism in end-stage renal disease patients in the U.S. and in European countries. A number of companies have launched or are planning to launch generic intravenous calcitriol in the U.S.

In March 2004, Amgen, Inc. received FDA approval for a new oral calcimimetic agent for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis. The majority of patients studied on this calcimimentic agent were also taking vitamin D hormone to treat secondary hyperparathyroidism.

Roche Pharmaceuticals markets oral calcitriol (brand name Rocaltrol®) and TEVA Pharmaceuticals markets generic oral calcitriol in the U.S. to manage secondary hyperparathyroidism in chronic kidney disease patients. These two competitive products are approved in the U.S. for the treatment of elevated parathyroid hormone in both end-stage renal disease and chronic kidney disease, pre-dialysis.

A number of companies, including Leo Pharmaceutical Products A/S, TEVA Pharmaceuticals and Chugai Pharmaceutical Company Co., Ltd., market oral or intravenous alfacalcidol, a synthetic analog of calcitriol, in Europe and Asia under various trade names for both secondary hyperparathyroidism and osteoporosis. Several companies, including Leo Pharmaceutical Products A/S, ILEX Oncology, Inc. and Chugai Pharmaceutical Co. LTD, are developing vitamin D hormone therapies to treat cancers. Leo Pharmaceutical Products A/S, Bristol-Myers Squibb Company and other companies are marketing a topical vitamin D hormone (brand name Dovonex®) in major markets of the world to treat psoriasis. Teijin Limited is marketing topical tacalcitol to treat psoriasis outside the U.S.

Government Regulation

Pharmaceutical products are subject to extensive regulation under the Federal Food, Drug and Cosmetic Act by the FDA in the U.S. and similar health authorities in foreign countries. This rigorous regulation governs, among other things, testing for safety and effectiveness, manufacturing, labeling, storage, record keeping, import, export, advertising, marketing and distribution of pharmaceutical products. Any new drug candidate must undergo lengthy, rigorous and costly pre-clinical testing, clinical trials and other procedures mandated by the FDA and foreign

regulatory authorities prior to approval for sale. Before testing agents with potential therapeutic value in healthy human test subjects, stringent government requirements for pre-clinical data must be satisfied. The data, obtained from studies in several animal species, as well as from laboratory studies, are submitted in an investigational new drug application to the FDA or its equivalent in countries outside the U.S. where clinical studies are to be conducted. Pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

Clinical trials are typically conducted in three sequential phases, although these phases may overlap. Phase I frequently begins with initial introduction of the compound into healthy human subjects. Prior to patient introduction, the product is tested for safety, adverse affects, dosage, tolerance, absorption, metabolism, excretion and preclinical

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pharmacology. Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects. Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population which suffers from the targeted illness at geographically dispersed study sites to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling. Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the investigational new drug application.

Data from pre-clinical and clinical trials are submitted to the FDA as a new drug application for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug is likely to take a number of years and requires the expenditure of substantial resources. Preparing a new drug application or marketing authorization application involves considerable data collection, verification, analysis and expense. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA or other health authorities may deny a new drug application or marketing authorization application if the authority s regulatory criteria are not satisfied or may require additional testing or information.

Even 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. Additional studies will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested and will be required if we seek additional indications for Hectorol® Injection and Hectorol® Capsules. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand marketing of the products. Further, if there are any modifications to the drug, including changes in indication, manufacturing process or labeling or a change in manufacturing facility, an application seeking approval of such changes will be required to be submitted to the FDA or other regulatory authority.

The manufacture and marketing of Hectorol® is subject to 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 also are subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Any enforcement action resulting from failure to comply with these requirements could affect the manufacture and marketing of Hectorol®. In addition, the FDA could withdraw a previously approved product from the market upon receipt of new information.

We participate in the Medicaid Rebate Program established by the Omnibus Budget Reconciliation Act of 1990. The Medicaid Rebate Program requires us to report certain pricing information, including but not limited to average manufacturer price and best price, to the Centers for Medicare and Medicaid Services on a periodic basis. We are also required to pay a periodic rebate for each unit of our product reimbursed by Medicaid to each state participating in the Medicaid program that is based on the pricing submissions we make to the Centers for Medicare and Medicaid Services. If we learn that pricing information reported to the Centers for Medicare and Medicaid Services in previous periods were incorrect, we are required to correct that pricing information. Such corrections could increase our rebate liability and interest for past periods. In addition, if we were found to have knowingly submitted false or inaccurate pricing information to the government, we could be subject to penalties under the False Claims Act, monetary penalties of $100,000 per item of false information under the federal Medicaid statute, penalties under the Civil Monetary Penalties Law, and potentially other civil and criminal penalties under federal and/or state law.

In addition, some states have initiated supplemental rebate programs under which pharmaceutical companies are required to agree to supplemental rebates to avoid pre-authorization requirements. Companies that do not agree to supplemental rebates may lose sales as their drugs are subject to pre-authorization screening before the drug is covered for individual patients. As more states adopt such supplemental programs, pharmaceutical company revenues are likely to decline.

As a condition of having our products covered by Medicaid, we signed an agreement with the Department of Health & Human Services that requires us to offer substantial discounts to Public Health Service Act covered entities. Under a formula set out in the Veterans Health Care Act of 1992, Public Health Service discounts are based on calculations from the Medicaid Rebate Program. Because Public Health Service pricing is derived from pricing

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information associated with the Medicaid Rebate Program, any errors in reporting Medicaid information would likely result in inaccurate Public Health Service prices. If we were found to have knowingly calculated false or inaccurate Public Health Service pricing, we could be subject to penalties under the False Claims Act, monetary penalties under the Civil Monetary Penalties Law, and potentially other civil and criminal penalties under federal law.

We also makes our products available to authorized federal government users under the Federal Supply Schedule of the General Services Administration. The Veterans Health Care Act of 1992 requires that prices for products purchased by certain federal entities (such as the Department of Veterans Affairs, the Department of Defense and the Public Health Service, including the Indian Health Service) be discounted under a formula set forth in the Act. As with pricing information reported under the Medicaid Rebate Program and the Public Health Service pricing program, we could face penalties under the False Claims Act, the Civil Monetary Penalties Act, and other civil and criminal statutes if we knowingly report inaccurate pricing information to these federal entities.

Our products are also reimbursed by Medicare. On December 8, 2003, the President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 referred to as MMA. The MMA adds a prescription drug benefit to the Medicare program and replaces the existing Medicare + Choice managed care option with a new managed care option, called Medicare Advantage. The prescription drug benefit, which begins in 2006, is voluntary and beneficiaries would pay a monthly premium after enrolling. Until that time, beneficiaries will have access to a drug discount card to obtain discounts on their drug purchases. The MMA also contains extensive changes to other aspects of the Medicare program, including payments for currently covered outpatient drugs and end-stage renal disease services. During 2004, the MMA reduces Medicare reimbursement for many covered outpatient drugs furnished in 2004 from 95% to 85% (or in some cases as low as 80%) of the average wholesale price that was in effect on April 1, 2003. Beginning in 2005, payment will be made on the basis of an average sales price methodology or a new competitive acquisition program. Drug products furnished in connection with renal dialysis services, such as Hectorol® Injection, will continue to be reimbursed at 95% of average wholesale price during 2004. Starting in 2005, Medicare s payment will be based on manufacturer s average selling price, and beginning in 2006, the Secretary of Heath and Human Services, referred to as the Secretary, has the authority to adopt a new payment methodology, which may include the average sales price methodology or acquisition costs. The Secretary is also required by the MMA to conduct a 2-year demonstration where payment is made for drugs and biologicals prescribed as replacements for existing drugs furnished as incident to a physician s services under Part B of Medicare. The demonstration is required to provide for cost-sharing in the same manner as applies under the new prescription drug benefits of Part D of Medicare. The demonstration is required to begin within 90 days of enactment and is limited to 50,000 Medicare beneficiaries in sites selected by the Secretary.

The MMA directs the Secretary to establish a new prospective payment system for renal dialysis services. Currently, Medicare pays a composite rate for each dialysis treatment. The composite rate includes dialysis services, but excludes separately billable injectable drugs, such as Hectorol® Injection, which are separately reimbursable at 95% average wholesale price to end-stage renal disease dialysis facilities. The MMA requires the Secretary to: (1) establish a basic case-mix adjusted prospective payment system for dialysis services beginning in 2005; (2) report to the Congress on the design and features of a bundled, fully case-mix adjusted prospective payment system for dialysis services; (3) conduct a demonstration study of a bundled payment system; and (4) make other changes, including increasing the composite rate by 1.6 percent in 2005 and restoring the exemption to the composite rate for pediatric facilities. By January 1, 2005, the Secretary is required to implement a basic case-mix adjusted payment system for dialysis services. The basic system will include two components: payment for those services currently under the composite rate and payment for the base line difference, or spread, between the Medicare payment amount to end-stage renal disease facilities for separately billed drugs and the facilities acquisition costs for the drugs. Under the basic system, Medicare will continue to pay providers separately for certain injectable drugs that are excluded from the current composite rate. By October 1, 2005, the Secretary is required to propose to Congress a fully case-mix adjusted, bundled prospective payment system for services furnished by end-stage renal disease facilities, including to

the extent feasible, drugs and other items that currently are separately billed by end-stage renal disease facilities. The Secretary also is required to establish a 3-year demonstration project of the fully case-mix adjusted payment system for end-stage renal disease services, beginning January 1, 2006.

Beginning in 2006, the Secretary will increase the case-mix adjusted payments to end-stage renal disease dialysis facilities to reflect the estimated growth in expenditures for certain injectable drugs. Beginning in January 1, 2007, the Secretary is required to adjust the spread component for new injectable drugs in the case-mix adjusted payment. The Secretary will determine these adjustments based on information about the acquisition cost of injectable drugs and the rate of growth in expenditures for these items from studies which will be conducted by the Office of Inspector General.

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Further, the MMA requires that the case-mix adjusted payment system result in the same aggregate amount of expenditures for such services as would have been made in 2005, 2006, and 2007 if payments were not case mix adjusted.

Medicare has sought to limit or reduce reimbursement paid to dialysis centers. Under the composite rate reimbursement paid to dialysis centers, each center has a financial incentive to reduce the costs that it incurs in providing treatment to patients. Dialysis centers generally seek substantial discounts from suppliers and shift to other suppliers of therapeutically similar services that are less expensive. These pressures are expected to increase and put pressure on our ability to increase our prices or recoup price increases.

Medicare currently bases its reimbursement on a discount off of average wholesale price. Average wholesale price is usually determined on the basis of prices we report to national reporting services, such as RedBook and First DataBank. We could face liability under false claims or anti-kickback laws if the federal government determined that we reported prices with the intent to set an artificially high average wholesale price to increase the profit for customers who are reimbursed by Medicare. In addition, under the MMA, we are required to report average sales price to the Centers for Medicare and Medicaid Services beginning in the first quarter of 2004. As with all prices reported to the federal government, we could be subject to penalties under the False Claims Act, Civil Monetary Penalties Law, and other criminal and civil statutes for knowingly reporting inaccurate prices.

Before our products can be marketed outside of the U.S., they are subject to regulatory approval similar to FDA requirements in the U.S., although the requirements governing the conduct of clinical trials and other premarket approval requirements vary widely from country to country, and the time spent in gaining approval varies from that required for FDA approval. FDA approval does not assure approval by other regulatory authorities, and we cannot predict whether foreign regulatory approvals will be granted. In some countries, the sales price of a drug product must also be approved. The pricing review period often begins after market approval is granted. Even if a foreign regulatory authority approves any of our products, we cannot predict whether satisfactory prices for our products will be approved.

We and our manufacturers must also comply with numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, current Good Laboratory Practices, current Good Manufacturing Practices and the experimental use of animals. We cannot predict the extent of governmental regulation or the impact of new governmental regulations which might have an adverse effect on the discovery, development, production and marketing of our products and require us to incur significant costs to comply with the regulations.

Our research and development processes involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result, and any such liability could exceed our financial resources. We believe we comply in all material respects with applicable environmental laws and regulations.

We are also subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices

might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly presenting, or causing to be presented, for payment to either government payors (such as Medicare, Medicaid, and programs of the Departments of Defense and Veterans Affairs) or non-governmental third-party payors, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws are punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (such as Medicare, Medicaid, and programs of the Departments of Defense and Veterans Affairs). If the government were to allege that we violated these laws or if we were convicted of violating these laws, there could be a material adverse effect on us. Our activities could be subject to challenge for the reasons discussed above as a result of the broad scope of these laws and the increased focus on pharmaceutical practices by state and federal law enforcement authorities.

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Federal law enforcement agencies and many state attorneys general have ongoing civil and criminal investigations against pharmaceutical companies alleging violations of Medicaid Rebate statutes, federal and state anti-kickback statutes, and false claims laws related to drug pricing. These enforcement actions arise from allegations that the companies fraudulently billed, reported, manipulated, or inflated prices for their pharmaceutical products that resulted in millions of dollars in overcharges to states. Many cases have been filed under seal under federal and state anti-kickback and false claims statutes and therefore are unknown to the pharmaceutical companies who may be the targets.

Employees

As of June 30, 2004, we had 140 full-time employees, including 27 in research and development, 22 in compliance, quality and regulatory affairs, 73 in sales and marketing and 18 in administration. Four of our employees have Ph.D. degrees and one is an MD. None of our employees are represented by a union, and we consider our employee relations to be good.

Customers

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 wholesaler distributors comprise 97% of the net accounts receivable balance as of June 30, 2004. These same five wholesaler distributors represented 95% of our product sales for the year ended June 30, 2004, with the largest of the five wholesaler distributors representing 39% of product sales. Metro Medical, Amerisource/Bergen, and American Medical Distributors each comprise greater than 10% of product sales.

Available Information

We make available free of charge on our website at www.bonecare.com our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after electronically filing or furnishing such material to the Securities and Exchange Commission. Information on our website is not part of this filing.

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RISK FACTORS

Investors and prospective investors in Bone Care should consider carefully the risks described below, in addition to other information in this filing. The risks and uncertainties described below are not the only ones facing our company. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that event, the trading price of our common stock could decline and investors may lose all or part of their investment.

RISKS RELATED TO OUR BUSINESS

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 our losses may continue.

We have incurred losses since we began operating. As of June 30, 2004, our accumulated deficit was approximately $54.7 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® Injection and Hectorol®Capsules. In fiscal year 2004 and subsequent fiscal years, we plan to make large expenditures to manufacture, market and sell Hectorol® 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®, 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 our losses will continue. 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 success in marketing and selling Hectorol® Injection and Hectorol® Capsules. We do not know whether we will achieve profitability or, if we do, whether we will be able to sustain profitability.

We currently derive all of our revenue from Hectorol®, and expect 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.

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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 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 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 only recently begun to expand our sales force and marketing capabilities, and our efforts to expand may not be successful. We may not be able to attract skilled sales/marketing personnel in a timely manner or at all. 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.

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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 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-α-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.

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

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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 manufacture 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.

All of our suppliers have FDA inspected facilities that are required to operate under current Good Manfacturing Practices regulations established by the FDA. In December 2001, Akorn, Inc. (previously the sole manufacturer of Hectorol® Injection) halted production of Hectorol® Injection until such time as certain general deviations from the FDA s current Good Manufacturing Practices could be remediated. The FDA s site inspection, which concluded in February 2003, resulted in additional inspectional observations that preclude submission of a supplement with respect to the manufacture and process improvements at Akorn. Accordingly, supply of Hectorol® Injection was constrained from December 2002 to March 2003. 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, although we are currently in the process of obtaining regulatory approval for an additional supplier. We rely on one supplier to formulate Hectorol®Capsules and another supplier to package Hectorol®. In addition, one of our suppliers is located in the Middle East, a geographic location subject to increased political instability, which could disrupt or halt the operations of this supplier. Although we believe that other suppliers may be available, any change in suppliers 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 substantial additional financing to build manufacturing facilities and to hire and train qualified personnel. We also would be subject to additional regulatory requirements and would be subject to risks associated with delays or difficulties encountered in manufacturing a 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.

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.

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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 sufficient 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 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 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.

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 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.

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RISKS RELATED TO OUR INDUSTRY

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;

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

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products for off-label uses, or uses not listed on the FDA-approved labeling. We and our manufacturers also are 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 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 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 represented 95% of our product sales for the year ended June 30, 2004, with the largest of those distributors representing 39% 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.

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.

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RISKS RELATED TO INTELLECTUAL PROPERTY

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 patent applications directed toward a stabilized form of doxercalciferol (Hectorol®) and the use of Hectorol® for the treatment of hyperparathyroidism associated with chronic kidney disease (Stages 1 through 4) . Should neither of these applications 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. 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, 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 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 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.

RISKS RELATED TO OUR STOCK

Concentration of ownership in our company by a few shareholders and features of our corporate charter may 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 September 1, 2004, our executive officers and directors beneficially own approximately 15% 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 and by-laws and certain provisions of Wisconsin law 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;

Certain provisions of Wisconsin law which may discourage certain types of transactions involving an actual or potential change of control;

Our board of directors may authorize the issuance of up to 2,000,000 shares of preferred stock and determine the price, rights, preferences and priviledges of those shares without any vote or action by shareholders; and

We have a shareholders rights plan.

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Under Wisconsin law, shareholders may be personally liable for debts we owe to our employees.

We are incorporated under the laws of the State of Wisconsin. Wisconsin law provides that shareholders of a Wisconsin corporation are personally liable for, in the case of shares without par value (such as our shares), up to an amount equal to the price for which the shares were issued, for all debts owing to employees for services performed for the corporation. Shareholders are not liable for wages to employees in excess of six months service for any individual employee.

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

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 2. ***PROPERTIES***

We lease approximately 34,000 square feet of office and laboratory space in Middleton, Wisconsin, which will expire in 2009. We believe our facilities are adequate to meet our needs for the foreseeable future.

ITEM 3. ***LEGAL PROCEEDINGS***

We may be a defendant from time to time in actions arising out of our ordinary business operations. There are no material legal proceedings pending.

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

None.

PART II

ITEM 5. ***MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS***

Our common stock is quoted on the Nasdaq National Market under the symbol BCII and has been publicly traded since May 1996. The following table sets forth high and low sales prices per share of our common stock, as reported on the Nasdaq National Market for fiscal years 2003 and 2004 as indicated.

	High	Low
Fiscal Year Ended June 30, 2003		
First Quarter	$ 7.82	$ 3.00
Second Quarter	12.64	5.53
Third Quarter	10.25	5.00
Fourth Quarter	14.00	6.95
Fiscal Year Ending June 30, 2004		
First Quarter	$14.97	$11.00
Second Quarter	15.05	11.77
Third Quarter	20.60	12.46
Fourth Quarter	26.60	18.51

As of August 24, 2004, approximately 170 shareholders of record held our common stock. This does not reflect beneficial shareholders who hold their stock in nominee or street name through various brokerage firms.

We have never declared or paid any cash dividends on our common stock, and we do not plan on paying any in the near future. Any future determination as to the declaration and payment of dividends will be at the discretion of our board of directors and will depend on then existing conditions, including our financial condition, results of operations, contractual restrictions, capital requirements, business prospects and other factors our board of directors deem relevant.

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ITEM 6. ***SELECTED FINANCIAL DATA***

The following table sets forth selected financial data for each of the five years in the period ended June 30, 2004.. Certain prior period amounts in the financial statements and the notes have been reclassified to conform to the fiscal 2004 presentation. You should read the financial statement data in conjunction with the discussion in Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included elsewhere in this filing. Our historical results are not necessarily indicative of results to be expected for any future period.

	Year Ended June 30,				
	2000	**2001**	**2002**	**2003**	**2004**
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenues:					
Product sales	$ 259	$ 5,997	$14,991	$ 19,518	$43,605
Other revenues	126				
	385	5,997	14,991	19,518	43,605
Cost and expenses:					
Cost of product sales	503	1,905	3,557	6,983	11,460
Research and development	4,048	4,873	6,772	6,670	9,108
Selling, General and administrative	6,282	9,542	12,823	18,117	24,833
	10,833	16,320	23,152	31,770	45,401
Loss from operations	(10,448)	(10,323)	(8,161)	(12,252)	(1,796)
Interest income, net	656	1,309	1,257	574	275
Loss before income tax	(9,792)	(9,014)	(6,904)	(11,678)	(1,521)
Income taxes	13				
Net loss	$ (9,805)	$ (9,014)	$ (6,904)	$(11,678)	$ (1,521)
Net loss per common share-basic and diluted	$ (0.89)	$ (0.70)	$ (0.49)	$ (0.82)	$ (0.10)
Shares used in computing basic and diluted net loss per common share	11,071	12,884	14,084	14,175	14,869

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	As of June 30,				
	2000	2001	2002	2003	2004
	(in thousands)				
Balance Sheet Data:					
Current assets:					
Cash and cash equivalents	$ 4,736	$ 1,843	$ 2,024	$ 3,065	$ 45,326
Marketable securities	4,972	15,080	18,437	13,625	68,777
Accounts receivable, net	30	3,347	4,286	2,815	4,733
Inventory	639	1,811	2,099	2,080	6,785
Other current assets	229	1,085	776	779	2,336
Total current assets	10,606	23,166	27,622	22,364	127,957
Marketable securities - noncurrent .		14,424	3,720	913	908
Property, plant, and equipment, net	446	1,503	1,785	1,889	1,527
Patent fees, net	959	1,025	1,198	1,323	1,785
Goodwill	449	359	359	359	359
Total assets	$12,460	$40,477	$34,684	$26,848	$132,536
Current liabilities Accounts payable	401	1,612	1,770	2,685	6,490
Accrued compensation payable	137	209	510	2,029	2,891
Accrued clinical study and research costs	214	148	152	603	1,002
Other accrued liabilities	152	70	2	102	214
Due to customers	409	135			
Allowance for sales returns		205	226	337	100
Deferred income	64				
Total current liabilities	1,377	2,379	2,660	5,756	10,697
Long-term liabilities				650	100
Total shareholders equity	11,083	38,098	32,024	20,442	121,739
Total liabilities and shareholders equity	$12,460	$40,477	$34,684	$26,848	$132,536

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ITEM 7. *MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

The following discussion and analysis should be read in conjunction with the Selected Financial Data and the accompanying financial statements and the related notes included elsewhere in this filing.

Overview

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

From our inception in 1984, we have generated revenues primarily from the sale of our products, and from our inception substantially all of our resources have been dedicated to:

- the development, patenting, pre-clinical testing, and clinical trials of Hectorol® Capsules and Hectorol® Injection;
- the development of manufacturing processes for Hectorol® Capsules and Hectorol® Injection;
- pursuing U.S. regulatory approvals of Hectorol® Capsules and Hectorol® Injection;
- the sales and marketing associated with the launch of Hectorol® Capsules and Hectorol® Injection; and
- research and development and pre-clinical testing of other potential product candidates.

Historically we have incurred losses since we began operating. In both the third and fourth fiscal quarters of 2004, we generated profits from operations, however, for the fiscal year ended June 30, 2004 we were unprofitable. As of June 30, 2004 we had an accumulated deficit of approximately $54.7 million. Our only sources of revenue have been:

- from the launch of Hectorol® 2.5 mcg Capsules and Hectorol® Injection;
- licensing fees associated with our early stage research collaborations, which licenses have since expired; and
- fees from conducting incidental laboratory assay services.

We estimate that total operating expenses will continue to increase in fiscal 2005. Further, development of LR-103, BCI-202 and other product candidates, or expansion of Hectorol® into other therapeutic areas, will require significant, time-consuming and costly research and development, pre-clinical testing and extensive clinical trials prior to

submission of any regulatory application for commercial use. We plan to continue pre-clinical testing of LR-103 and BCI-202 and began Phase I clinical trials on LR-103 in February 2004. The amount and timing of our operating expenses will depend on many factors, including:

the extent to which Hectorol® Capsules and Hectorol® Injection obtain expanded market acceptance;

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the costs of sales and marketing activities associated with Hectorol® Capsules and Hectorol® Injection and commercialization strategies with respect to Hectorol® 0.5 mcg Capsules;

the success of our co-promotion results with Cardinal Health for the Hectorol® 0.5 mcg Capsules;

the status of our research and development activities;

the costs involved in preparing, filing, prosecuting, maintaining, protecting and enforcing our patent claims and other proprietary rights;

our ability to maintain our current manufacturing capabilities through relationships with third parties or establish those capabilities internally;

technological and other changes in the competitive landscape; and

evaluation of the commercial viability or potential of product candidates, which could significantly affect future expenditures for sales, marketing and product development.

As a result, we believe that period-to-period comparisons of our financial results are not necessarily meaningful.

On June 14, 2004, we entered into a multi-year co-promotion agreement for the launch and commercialization of Hectorol® 0.5 mcg Capsules with nephrologists in pre-dialysis Stages 3 and 4 chronic kidney disease. Under the terms of the agreement, Cardinal Health PTS, LLC will provide contract sales force and medical communication services to support a specified level of promotion. We will sell Hectorol® 0.5 mcg Capsules through its distribution network and support the promotional effort through its nephrology focused sales force with an additional specified level of investment. For its efforts, Cardinal Health will receive a variable co-promotion fee based on the performance of Hectorol® 0.5 mcg Capsule sales. The fee as a percentage of Hectorol® 0.5 mcg Capsule revenue declines gradually over the term of the agreement. Initial sales of Hectorol® 0.5mcg Capsules are planned for the first quarter of fiscal 2005. Based on the terms of the variable co-promotion fee, Cardinal Health rather than us bears a significant portion of the costs of the product launch. As a result, we do not expect to realize any losses and depending on the success of the launch in 2005, may not realize significant profits in 2005.

Critical Accounting Policies and Estimates

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

Sales Returns and Allowances

Revenue is recognized when product is shipped into the marketplace. When revenue is recognized, we simultaneously record an estimate of various costs, which reduce product sales. These costs include estimates for product returns, 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, chargebacks, rebates, and discounts may differ from established reserves.

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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 clinics throughout the U.S. Management specifically analyzes accounts receivable, historical bad debts, customer credit-worthiness, percentage of accounts receivable by aging category, and changes, if any, in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. If the financial condition of our customers were to deteriorate, resulting in impairment in their ability to make payments, additional allowances may be required. Our actual losses from uncollectible accounts have been immaterial to date.

Excess and Obsolete Inventory

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

Cost of Inventory

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

Income Taxes

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

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

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

Results of Operations for Fiscal Year Ended June 30, 2004 compared to June 30, 2003

Product sales of Hectorol® (Injection and Capsules) were $43,604,628 for the year ended June 30, 2004, an increase of $24,086,354, or 123%, from the year ended June 30, 2003. Sales of Hectorol® Injection were $38,749,562 for the year ended June 30, 2004, an increase of $23,627,338, or 156%, from the year ended June 30, 2003. The increase in sales of Hectorol® Injection for fiscal year 2004 was primarily the result of:

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The efforts of an expanded and experienced sales force and contract initiatives with national dialysis companies (approximately $16.1 million);

A price increase effective July 1, 2003 (approximately $7.4 million);

The implementation of new and effective marketing programs; and

Manufacturing constraints in the first and second quarters of 2003.

Hectorol® Capsules sales were $4,855,066 for the year ended June 30, 2004, compared to $4,396,050 for the year ended June 30, 2003. The increase was due primarily to a price increase implemented in July 2003, a decrease in product returns, and prescription growth.

Gross margin on sales of Hectorol® was $32,144,668, or 74% of product sales, for the year ended June 30, 2004, compared to $12,535,099, or 64% of product sales for the year ended June 30, 2003. Gross margins for Hectorol® Injection and Hectorol® Capsules were 73% and 81% respectively, for 2004 compared to 59% and 83%, respectively, for 2003. The increase in gross margins was due to increased sales levels and reductions in manufacturing validation costs primarily for Hectorol® Injection.

Research and development (R&D) expense was $9,107,472 for the year ended June 30, 2004, an increase of $2,437,441, or 37%, from the year ended June 30, 2003. The increase in R&D expense was primarily due to purchases of LR-103 active pharmaceutical ingredients for clinical and preclinical research of approximately $1.0 million, personnel expenses primarily for senior management additions of approximately $0.5 million, expansion of our clinical support activities of approximately $0.7 million, and for consulting support of approximately $0.3 milllion.

Selling, general and administrative (SG&A) expense was $24,833,152 for the year ended June 30, 2004, an increase of $6,715,716, or 37%, from the year ended June 30, 2003. The increase in SG&A expense was primarily due to the planned expansion of our sales organization representing $2.5 million, marketing promotional programs representing approximately $1.7 million, consulting and marketing research expenses related to strategic business activities of approximately $0.7 million, recruitment fees and compensation expense for our board of directors including non-cash stock option expense of approximately $0.4 million, severance expenses for the former Vice President of Finance of approximately $0.4 million, an increase in management incentive compensation of approximately $0.4 million, expenses associated with the recruitment, hiring, and relocation of the new Vice President of Finance of approximately $0.2 million, and professional legal fees of approximately $0.2 million principally related to an increase in contractual, personnel and corporate governance activity.

Interest income was $274,795 for the year ended June 30, 2004, a decrease of $299,600 from the year ended June 30, 2003. The decrease was primarily due to lower average cash and marketable securities balances for the year ended June 30, 2004, as well as a decline in yield on our investments due to market conditions.

Results of Operations for Fiscal Year Ended June 30, 2003 compared to June 30, 2002

Product sales of Hectorol® increased to $19,518,274 for the year ended June 30, 2003, from $14,990,749 for the year ended June 30, 2002. This increase resulted from increased sales of Hectorol® Injection offset by a decrease in sales of Hectorol® Capsules. Hectorol® Injection, launched in August 2000, generated sales of $15,122,224 during the year ended June 30, 2003 compared to $9,448,115 in the year ended June 30, 2002, reflecting increased market acceptance in spite of our inability to supply Hectorol® Injection for approximately three months between December 2002 and March 2003. Hectorol® Capsule sales were $4,396,050 for the year ended June 30, 2003, compared to $5,542,634 for the year ended June 30, 2002. Fiscal year 2002 Hectorol® Capsule revenues benefited from a temporary supply shortage of the competitive drug Rocaltrol between August and December 2001.

Gross margins on product sales were $12,535,099, or 64% of product sales, for the year ended June 30, 2003 compared to $11,434,062, or 76% of product sales, for the year ended June 30, 2002. The gross margin on Hectorol® Injection sales was 59% and 71% for the years ended June 30, 2003 and 2002, respectively. The gross margin on Hectorol® Capsule sales was 83% and 85% for the years ended June 30, 2003 and 2002, respectively. Overall gross margins were lower as a percentage of sales in fiscal year 2003 compared to fiscal year 2002 due to an increased cost of Hectorol® Injection supplied by Draxis Pharma Inc. as compared to Akorn, Inc. of approximately 34%, increased spending for quality assurance of approximately $0.5 million, and costs associated with the validation activities for the Hectorol® Injection manufacturing processes of approximately $1.1 million.

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R&D expense was $6,670,031 in the year ended June 30, 2003, compared to $6,772,553 in the year ended June 30, 2002. The $102,522 decrease is attributable to a decrease in clinical support staff offset by consulting expenses related to validating computer network systems used in operating clinical software and internal costs to file a supplemental new drug application (NDA) for Hectorol® 0.5mcg Capsules.

SG&A expense was $18,117,436 for the year ended June 30, 2003, an increase of $5,294,860 from the year ended June 30, 2002. The increase was primarily due to market research and promotional spending for Hectorol® of approximately $2.7 million, the personnel expenses related to the recruitment, hiring and relocation of senior management personnel of approximately $2.0 million, insurance premiums for property, casualty and liability policies of approximately $0.4 million and legal fees of approximately $0.3 million.

Interest income decreased $682,776 to $574,395 in the year ended June 30, 2003, from $1,257,171 in the year ended June 30, 2002. The decrease was due to lower average cash and marketable security balances for the year ended June 30, 2003, as well as a decline in yield on our investments.

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 years ended June 30, 2004, June 30, 2003, and June 30, 2002, we have spent $9,107,472, $6,670,031, and $6,772,552, respectively, on R&D expenses. The major portion of these expenses were for personnel in research, clinical development, clinical support and regulatory compliance. In addition, we purchased approximately $1.0 million of LR-103 in 2004 for use in preclinical research and clinical trials.

The expense of research and clinical trial projects has not, on a project basis, been significant in 2004. The addition of new projects and trials and the future development of LR-103 and BCI 202 may have a material impact on our future operations, financial position, and liquidity. The impact of these projects, if any, are difficult to predict due to their early stage of progress and uncertainty.

Liquidity and Capital Resources

We require cash to fund our operations, make capital expenditures and for strategic investments. In May and June 2004, we completed an offering of five millon shares of common stock which resulted in approximately $101.4 of net proceeds. Our cash and cash equivalents, marketable securities and noncurrent marketable securities balances as of June 30, 2004 were $45,325,671, $68,776,698 and $908,376, respectively, totaling $115,010,745, an increase of $97,407,300 from the June 30, 2003 balances. Our cash and investments are invested in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

Cash used in operating activities was $4,120,868 for the year ended June 30, 2004 primarily to fund the net operating loss of $1,521,161, for inventory purchases of our products and to pay liabilities, principally management bonus compensation related to the fiscal year ended June 30, 2003.

We used $498,506 in cash for the purchase of capital assets, primarily computer and laboratory equipment. Our cash position was enhanced by $1,014,932 and $184,349 primarily from the exercise of stock options and for vehicle sales that were leased back, respectively.

Our cash and investments to-date and our profits in the third and fourth quarters of the fiscal year ended June 30, 2004 have been used to fund our operations and capital needs. We anticipate that annual expenditures for our active pharmaceutical ingredient, contract manufacturing, research projects, development of our current and planned products, regulatory activity, growth of our sales force, expansion of our marketing programs and development of the infrastructures to accommodate the planned growth and development, will increase in future years. Although we believe that our current cash and investments and our planned profits from product sales will be adequate to sustain our operations at least until June 30, 2005, there can be no assurance that we will be able to maintain profitability or positive

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cash flow from operations. We may require additional financing in the future to finance strategic investments, capital acquisitions and anticipated growth and development of existing and new products. As in the past, we plan to finance these activities largely through equity or debt financing and/or strategic or corporate collaborations. There can be no assurance that additional equity or debt financing or corporate collaborations will be available on terms acceptable to us, if at all. Our failure to maintain profitability or to raise additional capital on acceptable terms if and when needed could have a material adverse effect on our business, financial condition and results of operations.

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 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 other manufacturers, suppliers, formulators and vendors may be available to provide these goods and services to us, any change in suppliers could cause a delay in manufacturing 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 our own manufacturing facility, we would need additional funds and would have to hire and train additional personnel and comply with the extensive regulations applicable to the facility. We believe that our relationships with our suppliers are good.

We lease approximately 34,000 square feet of office and laboratory space in Middleton, Wisconsin. In June 2004, we entered into a new lease for new and existing space for approximately the same square footage within the current facility. This lease will become effective on our date of occupancy of the new space and has a term of five years. We expect to occupy the new space before the end of calendar year 2004. In conjunction with the construction of the new space, we plan to incur some costs related to leasehold improvements, furniture and computer equipment. The cash required for these planned capital purchases is not expected to have a significant negative impact on the existing cash and investment balances.

At June 30, 2004, we had state tax net operating loss carryforwards of approximately $46,036,000 and state research and development tax credit carryforwards of approximately $756,000, which will begin expiring in 2006 and 2012, respectively. We also had federal net operating loss carryforwards of approximately $50,872,000 and research and development tax credit carryforwards of approximately $2,394,000, which will begin expiring in 2011 and 2013, respectively.

Contractual Obligations and Commitments

As outlined in Note 6 of the Notes to Financial Statements included in this annual report on Form 10-K, we have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of June 30, 2004:

	Total	Less Than 1 Year	2-3 Years	4-5 Years	More Than 5 Years
Purchase Commitment (1)	$ 9,042,714	$ 9,042,714	$	$	$
Operating Lease Obligations (2)	5,032,481	1,061,824	2,103,499	1,602,494	264,664
	123,998	55,876	68,122		

Capital Lease Obligations (3)					
Total	$14,199,193	$10,160,414	$2,171,621	$1,602,494	$264,464

(1) Purchase commitments for purchases of the active pharmaceutical ingredients used in Hectorol® production and clinical and preclinical research, commitments for the manufacture of Hectorol® Injection and Hectorol® Capsules, and other service commitments, including consulting contracts, in the ongoing operations of the company.

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

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

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Recent Accounting Pronouncements

In December 2003, the Financial Accounting Standards Board (FASB) issued Interpretation 46R (FIN 46R), a revision to Interpretation 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46R clarifies some of the provisions of FIN 46 and exempts certain entities from its requirements. FIN 46R is effective at the end of the first interim reporting period ending after March 15, 2004. Entities that have adopted FIN 46 prior to this effective date can continue to apply the provisions of FIN 46 until the effective date of FIN 46R or the early adoption of FIN 46R. The adoption of FIN 46 and FIN 46R had no impact on our financial statements.

In March 2004, the FASB ratified the recognition and measurement guidance and certain disclosure requirements for impaired securities as described in Emerging Issues Task Force (EITF) Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments. The recognition and measurement guidance will be applied to other-than-temporary impairment evaluations in reporting periods beginning with our first fiscal quarter 2005. We do not believe the adoption of the recognition and measurement guidance in EITF Issue No. 03-1 will have a material impact on our financial statements.

ITEM 7A. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

Our sales from inception to date have been made solely to U.S. customers and, as a result, we have not had any exposure to factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. However, in future periods, we expect to sell in foreign markets, including Europe and Asia. Because our sales are made in U.S. dollars, a strengthening of the U.S. dollar could make our products less competitive in foreign markets.

As of June 30, 2004, we held $68,776,698 of short-term marketable securities and $908,376 of long-term marketable securities. The investments have been made for investment (as opposed to trading) purposes. Interest rate risk with respect to our investments is not significant because all such investments are U.S. dollar denominated and are:

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

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

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ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

BONE CARE INTERNATIONAL, INC.

INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders of
Bone Care International, Inc.:

We have audited the accompanying balance sheets of Bone Care International, Inc. as of June 30, 2004 and 2003, and the related statements of operations, shareholders equity, and cash flows for each of the three years in the period ended June 30, 2004. Our audits also included the financial statement schedule included in Item 15. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of Bone Care International, Inc. as of June 30, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2004, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

Deloitte & Touche LLP

Milwaukee, Wisconsin
September 8, 2004

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BONE CARE INTERNATIONAL, INC.
BALANCE SHEETS
As of June 30, 2003 and 2004

ASSETS	2003	2004
Current assets:		
Cash and cash equivalents	$ 3,065,218	$ 45,325,671
Marketable securities	13,624,826	68,776,698
Accounts receivable, net	2,814,753	4,732,698
Inventory	2,080,604	6,785,288
Other current assets	778,725	2,336,362
Total current assets	22,364,126	127,956,717
Marketable securities - noncurrent	913,401	908,376
Property, plant, and equipment, net	1,889,000	1,526,638
Patent fees, net	1,322,670	1,785,045
Goodwill	359,165	359,165
	$ 26,848,362	$ 132,535,941
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,684,838	$ 6,490,488
Accrued compensation payable	2,028,783	2,890,728
Accrued clinical study and research costs	603,048	1,001,818
Other accrued liabilities	102,601	214,010
Allowance for sales returns	336,620	100,000
Total current liabilities	5,755,890	10,697,044
Long-term liabilities	649,880	100,388
Commitments and Contingencies (Note 6)		
Shareholders equity:		
Preferred stock authorized 2,000,000 shares of $.001 par value; none issued		
Common stock authorized 28,000,000 shares of no par value; issued and outstanding 14,218,522 and 19,395,585 shares as of June 30, 2003 and 2004, respectively	73,640,801	178,868,933
Unearned compensation		(2,411,054)
Accumulated deficit	(53,198,209)	(54,719,370)

Total shareholders equity	20,442,592	121,738,509
	$ 26,848,362	$132,535,941

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

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BONE CARE INTERNATIONAL, INC.

STATEMENTS OF OPERATIONS

Years Ended June 30, 2002, 2003 and 2004

	2002	2003	2004
Product sales	$14,990,749	$ 19,518,274	$43,604,628
Cost and expenses:			
Cost of product sales	3,556,687	6,983,175	11,459,960
Research and development	6,772,552	6,670,031	9,107,472
Selling, general and administrative	12,822,576	18,117,436	24,833,152
	23,151,815	31,770,642	45,400,584
Loss from operations	(8,161,066)	(12,252,368)	(1,795,956)
Interest income, net	1,257,171	574,395	274,795
Loss before income tax	(6,903,895)	(11,677,973)	(1,521,161)
Income taxes			
Net loss	$ (6,903,895)	$(11,677,973)	$ (1,521,161)
Net loss per common share basic and diluted	$ (0.49)	$ (0.82)	$ (0.10)
Shares used in computing basic and diluted net loss per common share	14,084,313	14,174,594	14,868,525

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

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BONE CARE INTERNATIONAL, INC.

STATEMENTS OF SHAREHOLDERS EQUITY

Years Ended June 30, 2002, 2003, and 2004

	Shares	Common Stock	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (loss)	Total
Balance at June 30, 2001	13,955,372	$ 72,634,080	$	$(34,616,341)	$ 80,366	$ 38,098,105
Net loss for the year ended June 30, 2002				(6,903,895)		(6,903,895)
Unrealized loss on securities during the period					(26,409)	(26,409)
Comprehensive loss						(6,930,304)
Issuance of shares under stock option plan	201,400	856,075				856,075
Balance at June 30, 2002	14,156,772	73,490,155		(41,520,236)	53,957	32,023,876
Net loss for the year ended June 30, 2003				(11,677,973)		(11,677,973)
Unrealized loss on securities during the period					(53,957)	(53,957)
Comprehensive loss						(11,731,930)
Issuance of shares under stock option plan	61,600	150,646				150,646
Issuance of stock awards	150					

Balance at June 30, 2003	14,218,522	73,640,801		(53,198,209)		20,442,592
Net loss for the year ended June 30, 2004				(1,521,161)		(1,521,161)
Issuance of restricted stock units to executives		2,428,800	(2,428,800)			
Recognition of restricted stock compensation expense			17,746			17,746
Acceleration of stock option vesting		350,500				350,500
Issuance of common stock, net of offering costs	5,000,000	101,433,258				101,433,258
Issuance of shares under stock option plan	177,013	1,014,932				1,014,932
Issuance of stock awards	50	642				642
Balance at June 30, 2004	19,395,585	$178,868,933	$(2,411,054)	$(54,719,370)	$	$121,738,509

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

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BONE CARE INTERNATIONAL, INC.

STATEMENTS OF CASH FLOWS

Years Ended June 30, 2002, 2003, and 2004

	2002	2003	2004
Cash flows from operating activities:			
Net loss	$(6,903,895)	$(11,677,973)	$ (1,521,161)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation of fixed assets	720,138	771,790	824,083
Amortization of patents	177,720	152,451	179,475
Inventory write-off	165,817	11,144	199
Loss on disposal of fixed assets	4,041		800
Loss on write-off of patents		63,167	
Equity based compensation expense			368,888
Changes in assets and liabilities			
(Increase) decrease in accounts receivable	(938,269)	1,470,816	(1,917,945)
(Increase) decrease in inventory	(454,712)	7,721	(4,704,883)
(Increase) decrease in other current assets	309,507	(3,129)	(1,557,637)
Increase in accounts payable	157,122	915,173	3,805,650
Increase in current liabilities	102,231	2,070,479	1,321,664
Increase (decrease) in long term liabilities		649,880	(649,880)
Increase (decrease) in allowance for sales returns	21,100	110,520	(236,620)
Net cash used in operating activities	(6,639,200)	(5,457,961)	(4,087,367)
Cash flows from investing activities:			
Maturities of marketable securities	7,320,964	7,564,508	17,375,000
Purchase of marketable securities			(72,521,847)
Proceeds from the sale of property, plant, and equipment			35,985
Purchase of property, plant and equipment	(1,006,059)	(875,905)	(498,506)
Patent Fees	(350,649)	(340,039)	(641,850)
Net cash (used) provided in investing activities	5,964,256	6,348,564	(56,251,218)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net			101,433,258

Proceeds from exercise of stock options	856,075	150,646	1,014,932
Proceeds from capital lease obligation from sale-leaseback			184,349
Repayment of capital lease obligation from sale-leaseback			(33,501)
Net cash provided by financing activities	856,075	150,646	102,599,038
Net increase in cash and cash equivalents	181,131	1,041,249	42,260,453
Cash and Cash Equivalents at beginning of year	1,842,838	2,023,969	3,065,218
Cash and Cash Equivalents at end of year	$ 2,023,969	$ 3,065,218	$ 45,325,671

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

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS

Years Ended June 30, 2002, 2003 and 2004

(1) Summary of Significant Accounting Policies

Description of Business

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

Revenue Recognition

We record sales and the related costs of Hectorol® Capsules and Hectorol® Injection based on shipments to customers reduced by the estimated future returns and allowances. Revenue is recognized at the time of shipment as risk of loss has transferred to the customer, delivery has occurred, and collectibility is reasonably certain. Customers have a right to return product in accordance with our returns policy. In accordance with Statement of Financial Accounting Standards (SFAS) No. 48, Revenue Recognition When Right of Return Exists , our June 30, 2003 and June 30, 2004 balance sheets include an accrual of $336,620 and $100,000, respectively, for the estimated amount of future returns, based on historical experience related to Hectorol® Capsules and Hectorol® Injection.

Segments

Our current commercial focus is in nephrology utilizing Hectorol®, our novel vitamin D hormone therapy, to treat secondary hyperparathyroidism in patients with moderate to severe chronic kidney disease and end-stage renal disease. We currently derive our revenues from two products, Hectorol® Injection and Hectorol® 2.5 mcg Capsules. Hectorol® 0.5 mcg Capsules were approved by the FDA in April 2004. As of June 30, 2004 no product sales for Hectorol® 0.5 mcg Capsules have been recognized. Revenue performance by product is as follows:

	Years Ended June 30,		
	2002	**2003**	**2004**
Hectorol® Injection	$ 9,448,115	$15,122,224	$38,749,562
	5,542,634	4,396,050	4,855,066

Hectorol® Capsules 2.5mcg			
	$14,990,749	$19,518,274	$43,604,628

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

Cash, Cash Equivalents and Marketable Securities

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

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

In March 2004, the FASB ratified the recognition and measurement guidance and certain disclosure requirements for impaired securities as described in Emerging Issues Task Force (EITF) Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments. The recognition and measurement guidance will be applied to other-than-temporary impairment evaluations in reporting periods beginning with our first fiscal quarter 2005. We do not believe the adoption of the recognition and measurement guidance in EITF Issue No. 03-1 will have a material impact on our financial statements.

Accounts Receivable

Accounts receivable is stated net of allowance for doubtful accounts of $111,200 and $72,070 at June 30, 2003 and June 30, 2004, respectively.

Inventory

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

	June 30,	
	2003	**2004**
Raw materials	$1,293,329	$1,659,734
Work-in-process	182,998	89,388
Finished goods	604,277	5,036,166

$2,080,604	$6,785,288

We periodically reviews our inventory carrying levels. During fiscal years 2002, 2003 and 2004, we wrote-off $165,817, $11,144 and $199, respectively, of inventory representing amounts, which we estimated would not be sold prior to expiration.

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

Property, Plant and Equipment

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

	June 30, 2003	June 30, 2004
Leasehold Improvements	$ 588,632	$ 588,632
Furniture and Fixtures	545,547	524,455
Machinery and Other Equipment	3,100,108	3,502,221
	4,234,287	4,615,308
Less: Accumulated Depreciation	(2,345,287)	(3,088,670)
	$ 1,889,000	$ 1,526,638

Depreciation and Amortization

Depreciation and amortization are provided for in amounts sufficient to relate the cost of depreciable assets to operations over their estimated service lives. Accelerated methods of depreciation are used for financial statement and income tax reporting purposes for all asset classes except for leasehold improvements, which are depreciated based on straight-line for financial statement reporting and accelerated methods for income tax reporting. The cost of property, plant and equipment are depreciated over the following estimated useful lives:

Asset classification	Estimated useful life
Machinery, furniture, and fixtures	3 7 years
Leasehold improvements	Lesser of 5 years or remaining leasehold period

Intangible Assets

Legal costs incurred to register patents are capitalized when incurred and are amortized on a straight line basis over the life of the patent. We continuously evaluate whether events and circumstances have occurred that indicate the remaining estimated useful life of intangibles may warrant revision or that the remaining balance of intangibles may not be recoverable. If the future undiscounted cash flows are less than the carrying value, a loss is recognized for the difference between the fair value and the carrying value of the intangible asset. The cost and accumulated amortization for patents at June 30, 2003 was $2,454,622 and $1,131,952, respectively. The cost and accumulated amortization for patents at June 30, 2004 was $3,096,472 and $1,311,427, respectively. The average remaining useful life of our patents as of June 30, 2004 was approximately 10.7 years.

The aggregate amounts of anticipated amortization of patent fees for each of the next five fiscal years and thereafter are as follows:

Year	
2005	$ 201,928
2006	200,650
2007	190,611
2008	189,283
2009	169,201
Thereafter	833,372
Total	$1,785,045

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

The Company evaluates goodwill in accordance with SFAS No. 142, Goodwill and Other Intangible Assets. Under SFAS No. 142, an assessment of fair value is used to test for impairment of goodwill on an annual basis or when circumstances indicate a possible impairment. The Company performed the annual assessment on June 30, 2002, 2003, and 2004 and found no instances of impairment.

Shipping and Handling Costs

Shipping and handling costs associated with product sales are included in cost of sales.

Research and Development Costs

Materials, labor and overhead expenses related to research and development projects are charged to operations as incurred.

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.

For disclosure purposes only under SFAS No. 123, *Accounting for Stock-Based Compensation*, the Black-Scholes option pricing model was used to calculate the fair value of stock options using the following weighted-average assumptions:

	2002	2003	2004
Risk-free interest rate	4.1%	3.4%	3.6%
Expected market price volatility factor	0.60	0.62	0.67
Weighted average expected life	6.0 years	6.0 years	6.0 years

No dividends are expected to be paid.

The effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS 123, Accounting for Stock-Based Compensation, to the stock options issued under these plans was as follows:

	2002	2003	2004

Net loss as reported	$(6,903,895)	$(11,677,973)	$(1,521,161)
Compensation expense in reported net income			368,888
Less pro forma compensation expense	(1,054,582)	(1,656,210)	(3,831,247)
Pro forma net loss	$(7,958,477)	$(13,334,183)	$(4,983,520)
Net loss per share basic and diluted:			
As reported	$ (0.49)	$ (0.82)	$ (0.10)
Pro forma	$ (0.57)	$ (0.94)	$ (0.34)

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

Compensation expense of $350,500 was recognized for the year-ended June 30, 2004 due to the acceleration of unvested stock options as part of a severance agreement for the former VP Finance and for a retiring Board member. The expense recognized was based on the difference between the option grant price and the fair market value at the respective dates of separation.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company s employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair market value estimate, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

Net Loss Per Share

Net loss per share is based on a weighted average number of shares of common stock of 14,084,313, 14,174,594, and 14,868,525 for the years ended June 30, 2002, 2003 and 2004, respectively. Options to purchase common stock and restricted stock grants have been excluded from the calculation of diluted earnings per share as the impact of these options and restricted stock grants on diluted earnings per share would be antidilutive. The excluded options and restricted stock units totaled 689,133, 1,931,233, and 2,486,135 for the years ended June 30, 2002, 2003 and 2004, respectively.

Income Taxes

Income taxes are accounted for under the asset and liability method prescribed by FASB Statement No. 109. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and credit carry forwards. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The amount of deferred tax assets is reduced to the amount of any tax benefits that Bone Care believes are more likely than not to be realized. Because Bone Care has not yet reached profitability and future profitability cannot be assured, no value has been recorded for deferred tax assets.

Fair Value of Financial Instruments

The fair value of financial instruments other than securities, which consisted of cash and cash equivalents, receivables, accounts payable and accrued liabilities, approximated their carrying values at June 30, 2003 and 2004 due to the short-term nature or underlying terms of these instruments. The fair value of marketable securities is based on quoted market prices.

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

Concentration of Risk

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

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

Our customers primarily consist of wholesale distributors of pharmaceutical products. We utilize these wholesale distributors as the principal means of distributing our products to clinics and hospitals. Five individual wholesale distributors comprised 97% of the net accounts receivable balance as of June 30, 2004. These same five wholesale distributors represented 95% of our product sales for the year ended June 30, 2004, with the largest of the five wholesale distributors representing 39% of product sales. As of June 30, 2003 five individual customers comprised 88% of the net accounts receivable balance. These same five customers represented 92% of our product sales for the year ended June 30, 2003, with the largest of the five companies representing 34% of product sales. As of June 30, 2002 five individual customers comprised 62% of the net accounts receivable balance. These same five customers represented 69% of our product sales for the year ended June 30, 2002, with the largest of the five companies representing 27% of product sales.

At June 30, 2004, cash and cash equivalents includes $22.0 million of commercial paper and a $10.0 million certificate of deposit, bothfrom a single issuer, as well as, $10.0 million in a single money market fund.

Our marketable securities at June 30, 2004 consisted of $40.0 million of commercial paper from four different issuers and a variety of corporate and municipal bonds, with none of the bonds exceeding $2.0 million from any one issuer. One of the four issuers of this $40.0 million of commercial paper is the issuer of the $22.0 million of commercial paper classified as cash and cash equivalents.

Advertising Expenses

We expense advertising costs as incurred. Advertising expenses were $688,758, $944,362, and $891,315 for years ended June 30, 2002, 2003 and 2004, respectively.

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 financial statements and the notes have been reclassified to conform to the fiscal 2004 presentation.

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

(2) Shareholders Equity

In May 2004, we completed a public offering of 4,500,000 shares of common stock at a price of $21.75 per share. We received proceeds of $91,210,758 from the sale of the shares of common stock, net of offering expenses. In June 2004, the underwriters exercised their over-allotment option to acquire 500,000 additional shares of common stock at a price of $21.75 per share. We received additional proceeds of $10,222,500 from the sale of the 500,000 shares of common stock, net of offering expenses. Total offering costs were $7,316,742, which consisted of underwriter fees, legal and audit fees, printing costs, filing fees, and travel costs.

(3) Stock Options and Restricted Stock Awards

We have granted options to key employees and directors under three separate programs.

Under the first option program, titled the Bone Care International, Inc., 1996 Stock Option Plan, a total of 1,000,000 shares of common stock were made available. This stock option plan was amended in November 2000 and November 2001 to increase the number of available shares to 2,300,000 of which 78,889 remained available for grant at June 30, 2004. Options granted under this program have an exercise price equal to our common stock trading price on the date of the grant and vest over periods ranging from one to five years. The options will expire 10 years from the grant date, or upon termination of employment.

Under the second option program, titled the Bone Care International, Inc., 2002 Stock Incentive Plan, a total of 750,000 shares of common stock were made available in November 2002 of which 445 remained available for grant at June 30, 2004. Under the 2002 Plan, the Board authorized Compensation Committee may grant to eligible participants non-qualified stock options and incentive stock options to purchase shares of common stock. Options granted under this program have an exercise price equal to our common stock trading price on the date of the grant and vest over a period of three years. The options will expire 10 years from the grant date, or upon termination of employment.

Under the third option program, titled the Bone Care International, Inc., 2003 Stock Incentive Plan, a total of 300,000 shares of common stock were made available in November 2003 of which 144,918 remained available for grant at June 30, 2004. Under the 2003 Plan, the Compensation Committee may grant to eligible participants non-qualified stock options and incentive stock options to purchase shares of common stock and restricted stock awards. Options granted under this program have an exercise price equal to our common stock trading price on the date of the grant and vest over a period of three years. The options will expire 10 years from the grant date, or upon termination of employment. Restricted stock awards are shares of common stock granted subject to a restricted period that is designated by the Compensation Committee.

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

A summary of stock option activity and related information is presented below:

	Year ended June 30,					
	2002		2003		2004	
	Options	Weighted average exercise price	Options	Weighted average exercise price	Options	Weighted average exercise price
Outstanding beginning of year	1,018,683	$11.03	689,133	$12.51	1,931,233	$ 7.32
Granted	189,000	16.30	1,490,800	4.99	844,850	15.16
Exercised	(201,400)	4.25	(61,600)	2.45	(177,013)	5.73
Terminated/canceled	(317,150)	15.24	(187,100)	9.46	(227,935)	11.66
Outstanding end of year	689,133	$12.51	1,931,233	$ 7.32	2,371,135	$ 9.82
Exercisable at end of year	324,866	$ 8.95	299,033	$12.16	997,434	$ 6.86
Weighted average fair value of options granted during year		$ 9.78		$ 3.00		$ 9.52

The options outstanding at June 30, 2004 have been segregated into six ranges for additional disclosure as follows:

	Options outstanding			Options exercisable	
Range of exercise prices	Options outstanding at June 30, 2004	Weighted average remaining contractual life	Weighted average exercise price	Exercisable at June 30, 2004	Weighted average exercise price
$2.11	23,600	1.6	$ 2.11	23,600	$ 2.11
$3.40 $3.48	788,952	8.1	3.42	515,271	3.42

$5.55-$7.95	206,900	7.7	6.19	142,963	6.21
$9.00 $13.00	867,650	8.7	11.61	176,467	10.36
$14.15-$21.12	421,033	8.7	18.25	136,733	16.52
$21.86-$24.66	63,000	9.7	23.72	2,400	23.56

Excluded from the stock option activity shown above were 115,000 restricted stock units that were granted on June 22, 2004 to the executive management team. These restricted stock awards will vest one-third annually over the next three years. The fair value of the restricted stock awards at the date of grant of $2.4 million will be recognized as compensation expense over the three-year vesting period.

(4) Shareholders Rights Plan and Preferred Stock

In 1996, we adopted a Shareholders Rights Plan. Under this plan, each share of common stock has associated with it one preferred share purchase right (a Right). Under certain circumstances, each Right would entitle holders to purchase from us 1/200th of one share of Series A Junior Participating Preferred Stock for the price of $12.50 per 1/200th of a share. The Rights do not have voting or dividend rights and, until they become exercisable, have no dilutive effect on per-share earnings. The Rights are not presently exercisable and are transferable only with the related shares of common stock. The Board of Directors has designated 140,000 shares of the Preferred Stock as Series A Junior Participating Preferred Stock in connection with the Rights.

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

(5) Income Taxes

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

Significant components of our deferred tax assets at June 30, 2003 and 2004 are as follows:

	2003	2004
Deferred tax assets:		
Inventory reserves	$ 331,000	$ 250,000
Deferred income	131,000	39,000
Accrued liabilities	798,000	979,000
Allowance for doubtful accounts	31,000	28,000
Other	120,000	172,000
Federal net operating loss carryforward	16,582,000	17,296,000
Federal R&D tax credit carryforward	2,040,000	2,394,000
State net operating loss carryforward	2,128,000	2,210,000
State R&D tax credit carryforward	410,000	499,000
Valuation allowance	(22,064,000)	(23,184,000)
Deferred tax assets	507,000	683,000
Deferred tax liabilities:		
Patents	(507,000)	(683,000)
Total deferred taxes	$	$

At June 30, 2004, $4.5 million of the federal net operating loss carryforwards in the table above relates to the tax benefits of stock option exercises. To the extent the related valuation allowance for these amounts is reversed, they will be credited to common stock rather then net income. 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 intime in which we have realized a cumulative profit over a period of the three consecutive fiscal years, management may have a sufficient basis to conclude that some or all of the valuation allowance may be

reduced.

The following table summarizes the principal reasons for the difference between the effective tax rate and the U.S. federal statutory income tax rate:

	2002	2003	2004
U.S. federal income tax (benefit) at statutory rate	$(2,347,000)	$(3,971,000)	$(517,000)
State income tax, net of federal benefit	(337,000)	(498,000)	(209,000)
Research activities credits	(490,000)	(343,000)	(354,000)
Permanent items and other	279,000	52,000	247,000
Change in valuation allowance	2,895,000	4,760,000	833,000
Income tax expense	$ 0	$ 0	$ 0

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

(6) Contractual Obligations and Commitments

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

	Total	Less Than 1 Year	2-3 Years	4-5 Years	More Than 5 Years
Purchase Commitment (1)	$ 9,042,714	$ 9,042,714	$	$	$
Operating Lease Obligations (2)	5,032,481	1,061,824	2,103,499	1,602,494	264,664
Capital Lease Obligations (3)	123,998	55,876	68,122		
Total	$14,199,193	$10,160,414	$2,171,621	$1,602,494	$264,464

(1) Purchase commitments for purchases of the active pharmaceutical ingredients used in Hectorol® production and clinical and preclinical research, commitments for the manufacture of Hectorol® Injection and Hectorol® Capsules, and other service commitments including consulting contracts in the ongoing operations of the company.

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

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

We lease approximately 34,000 square feet of office and laboratory space in Middleton, Wisconsin. Total lease expense was $649,182, $668,045, and $668,045 for the years ended June 30, 2002, 2003, and 2004, respectively. At June 30, 2004 capitalized lease cost and accumulated amortization was $184,349 and $36,071, respectively.

Gross future minimum operating and capital lease payments are as follows:

	Operating Leases	Capital Leases
2005	$1,061,824	$ 55,876
2006	1,084,125	50,899

2007	1,019,374	17,223
2008	817,056	
2009	785,438	
Thereafter	264,664	
Total lease obligation	$5,032,481	$123,998

(7) Deferred Compensation Plan

We have established a 401(k) plan covering substantially all employees. Employer contributions to the plan are at the discretion of the Board of Directors. Our policy is to fund the 401(k) plan contributions as they accrue. 401(k) expense amounted to $166,675, $163,072 and $232,008 for the years ended June 30, 2002, 2003, and 2004, respectively.

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

(8) Marketable Securities

Securities as of June 31, 2004 include the following:

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

At June 30, 2004, the unrealized loss on commercial paper represents losses on fixed income securities and is primarily attributable to changes in market interest rates. We do not believe the unrealized loss 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.

Securities as of June 30, 2003 include the following:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Held-to-Maturity				
Corporate bonds	$ 4,688,227	$105,079	$	$ 4,793,306
Available-for-Sale				
Municipal bonds	7,850,000			7,850,000
Corporate bonds	2,000,000			2,000,000
	9,850,000			9,850,000
Total marketable securities	$14,538,227	$105,079	$	$14,643,306

Scheduled maturities of marketable securities at June 30, 2004:

	Available-For-Sale		Held-To-Maturity	
	Cost	Fair Value	Amortized Cost	Fair Value
Fiscal Year				
2005	$27,750,000	$27,750,000	$41,026,698	$40,988,104
2006			908,376	943,839
Total	$27,750,000	$27,750,000	$41,935,074	$41,931,943

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BONE CARE INTERNATIONAL, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Years Ended June 30, 2002, 2003 and 2004

(9) Related Party Transactions

Martin Barkin, M.D. was a member of our Board of Directors until April 2004 and is the President and Chief Executive Officer of Draxis Health, Inc. (a pharmaceutical company). Effective April 30, 2004, Martin Barkin resigned from the board.

We initially granted Draxis Health Inc. a license to use and sell Hectorol® in Canada for secondary hyperparathyroidism, osteoporosis and other metabolic bone diseases. We also granted Draxis a license in Canada to all know-how developed by or on behalf of us relating to the use of Hectorol® for those indications. Draxis received marketing approval for Hectorol® Capsules in Canada in May 2001. Draxis sold its Canadian pharmaceutical business to Shire Pharmaceuticals Group in July 2003. In conjunction with that sale, we entered into a new manufacturing and supply agreement and patent and trademark license agreement with Shire that replaced and superceded all previous agreements with Draxis. The patent and trademark agreement transfers to Shire the exclusive right to use and sell Hectorol® previously granted to Draxis and requires a royalty for use of the Hectorol® trademark. The manufacturing and supply agreement provides for the sale of Hectorol® from us to Shire for distribution in Canada only. As of June 30, 2004, no balance was reported as part of accounts receivable for amounts owed from Draxis.

In April 2002, we entered into a manufacturing agreement with Draxis Pharma, a division of Draxis Health Inc. to produce Hectorol® Injection in Canada. We began receiving commercial shipments in March 2003 for customer sales in the U.S. We purchased approximately $8.8 million and $2.0 million of Hectorol® Injection from Draxis Pharma for the period July 1, 2003 through April 30, 2004 and in the year ended June 30, 2003, respectively.

(10) Quarterly Financial Data (Unaudited)

Summary quarterly financial data for the years ended June 30, 2004 and 2003 are summarized as follows:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(In thousands except for per share data)			
2004:				
Product sales	$ 8,125	$ 9,116	$11,617	$14,747
Gross margin	5,707	6,684	8,689	11,064
Net earnings (loss)	(2,102)	(478)	302	757
Net loss per share basic	$ (0.15)	$ (0.03)	$ 0.02	$ 0.05
Net loss per share diluted	$ (0.15)	$ (0.03)	$ 0.02	$ 0.04
2003:				
Product sales	$ 5,417	$ 3,743	$ 3,078	$ 7,280
Gross margin	3,908	2,283	1,551	4,793
Net loss	(1,631)	(4,128)	(4,625)	(1,294)
Net loss per share basic and diluted	$ (0.12)	$ (0.29)	$ (0.33)	$ (0.09)

The sum of the four quarters per share amounts may not equal the annual per share amount due to changes during the year in the weighted average number of shares outstanding and the dilutive impact of stock options for profitable quarters.

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ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

None.

ITEM 9A. ***CONTROLS AND PROCEDURES***

As of June 30, 2004, our management, including our chief executive officer and chief financial officer, have conducted an evaluation of the effectiveness of disclosure controls and procedures, pursuant to Rule 13a-15 of the Securities Exchange Act of 1934, as amended. Based on that evaluation, our 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 annual report has been made known to them in a timely fashion.

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

ITEM 10. ***DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT***

We incorporate by reference the information required by Item 10 from our definitive Proxy Statement for our 2004 Shareholders Meeting (Proxy Statement), which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year.

ITEM 11. ***EXECUTIVE COMPENSATION***

We incorporate by reference the information required by Item 11 from the Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year.

ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

We incorporate by reference the information required by Item 12 from the Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year.

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS***

We incorporate by reference the information required by Item 13 from the Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

We incorporate by reference the information required by Item 13 from the Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year.

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PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***

1. *Financial statements*
   Reference is made to the separate index to our financial statements contained on page 30 hereof.

2. *Financial statement schedule*

Valuation and Qualifying Accounts and Reserves

For the Years Ended June 30, 2004, 2003, and 2002

	Balance at beginning of period	Charged to costsand expenses	Deductions and other	Balance at end of period
2004: Allowance for doubtful accounts	$ 111,200	$ (8,370)	$30,760	$ 72,070
2004: Tax valuation allowance	22,064,000	1,120,000		23,184,000
2003: Allowance for doubtful accounts	152,960	39,738	81,498	111,200
2003: Tax valuation allowance	17,186,000	4,878,000		22,064,000
2002: Allowance for doubtful accounts	100,000	40,007	12,953	152,960
2002: Tax valuation allowance	13,503,000	3,683,000		17,186,000

3. *Exhibits*
   Reference is made to the separate exhibit index contained on page 58 hereof.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.
/s/ PAUL L. BERNS

By: Paul L. Berns
President and Chief Executive Officer

Date: September 10, 2004

Pursuant to the requirements of the Securities Exchange Act of 1934, the following persons on behalf of the Registrant and in the capacities and on the dates indicated have signed this report below.

/S/ PAUL L. BERNS Paul L. Berns	President and Chief Executive Officer and Director (Principal Executive Officer)	September 10, 2004
/S/ BRIAN J. HAYDEN Brian J. Hayden	Vice President Finance (Principal Financial and Accounting Officer)	September 10, 2004
/S/ MICHAEL D. CASEY Michael D. Casey	Director	September 10, 2004
/S/ HERBERT J. CONRAD Herbert J. Conrad	Director	September 10, 2004
/S/ CHARLES R. KLIMKOWSKI, CFA Charles R. Klimkowski, CFA	Director	September 10, 2004
/S/ RICHARD B. MAZESS, PH.D. Richard B. Mazess, Ph.D.	Director	September 10, 2004
/S/ GARY E. NEI Gary E. Nei	Director	September 10, 2004
/S/ EDWARD STAIANO Edward Staiano, Ph.D.	Director	September 10, 2004
/S/ KLAUS R. VEITINGER, M.D. PH.D. Klaus R. Veitinger, M.D. Ph.D.	Director	September 10, 2004

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BONE CARE INTERNATIONAL, INC.

INDEX TO EXHIBITS

Exhibit Number	Document Description
3.1(a)	Restated Articles of Incorporation of Registrant (1) (Exhibit 3.1, Amendment No. 3 to Form 10/A).
3.1(b)	Articles of Amendment to Articles of Incorporation of Registrant (2) (Exhibit 3.1(b)).
3.2	By-Laws of Registrant (3) (Exhibit 3.2).
4.1	Shareholders Rights Agreement between Bone Care and Norwest Bank Minnesota, N.A. (1) (Exhibit 4.1, Amendment No. 3 to Form 10/A).
4.2	First Amendment to Shareholder Rights Agreement between Bone Care and Norwest Bank Minnesota, N.A. (1) (Exhibit 4.2, Amendment No. 4 to Form 10/A).
10.1*	Incentive Stock Option Plan (1) (Exhibit 10.4).
10.2*	1996 Stock Option Plan (4) .
10.3	Amended and Restated License Agreement effective as of June 8, 1998, by and between Bone Care and Draxis Health, Inc. (5) (Exhibit 10.6).
10.4*	Form of Stock Option Agreement (2) (Exhibit 10.7).
10.5	Agreement, effective as of May 1, 1987, by and between the Wisconsin Alumni Research Foundation and Bone Care (confidential material appearing in this document has been omitted and filed separately with the Securities and Exchange Commission in accordance with the Securities Act of 1933, as amended, and 17 C.F.R. 230.406 and 200.80 promulgated thereunder. Omitted information has been replaced with asterisks). (2) (Exhibit 10.8).
10.6*	2002 Stock Incentive Plan. (6)(Exhibit 4.6)
10.7*	2003 Stock Incentive Plan. (6)(Exhibit 4.7)
10.8	Co-Promotion Agreement dated as of July 14, 2004 between Cardinal Health PTS, LLC and Registrant (7).
10.9*	Severance Agreement between the Registrant and Paul L. Berns.
10.10*	Severance Agreement between the Registrant and James V. Caruso
10.11*	Severance Agreement between the Registrant and Brian J. Hayden
10.12*	Severance Agreement between the Registrant and Jeffrey J. Freitag

10.13*	Severance Agreement between the Registrant and Carmine J. Durham
10.14*	Severance Agreement between the Registrant and R. Andrew Morgan
10.15*	Severance Agreement between the Registrant and C. Basil Mundy
23	Consent of Deloitte & Touche LLP.
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 U.S. Code.
32.2	Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the U.S. Code.

(1) Incorporated by reference to exhibits filed with Registrant s Form 10 Registration Statement (Registration Number 02-27854) filed under the Securities Exchange Act of 1934. Parenthetical references to exhibit numbers are to the exhibit numbers in the Form 10 or, if applicable, the amendment to the Form 10.

(2) Incorporated by reference to exhibits filed with the Registrant s Form S-1 Registration Statement (Registration Number 333-43923) filed under the Securities Act of 1933. Parenthetical references to exhibit numbers are to exhibit numbers in the Form S-1.

(3) Incorporated by reference to the exhibits filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 (File No. 0-27854). Parenthetical references to exhibit numbers are to the exhibit numbers in the Form 10-Q.

(4) Incorporated by reference to exhibit 4.5 of the Registrants Registration Statement on Form S-B (Registration Number 333-55174) filed under the Securities Act of 1933.

(5) Incorporated by reference to exhibits filed with the Registrant s Form S-1/A Registration Statement(Registration Number 333-43923) filed under the Securities Act of 1933. Parenthetical references to exhibit numbers are to exhibit numbers in the Form S-1/A.

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(6) Incorporated by reference to exhibits filed with the Registrant s Registration Statement on Form S-8 (Registration Number 333-111968) filed under the Securities Act of 1933. Parathetical references to exhibit numbers are to the exhibit numbers in Form S-8.

(7) Confidential material appearing in this document was omitted and filed separately with the Securities and Exchange Commission in accordance with Section 24(b) of the Securities Exchange Act of 1934, as amended, and rule 24b-2 promulgated thereafter. Omitted information was replaced with asterisks.

* Indicates a management contract or compensatory plan or arrangement.