

BONE CARE INTERNATIONAL INC

Form DEFA14A

May 05, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**SCHEDULE 14A**

**SCHEDULE 14A INFORMATION**

**Proxy Statement Pursuant to Section 14(a) of the Securities  
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**BONE CARE INTERNATIONAL, INC.**

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Bone Care will file with the Securities and Exchange Commission (the SEC), and furnish to its shareholders, a proxy statement soliciting proxies for the meeting of its shareholders to be called with respect to the proposed merger between Bone Care and Genzyme Corporation. **BONE CARE SHAREHOLDERS ARE ADVISED TO READ THE PROXY STATEMENT WHEN IT IS FINALIZED AND DISTRIBUTED TO THEM BECAUSE IT WILL CONTAIN IMPORTANT INFORMATION.** Bone Care shareholders and other interested parties will be able to obtain, without charge, a copy of the proxy statement (when available) and other relevant documents filed with the SEC from the SEC's website at <http://www.sec.gov>. Bone Care shareholders and other interested parties will also be able to obtain, without charge, a copy of the proxy statement and other relevant documents (when available) by directing a request by mail or telephone to Bone Care International, 1600 Aspen Commons, Middleton, WI, 53562, telephone: 608-662-7800, or from Bone Care's website, <http://www.BoneCare.com>.

Bone Care and certain of its directors, executive officers and other members of management and employees may, under SEC rules, be deemed to be participants in the solicitation of proxies from Bone Care shareholders with respect to the proposed merger. Information regarding the people who may be considered participants in the solicitation of proxies will be set forth in Bone Care's proxy statement relating to the proposed merger when it is filed with the SEC. Information regarding certain of these people and their beneficial ownership of Bone Care common stock as of October 12, 2004 is also set forth in Bone Care's proxy statement for its 2004 Annual Meeting of Shareholders, which was filed with the SEC on October 25, 2004.

This filing contains forward-looking statements, including statements about the completion of a merger transaction between Genzyme and Bone Care and the timing thereof, the expected impact on Genzyme's earnings, 2005 revenue guidance for Hectorol, plans to initiate a sevelamer carbonate study and the timing thereof, integration of Bone Care's operations and the Hectorol sales and marketing operations, and plans for registration of Hectorol outside the

U.S. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties include, among others, the possibility that the transaction is not completed; the possibility that the transaction does not obtain FTC clearance on terms acceptable to the companies; the possibility that other closing conditions are not met, including receipt of Bone Care shareholder approval; the actual timing and content of submissions to and decisions made by regulatory authorities, including those outside of U.S. in regards to Hectorol; the ability to attract and retain qualified sales forces; the accuracy of the companies' information concerning the CKD marketplace, including growth projections; and the risks and uncertainties described in reports filed by Genzyme and Bone Care with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, including without limitation the information under the heading "Factors Affecting Future Operating Results" in Genzyme's Annual Report on Form 10-K for the year ending December 31, 2004, and under the heading "Contingencies" in Bone Care's Quarterly Report on Form 10-Q for the quarter ended December 31, 2004. We caution investors not to place substantial reliance on the forward-looking statements contained in this filing. These statements speak only as of the date of this filing, and we undertake no obligation to update or revise the statements.

THE FOLLOWING IS A TRANSCRIPT OF A CONFERENCE CALL OF BONE CARE INTERNATIONAL, INC. AND GENZYME CORPORATION ON WEDNESDAY, MAY 4, 2005.

**FINAL TRANSCRIPT GENZ    Genzyme Corporation Conference Call Announcing Merger Agreement with Bone Care International Event Date/Time: May. 04. 2005 / 10:15AM ET © 2005 Thomson Financial. Republished with permission. No part of this publication may be reproduced or transmitted in any form or by any means without the prior written consent of Thomson Financial.**  
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## **C O R P O R A T E   P A R T I C I P A N T S**

**Sally Curley**

*Genzyme   VP of IR*

**Henri A. Termeer**

*Genzyme   Chairman and CEO*

**Paul Berns**

*Bone Care International   President and CEO*

**Mike Wyzga**

*Genzyme   CFO*

**John Butler**

*Genzyme   President, Genzyme Renal Division*

## **C O N F E R E N C E   C A L L   P A R T I C I P A N T S**

**Sena Lund**

*Cathay Financial   Analyst*

**Jessica Hanover**

*Robert W. Baird   Analyst*

**Ian Somaiya**

*Thomas Weisel Partners   Analyst*

**Phil Nadeau**

*SG Cowen   Analyst*

**Meg Malloy**

*Goldman Sachs   Analyst*

**Mark Augustine**

*CSFB   Analyst*

**Yaron Werber**

*Smith Barney   Analyst*

**Mark Schoenebaum**

*Bear Stearns   Analyst*

**Alexandra Lee**

*Sustainable Growth   Analyst*

**Louis Sarks**

*Chesapeake Partners   Analyst*

**P R E S E N T A T I O N**

**Operator**

Good day and welcome, everyone, to today's Genzyme Corporation and Bone Care International conference call. As a reminder, today's call is being recorded. At this time for opening remarks and introductions I would like to turn the call over to Vice President of Investor Relations for Genzyme, Ms. Sally Curley. Please go ahead, ma'am.

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**Sally Curley** - *Genzyme VP of IR*

Thank you. Welcome to the Genzyme Corporation and Bone Care International conference call today. On behalf of both companies I'd like to remind everyone that the press release and this call may be found on Genzyme's website, as well as Bone Care's website.

We will be making some forward-looking statements on this call about the proposed merger and our future business plans. Forward-looking statements include statements about the timing of the merger; the receipt of required regulatory and shareholder approval; the impact of the deal on Genzyme's earnings; revenue guidance for Hectorol; our estimates of the vitamin D and CKD markets; our assessment of competitors (technical difficulty) future development plans for Hectorol sevelamer carbonate. These statements are subject to a number of risks and uncertainties, and our actual results may differ materially. Please refer to our press release and the risk factors in both companies' 10-K and Bone Care's Q1 10-Q for more information regarding those risks.

Lastly, in response to your feedback, I'd like to ask again that each participant limit themselves to one question and one follow-up so that we can allow everyone to participate in the call.

With that I will now introduce our Chairman and CEO, Mr. Henri Termeer.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Thank you Sally, and thank everybody participating today. This is a very exciting moment indeed. The combination of Bone Care International and the renal activities, the Renagel activities within Genzyme is a very, very, very attractive combination, very strategic, and financially extremely strong.

As we said in the press release, this is a neutral transaction, assuming that it will close later this year, for '05. But it will still be accretive thereafter. The reason that it is accretive is that this product fits so very, very well - this is Hectorol - into the Renagel platform that we've developed over the last number of years. There's tremendous synergy, and there's tremendous strengthening that happens by combining the marketing and sales capabilities of Bone Care with those of the Renagel organization within Genzyme. It broadens the platform clearly; diversifies the renal platform for Genzyme clearly. The kind of transaction that we've spoken to you about, we will be contemplating. And it fits in that sense very well into our future plans.

There is a number of very important considerations that we brought into this discussion. It was very important for us to understand the clinical differentiation of this program and the reasons why it gained its market share that it did. (technical difficulty) understand that we could grow this franchise and sales number, the drug franchise, and develop a growing business over many years. And the basis for that is clearly here around this program.

At Bone Care International Hectorol was not in use. It is not yet introduced internationally. It's clearly an area where we are very successful with Renagel. And so our full intent to introduce this program throughout the globe alongside the Renagel program.

Very importantly, the oral form of Hectorol is primarily sold in the chronic kidney disease area, the earlier stages, not the end stage renal disease dialysis market. And that is an area we're very attracted to also for Renagel. As you know, we're developing sevelamer carbonate to enter this field. We've just entered first stage clinical trials. We will have further clinical trials starting this year. And by (technical difficulty) we expect to be able to introduce Renagel to the

CKD market, the earlier stage CKD market. Hectorol, the oral form is currently already in this market. And the combination of these programs, these two products, is very attractive indeed for this much larger footprint market.

So we're excited about this. This is a very accretive transaction for Genzyme, which has very long legs in terms of the growth that we can expect from this product and follow-on product in the same space. It is a very, very strong product that has been proven in a competitive environment to gain market share in the United States in a very convincing way.

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So with that I would like to introduce to people that are participating on the call this morning. There's the President, the CEO, Paul Berns, of Bone Care International; also, the Chief Financial Officer Brian Hayden. On the Genzyme side you have Mike Wyzga, our Chief Financial Officer, who will guide us through the financial structure of the deal; and the President of Genzyme Renal Division, John Butler, who will talk about integration of this organization and this marketing program into the Genzyme picture. So at this moment I would like to ask Paul Berns to make a few comments.

**Paul Berns - Bone Care International - President and CEO**

Thank you, and good morning everyone. As Henri has mentioned, we are pleased to announce this transaction which provides value for clearly patients, clinicians and our shareholders. And we're very enthusiastic by joining with Genzyme in their renal organization that we will provide our organization the opportunity to work with one of the world's leading biotechnology companies that shares our commitment to innovation and excellence and execution in delivering therapies that meet height unmet medical needs.

I wanted to say to everyone this morning, and as I've reported in the past to those constituents following our Company, that during my tenure with Bone Care since joining the Company back in 2002, the employees of Bone Care have clearly been engaged in building our business and value for our shareholders.

And I have discussed on each and every conference call four key specific corporate priorities, the first of which is focus on excellence and execution of our customer plans to drive performance; the second, continuing to be proactive in building our Company as we review opportunities regarding acquisitions of products, companies and other key strategic business arrangements to drive value for our shareholders, our employees and our customers; third, to pursue scientific innovation and development of therapeutic products; and then finally, always to lead with ethics to ensure quality business decisions which create value in fact for those constituents, as just mentioned. And it's clear to us that not only does the merger of Bone Care and Genzyme accomplish these four priorities, but frankly much more. And as I have said, we believe this merger creates significant value for all parties involved.

Over the course of the past three years, the employees of Bone Care have executed our plans with extreme precision, which has included expansion of our share of our vitamin D market of Hectorol to a greater than 20% share to date through developing strong business relationships with our customers and an unsurpassed and utilizing Hectorol's unsurpassed product profile in advancing the quality of health care that physicians may afford their patients with the use of Hectorol as an important pharmaceutical tool.

With that, I would like to take a few moments to expand on the why behind Hectorol's success in acquisitioning market share and the strong interest clinicians have in utilizing it in the management of their secondary hyperparathyroid chronic kidney disease patients.

Hectorol, as some of you may or may not know, is a pro-hormone formulation that clearly has unsurpassed efficacy and safety in the treatment of chronic kidney disease with vitamin D deficiency in the context of treating secondary hyperparathyroidism. Hectorol maintains vitamin D hormone levels within the normal physiologic range, which is very different than what our other competitor or participant in the marketplace provides from a pharmacokinetics/pharmacodynamic standpoint. Hectorol because of that affords patients a very low incidence of adverse events in the context of hypercalcemia in particular. And that gives physicians in the market research. And clearly, as demonstrated in the utility of our product, we believe confers here again the clinical, meaningful utility of Hectorol in the management of this disease unparalleled to other therapies.

We have Hectorol available in the injectable and oral forms, as Henri has mentioned, which further expand utility of the Hectorol brand line and market opportunities. Hectorol, here again, as Henri mentioned a few moments ago, is the first and only oral vitamin D2 hormone treatment available for predialysis chronic kidney disease, and the only prohormone available D2 analog

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period on the market. In addition, we have an outstanding sales organization that has consummated tremendous relationships from a physician opinion leader perspective, as well as a business operational perspective.

The growth in our business, and the traction we have gained in the acquisition of market share, as I've spoken to, has clearly allow us to transition our Company to one of profitability, which we achieved in the third quarter of our last fiscal year, which was fiscal year 2004. And we have continually quarter-over-quarter grown revenues and continue to grow profitability for our Company to the benefit here again of our shareholders. Most recently we launched our Hectorol 0.5 microgram capsule, which commercially took place last August into an undeveloped, unserved yet high potential predialysis chronic kidney disease market.

In review of that performance, it's clear that we've accomplished what we had set out to achieve and more in a very short time frame. And for that, those that had believed in our abilities will reap the rewards of these accomplishments for our stockholders. Here again we feel quite an accomplishment in a very short period time, clearly centered around the product profile of Hectorol and the outstanding employees of our Company.

Our corporate performance is a tribute to hard work and dedication of our employees in general. With the strength of a world-class organization like Genzyme behind the development and commercialization of our product, the patient community that is afflicted with the terrible diseases that we treat we believe will benefit greatly, to Henri's earlier points. It's clear to us again that the combination of two world-class sales organizations will provide a great share voice and outreach in the renal community and support the mission of optimizing clinical patient care.

We are absolutely thrilled and very excited about moving forward in the transition with our friends and colleagues from Genzyme. And with that, Henri, I will turn the call back over to you.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Thank you very much Paul. At this moment I will ask Mike Wyzga, our Chief Financial Officer, to go through the transaction.

**Mike Wyzga** - *Genzyme CFO*

Thank you Henri. Let me walk through both the transaction, as well as the process.

The agreement right now contemplates an all-cash acquisition. Genzyme will pay \$33 per share. The options outstanding will be accelerated and cashed out at the deal price less their exercise price. Bone Care right now has approximately 21.5 million fully diluted shares outstanding, so the aggregate deal price is about \$720 million; about \$600 million after deducting Bone Care's \$119 million in cash. The liabilities on the balance sheet, on the last balance sheet, were under \$11 million, and they don't have any debt.

As far as the process goes, Bone Care will need to prepare proxy materials and then convene a meeting of its shareholders to approve the transaction. We expect Bone Care will file preliminary proxy materials with the SEC within the next two weeks. If the SEC does not comment on the proxy materials then Bone Care could mail them within the next two weeks later and have a meeting approximately four weeks after the mailing. We expect about 60 days between the signing and the closing.

There are two substantial conditions upon closing. They are the Bone Care shareholder stockholder approval and clearance of the HSR, Hart-Scott-Rodino.

There is a breakup fee of \$19 million plus an additional \$900,000 in reimbursement for out-of-pocket costs. The agreement is subject to customary reps and warranties and covenants, and those are consistent with Genzyme's other transactions. With the closing expected in the third quarter, as Henri mentioned, we expect the transition to be neutral to our earnings on a non-GAAP

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basis for 2005 and accretive on a non-GAAP basis beyond. We'll give specific advice upon completion of the purchase accounting, which is approximately going to take about three or four weeks.

With that, let me turn it back to Henri for questions and answers.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Before we do that, let me ask John Butler to comment on the integration of the organizations.

**John Butler** - *Genzyme President, Genzyme Renal Division*

Thank Henri. We're obviously very excited about integrating the Bone Care team into the Genzyme Renal Division. This is an important strategic acquisition for us on a number of fronts.

First, in our current dialysis market, this really does allow us to add a very, very professional sales and marketing organization that will increase our share voice with a strong synergistic message for both products.

Additionally, we have spoken to you often about our desire to move into CKD. As Henri mentioned, we've recently begun our clinical trials with sevelamer carbonate in dialysis patients, and expect to begin a CKD trial later this year. Hectorol 0.5 micrograms allows us to enter this market immediately with the first product approved to treat secondary hyperparathyroidism in stage 3 and 4 patients. We know this is a very large and growing market, and is currently a very underserved patient population. And it's a population that fits very, very well with the expected population we will be serving with sevelamer carbonate.

As we have told you in the past, approximately 40% of our current revenues for Renagel come from outside of the United States. We do look forward to utilizing the infrastructure we've built internationally to launch Hectorol globally. Right now we will begin to assess what's needed to accomplish that and move that process forward as quickly as possible.

Henri, I will turn it back to you.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Operator, at this moment we can go to Q&A.

## QUESTIONS AND ANSWERS

**Operator**

(OPERATOR INSTRUCTIONS) Sena Lund, Cathay Financial.

**Sena Lund** - *Cathay Financial Analyst*

Good morning. Congratulations on the deal. Just quickly on Bone Care, can you just talk about the cost of manufacturing, and also touch the sales infrastructure you will be getting; how many people, how many ? And how much synergy have you (indiscernible) into your guidance of neutral this year and accretive next year?

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**Henri A. Termeer** - *Genzyme Chairman and CEO*

If I can guide this question to Paul for the first part, and for the synergy part to John.

**Paul Berns** - *Bone Care International President and CEO*

Thank you Henri. The cost of manufacturing, as we've reported, I think what you're speaking to is cost of goods, if you will, or gross margin, said another way. We reported gross margins of 74% in our third-quarter conference call of last week. And over time we expect those gross margins to modulate up appropriately as we continue to extract continuing manufacturing efficiencies, if you will, and the supply efficiencies.

**John Butler** - *Genzyme President, Genzyme Renal Division*

And on the sales and marketing infrastructure, Bone Care has about 100 people currently in the sales organization. What we're currently or about to begin is an assessment of what the optimal organization looks like as you integrate the over 100 people that Genzyme Renal has in place with Bone Care and get to the right number. So we don't know exactly where that will come out yet. But we do expect that the majority of the folks from Bone Care will be integrated into Genzyme Renal.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Next question.

**Operator**

Jessica Hanover, Robert Baird.

**Jessica Hanover** - *Robert W. Baird Analyst*

I guess along the lines of the previous question if you could comment on what Genzyme or how Genzyme intends to deal with the existing partnership that Bone Care has with Cardinal Health relative to the 0.5 microgram Hectorol oral. And also maybe if you could comment a little more on what your anticipated regulatory pathway for bringing Hectorol to Europe is, and if you could talk about the opportunity and the dynamics in that market.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Let me ask John Butler to answer those questions.

**John Butler** - *Genzyme President, Genzyme Renal Division*

To the first question, we have not yet (technical difficulty) the Cardinal relationship and how that will fit in going forward. So we will be doing that obviously as we look at the entire organization, and really put in place an organization that makes most sense for Renagel and Hectorol combined.

Second, in Europe what we plan to do is open up a dialogue as early as possible with the EMEA and understand from their perspective given the package that's been approved in the US what their expectations are for approval in Europe. And until we have that conversation it's difficult for me to speculate what it would take to be approved in Europe.

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**Henri A. Termeer** - *Genzyme Chairman and CEO* I think is fair to say, John, the assumption that we the conservative assumption that we re making is that we will do clinical trials in Europe as part of the process to get the product approved.

**John Butler** - *Genzyme President, Genzyme Renal Division*

That is part of the assumption that went into our evaluation, yes.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Next question.

**Operator**

Ian Somaiya, Thomas Weisel Partners.

**Ian Somaiya** - *Thomas Weisel Partners Analyst*

Thank you for taking my questions. I have two; the first for John. How much overlap do you see in a given patient in terms of the patient getting Renagel as well as Hectorol? And then I have a follow-up question to that.

**John Butler** - *Genzyme President, Genzyme Renal Division*

We certainly think that in the dialysis space where Renagel is indicated, we know about 95% of patients require a phosphate binder. We think it s something like 75% of patients or so who require vitamin D therapy for elevated PTH levels. We believe that with Renagel and Hectorol we have the superior products for treating both of those conditions, and that s how we will direct it.

**Ian Somaiya** - *Thomas Weisel Partners Analyst*

Does that provide an opportunity to at least co-package the drugs maybe in the CKD population given the oral formulation?

**John Butler** - *Genzyme President, Genzyme Renal Division*

Remember, we are just beginning trials for sevelamer carbonate, and that would be our CKD product for phosphate binding. So we do have some time before that's available. And we will have time to make any kind of assessment like that.

**Ian Somaiya** - *Thomas Weisel Partners Analyst*

Okay.

**Operator**

Phil Nadeau, SG Cowen.

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**Phil Nadeau** - *SG Cowen Analyst*

Thanks for taking my question, and congratulations on the transaction. I actually have two related questions. The first is it looks like on Bone Care's third-quarter call they reported about 100% revenue growth for Hectorol. I'm wondering, Henri, if you feel that that growth can be extended and how far out can that be extended? And the second related question is what is the patent life on the drug and how long do you expect to have exclusivity?

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Growing at the level of 100% is only possible in the early days of market introduction. That's really where this program is currently. It is in the early days of penetrating the market. This is a remarkable performance if you look at the competition in this case. And it is extremely gratifying, and very important to us to understand where it came from. And it comes across from an appreciation of what this product does and how it performs and the clinical picture.

In the end the market share at this moment, maybe that is published data that Paul can talk about. You can't grow at 100% all the time. But this product has a lot of legs left beyond end stage renal disease market in, as we said, the early CKD market, and of course internationally. So we would expect the product to continue to grow at very, very strong rates. As you know Genzyme Corporation measures its future generally with 20% yearly increments in terms of top line. It's very important for us to understand that we can do that; we can do that in a sustainable manner. And we measure everything we do in that regard, including this particular program. And they have satisfied us that we can grow this program for a very reasonable period of time over the next three, four, five years. There is a tremendous amount of space left.

And it is little known (ph) to be I am well satisfied that I truly understood the potential of these kinds of products, as also quite clearly understand the potential of these kinds of products in the CKD market like Renagel. That's a very, very exciting new space for us. And this gives us a step into that direction.

You had a second question as well on the patent life. Paul, would you like to comment on that?

**Paul Berns** - *Bone Care International President and CEO*

As you know, back in December Bone Care announced a notice of allowance from the patent office for a composition of matter patent that specifically speaks to claims in the patent as it relates to pharmaceutical compositions around stabilized hydroxy vitamin D2. That patent specifically speaks to claim purity levels and allowed impurities and residual solvents. That patent is expected to be issued in the June timeframe based on the PTO processing time and a confirmation we receive from them, and that will provide us a composition of matter patent through the year 2021.

**Operator**

Meg Malloy, Goldman Sachs.

**Meg Malloy** - *Goldman Sachs Analyst*

Could you elaborate a little bit more on two things, the average annual cost for treatment penetration and competition please, and I guess for the oral and the injectable form?

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**Henri A. Termeer** - *Genzyme Chairman and CEO*

I give this question to Paul.

**Paul Berns** - *Bone Care International President and CEO*

The pricing of the products at the end user is somewhat proprietary based on contracting activities. But on a general 60,000 foot level basis it ranges somewhere in the neighborhood of between 1200 and \$1500 a year for the injectable and the oral product. Of course that can fluctuate looking at amount of medication is required for the patient to manage their disease. So you will have a range, if you will.

And additionally speaking, one thing I would have everybody remember is that the dialysis market alone is expected when one looks at potential over the next five years based on the National Kidney Foundation statistics to more than double in patient life and size, fueled by various comorbid conditions - diabetes, hypertension, and so forth. And so one would expect that here again there will be a significant number of significant patient growth and opportunity and utilization of Hectorol and Renagel in that market as it continues to expand, and therefore I think tremendous commercial opportunities going forward in that capacity.

Your second question I believe was

**Meg Malloy** - *Goldman Sachs Analyst*

I just wanted to get an understanding of penetration for the dialysis and predialysis, and also who is a competition in each market.

**Paul Berns** - *Bone Care International President and CEO*

In the dialysis sector, as I spoke to earlier, Abbott had been the primary supplier of the hormone therapies in the US market space for years. Their first entry was Pelsatril (ph), which has since gone generic. It's a D3 vitamin replacement, vitamin D hormone replacement therapy. The second product they introduced in 1998 is called Zemplan. It's a D2 analog active agent. As you know, Hectorol came into the market in April of 2000.

The net-net is from a market penetration perspective we exited the third quarter the fiscal year '05 with results that we announced last week with just over a 20 share. We've grown our injectable market share to just over a 20 share of the vitamin D hormone treated dialysis patient, which is substantial growth. And we continue to see substantial growth quarter-over-quarter.

On the oral marketplace, here again generic Pelsatril (ph) has been available and indicated for predialysis for years. It hasn't been the most user-friendly product because of complications and adverse events and high rates of hypercalcemia at required doses. Hectorol as a novel pro-hormone D2 analog for predialysis clearly represents a very important advent and new opportunity and tool for physicians to treat the disease. And it here where we're building and have been phasing in launch activities. As Henri spoke to, we are very early in the growth phase of these products,

and particularly in predialysis with the launch just happening early last August. And there we are in the mid single digit market share of the D hormone treated lives there as well and continue to grow. Those population of patient is substantially larger as an overall population to be treated just based in epidemiologic data. And here again we expect concurrent growth in that population between now and the year 2010 going forward.

**Operator**

(OPERATOR INSTRUCTIONS) Mark Augustine, CSFB.

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**Mark Augustine** - *CSFB Analyst*

Thanks. I wanted to ask you may have gotten to this actually in the earlier questions if you have estimate for the actual number of US locations, how many of them are on Renagel and what do we know about Renagel dose in those patients?

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Between John and Paul, can you clarify that an answer to this question?

**John Butler** - *Genzyme President, Genzyme Renal Division*

It's impossible to say how many Hectorol patients are on Renagel at this point. We don't know how many are. What we do know is in every study of Renagel that we've done, every clinical trial that we've done, we've seen vitamin D doses increase by about 30% as you're not without adding calcium not get the PTH effect there, and vitamin D is able to be dosed more efficiently. So based on that data my expectation would be that in Renagel patients the doses of Hectorol are potentially higher. But it's impossible to say how many Hectorol patients are on Renagel. Paul, do you have any other?

**Paul Berns** - *Bone Care International President and CEO*

No, I agree with John. It's difficult to triangulate on those numbers.

**Operator**

Yaron Werber, Smith Barney.

**Yaron Werber** - *Smith Barney Analyst*

Congratulations. I wanted to ask two quick questions, number one maybe just referring to Bone Care's last quarter. The gross margins were actually down (indiscernible) quarter-over-quarter or two quarters ago relating to some price competition, and I wanted to know whether you think that's stabilized going forward. You have mentioned previously expecting it's going to be around 74% or so and improving. I just wanted to understand what gave you that confidence that the pricing is going to stabilize. And then two, just what are you seeing so far (indiscernible) competition?

**Paul Berns** - *Bone Care International President and CEO*

I'll address that, Henri. As I have stated on last week's conference call, and Jim Caruso, our Head of Commercial Operations, I believe went through that data for the gross margins, those are reflected as many injectable manufacturers dealt with the CMS policy that came into effect in January. We had a modest movement in our minor movement in our gross margin. We believe that for all essential purposes that that will stabilize given the environment that we're in from a commercial business to business contracting perspective. And that over time, frankly, as we continue to build volume in the marketplace and here again reap the benefits of additional commercial activities and supply activities that go along with that from our perspective our margins continue to grow. And there's proprietary pricing and contracting activities that we have strategized around that give us additional confidence that we will see those margins modulate up over time appropriately.

And your second question again? Sensipar. We really don't view Sensipar as a competitor. Frankly, it's clear that they've been a year into the market now past the honeymoon phase. And I would suggest to all of us, given the clinical evidence that even

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their own Phase III pivotal studies clearly showed that Sensipar is used in combination with the gold standard of D hormone therapy and oral phosphate binder therapy.

If anything my contention is from a Bone Care perspective that our friends at Amgen have done a very important service in helping to further build the share of voice and the call to action to identify and manage dialysis patients that deal with secondary hyperparathyroidism, and that the polypharmacy approach of D hormone therapies, oral phosphate binders such as a Renagel as the class leader in calcium-based calcium-free phosphate binders. And certainly their position as using Sensipar in polypharmacy as add-on therapy makes sense. That clearly is borne out with the IMS prescription tracking data that would support that. Here again the clinical literature that supports that patients need to be treated for the underlying pathophysiology, which is the D hormone deficiency and the phosphorus imbalance.

### **Operator**

Mark Schoenebaum, Bear Stearns.

### **Mark Schoenebaum - Bear Stearns Analyst**

Thanks so much for taking my question, and I'd like to add congratulations. Sounds like it makes a lot of sense. My question is thinking back to Renagel days from years past, can you talk to us about what is in the wholesaler channel right now for Hectorol, especially oral? What is a normal level? Where we are right now? How can we think about that? Is IMS data accurate?

And then also, someone else asked what the oral price was. I thank you gave us the injectable price, but not the oral price per year.

### **Paul Berns - Bone Care International President and CEO**

Let me answer the latter first. The oral price is roughly in the same price range on a per treatment per year. Here again it fluctuates based on dose, so you have to allow for a range in actual price realized.

As it relates to pipeline wholesaler pipelines and so forth, as you know the standard in the industry that we have spoken to many times in our calls is one month of inventory is approximately six weeks, which is reasonable for the CKD products and the injectables and the oral products in particular for us. We have always been slightly below those levels or within operating at that range, never above from that in the context in how we manage our business. So the results that we report on a quarter-over-quarter basis are highly and tightly demand driven, and we are very proud of that activity. So from a Bone Care management perspective of its business, that's been consistent history for us in how we supply the wholesalers, supply the clinician and the retail pharmacies that need the product. The IMS data that you look at on the injectable is going to be spotty at best because as you know IMS does not track injectable data very well at all.

**Operator**

Alexandra Lee (ph), Sustainable Growth.

**Alexandra Lee** - *Sustainable Growth Analyst*

Could you go over the patent on Hectorol please?

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**Paul Berns** - *Bone Care International* President and CEO

Sure. We're going to get a patent that claims stabilized hydroxy vitamin D2. There are a number of claims in the patent application including groups that relate to pharmaceutical compositions including such stabilized hydroxy D2.

The stabilized hydroxy vitamin D2 product for which the USPTO has given that the patent will be granted (technical difficulty) by a profile of claimed purity level and allowed impurities of residual solvents. What this means is that Bone Care is the only Company that can put a product on the market that meets the profile of claimed purity level and allowed impurity of residual solvents with the improved stability of the product that the profile brings. This is particularly important as Hectorol is covered by this new composition of matter patent.

**Operator**

Louis Sarks (ph), Chesapeake Partners.

**Louis Sarks** - *Chesapeake Partners* Analyst

I have a couple of questions. One, can you give us the background of the transaction? What brought you all together?

**Henri A. Termeer** - *Genzyme* Chairman and CEO

As you know, Genzyme continues to look very carefully at its environment and its opportunity (technical difficulty) that includes the outside world. And this was obviously something that we were following for quite awhile. There is not that many programs in the dialysis field. So we were very aware of the Hectorol program, and we were looking at it very carefully over now three, four, five years as far as I remember. And this was a particularly good time for us. The product really got confirmed very strongly. And we sought each other out, and started to discuss things, and eventually came to an agreement. It's a very, very actually very natural way because it was such a natural strategic fit between these two programs.

And you had a few other questions, you said. Hello?

**Operator**

Ian Somaiya, Thomas Weisel Partners.

**Ian Somaiya** - *Thomas Weisel Partners* Analyst

One question I had was on the manufacturing. What's the potential to transfer the manufacturing of Hectorol to one of the Genzyme facilities, and what kind of margins could you potentially achieve?

**Henri A. Termeer** - *Genzyme Chairman and CEO*

It's always intriguing. As you know, we produce 99% of the products that we market ourselves. In the case of Renagel, over the first three or four years of the program we spend a significant investment to bring it in-house, and it was extremely beneficial, as you may recall.

We will look at this. It was not our first priority. What we did look at is that our manufacturing's stable manufacturing condition here, and we assured ourselves that there was. But at the natural way of Genzyme looking at all aspects of programs, including manufacturing, we also look at this one. But we haven't come to any particular conclusions.

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**Operator**

Louis Sarks, Chesapeake Partners.

**Louis Sarks** - *Chesapeake Partners Analyst*

I was just wondering if there were any tests or sales levels or things like that that Bone Care needs to any hurdles they need to make (indiscernible) the transactions.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

We would expect that Bone Care continues to be as successful as they have shown themselves to be; stay very focused on the task of bringing the products to the market, and that there are no tests included in the transaction.

**Operator**

There are no further questions. Sir, I will turn the call back over to you.

**Henri A. Termeer** - *Genzyme Chairman and CEO*

Thank you very much everybody participating this morning. This is obviously a very, very exciting transaction for both companies. It is always tremendous when you have this kind of a fit in a transaction tremendous synergy, tremendous future, and early days in the possibilities for this product.

We look forward to updating you as the transaction progresses to closure in about 60 days, as our Chief Financial Officer, Mike Wyzga, was explaining. And we will update you next time around, which I believe to be at our earnings call analyst day.

Let me tell you something about analyst day. We are oversubscribed, unfortunately. So we don't want to attract more people to come there, but it is webcast and we invite everybody to listen in. It's a very interesting program. This obviously will play a role in the overall program, but many other aspects of the Company will be explained as well.

So again, thank you very much. Any further questions, please contact us directly through the investor relations group or through (indiscernible) directly. Thanks a lot.

**Operator**

That concludes today's Genzyme Corporation and Bone Care International conference call. We thank everyone for your participation and wish you a great day.

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