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Event Transcript

AMGN - Q3 2003 Amgen Earnings Conference Call

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OVERVIEW

In 3Q03, AMGN's business continued to demonstrate strong performance both domestically and internationally in the key therapeutic areas of oncology, inflammation, and nephrology. Adjusted 3Q03 EPS was \$0.53 per share. Co. has revised its revenue guidance to a range of \$8.1-8.4b from \$8.0-8.5b. Q&A Focus: Aranesp, NEUPOGEN/Neulasta conversion, and ABX-EGF program.

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FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

CORPORATE

Cary Rosansky
Amgen Inc - Director of Investor Relations

Kevin Sharer
Amgen Inc - Chairman and CEO

Richard Nanula
Amgen Inc - EVP, Finance Strategy and Communications and CFO

George Morrow
Amgen Inc - EVP, Global Commercial Operations

Roger Perlmutter
Amgen Inc - EVP, Research and Development

Beth Seidenberg
Amgen Inc - SVP, Clinical Development

PRESENTATION

Operator

Good afternoon ladies and gentleman. My name is Paul and I'll be your conference facilitator today. At this time I would like to welcome everyone to Amgen's Third Quarter Earnings Conference Call.

[operator instructions]

Thank you, Ladies and gentlemen, I would now like to introduce Cary Rosansky Senior Director of Investor Relations Mr. Rosansky. You may begin.

Cary Rosansky - Amgen Inc - Director of Investor Relations

Thank you, Paul. Good afternoon and welcome, everybody. Before we start, I need to make cautionary statement. When we estimate revenues, operating margins, capital expenditure, cash and other financial metrics and discuss legal, arbitration, political and regulatory or clinical results such, estimates and results are forward-looking statements and of course, no assurance can be given that the estimates will be accurate and actual results could vary materially.

On this call, we may discuss GAAP and non-GAAP financial measures. In accordance with SEC regulation G, you can find a reconciliation of the measures on our Web site at www.amgen.com and that's within the investor section of the Web site. Please refer to Amgen's most recent form 10K and 10Q reports for additional information on the uncertainties and risk factors related to our business.

If you have not received our press release call Denise Barrill at 805-447-3433 and she'll resend it. If you have further questions after this conference call, please contact my office at 805-447-4634. This conference call is being Webcast via the Amgen home page and it will be archived for 72 hours following the call.

I would like to introduce Kevin Sharer, Amgen's Chairman and Chief Executive Officer.

Kevin Sharer - Amgen Inc - Chairman and CEO

Thanks, Cary. Good afternoon. With me today are Richard Nanula Executive Vice President Finance Strategy and Communications and Chief Financial Officer, George Morrow, Executive Vice President and Global Commercial Operations,

CONFERENCE CALL PARTICIPANTS

Robert Goldman
Budingham Research - Analyst

Eric Schmitt
S.G. Cowan - Analyst

Mark Schoenebaum
Piper Jaffray - Analyst

May Kin Ho
Goldman Sachs - Analyst

Craig Parker
Lehman Brothers - Analyst

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Roger Perlmutter, Executive Vice President, Development and Beth Sdenberg, Senior Vice President of Clinical Development.

In the third quarter, our business continued to demonstrate strong performance both domestically and internationally in our key therapeutic areas oncology, inflammation and nephrology. In addition to the commercial progress, we continue to invest in Research and Development to maximize our opportunities for long-term growth through a combination of both internal discovery and outreach efforts. Amgen's management team is focused on insuring that we have sufficient pipeline productivity to provide sales and earnings growth for many years to come.

The pipeline has increased in scope, scale and capabilities we have accelerated the introduction of new molecules into the development. We now have almost 40 development programs. We are planning Amgen's first ever pipeline review in the first quarter of next year to provide further insight into the R&D progress we have made, additional details will be announced as we get closer to the date. We have also expanded our efforts to insure that Amgen is the partner of choice for acquisition and licensing opportunities.

The entire senior management team has actively participated in three outreach days and key biopharmaceutical markets in the U.S. in the past three months. These outreach days provide an opportunity to present Amgen's capabilities and interests to Senior Biopharmaceutical Executives to see how Amgen can maximize their efforts. We have planned additional days in San Francisco and Europe this year.

Earlier this month we announced a licensing agreement with a private Swedish company the rights to develop and commercialize a novel small molecule for the treatment of type two diabetes and certain other metabolic disorders. This agreement is our effort to build a pipeline base on novel therapeutics in global market. Roger will provide enhanced details on the Research and Development progress we have made in the past quarter. Commercially, Amgen continues to do well by penetrating the oncology and nephrology markets.

Neupogen and Xeloda (ph) that combined have economic value in protective and cycling use of growth factors in appropriate risk assessment for patients threatened by neutropenic complications. Enrel will continue to expand its already broad use of the series of regulatory approvals. In addition, our renalology and dermatology sales forces, each has new label claims to demonstrate Enrel's value to rheumatologists and sorry

ya Research this patients George will provide more detail on the commercial pie lesson, the market dynamics release products.

I would like to congratulate our cynic counsel (ph) team for all their hard work worth the time the NBA filing food and drug administration. If approved, cynic counsel will represent Amgen's first small molecule, this marvel therapy treatment may help chronic kidney disease patients with secondary hypothyroidism who are at risk of significant bone disease and cardiovascular complications.

Now let's begin off Richard and I will review the financial performance for the quarter. Richard.

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

Thanks Kevin, before I begin I want to mention that our comparisons with the Q3 2002 reports reflect the fact that we acquired Emrel on July 15th of 2002 and here it's been oncology, the same month. The comparison year over year is starting to reflect the more comparable picture than the last few quarters. I'm pleased to report that adjusted earnings per share for the third quarter were 53 cents per share, an increase of 56% over adjusted earnings per share for the same period a year ago.

Adjusted earnings per share in adjusted northwest income for the third quarter exclude certain expenses related to the acquisition of Immunex and a one-time expense of \$47 million related to the legal settlement associated with the company's lawsuit with Jen Nentech regarding our process for producing Neupogen and Neulasta.

Total product sales were \$2.1 billion, an increase of 54% over the third quarter last year. U.S. product sales were approximately \$1.8 billion, an increase of 47% versus a third quarter of last year, and accounted for 86% of total product sales. International sales were \$300 million, up 117% versus the same quarter last year. Without the benefit of --beneficial foreign exchange this quarter, international sales would have grown 91%. Combined ep general and worldwide Aranesp sales for the third quarter were \$1.1 billion, an increase of 58% versus the same quarter last year. This increase was primarily driven by strong world wide Aranesp demand.

Ep general sales were \$626 million for the third quarter, an increase of 12% versus the same quarter last year president. The third quarter year over year growth is principally due to favorable revised estimates of dialysis demands were spillover for prior

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2

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

quarters as a result of our contractual relationship with Johnson & Johnson. Once again, please refer to our form 10-K for a more detailed discussion of this relationship and its impact on the our reported even general sales and inscription is spill over. Even Jen demand in the third quarter grew in the mid single digit range compared to the prior year. With the full year, we continue to expect good dialysis patient growth in the 4% to 5% range will principally drive even Jen sales

Worldwide Aranesp sales in the third quarter were \$438 million, versus \$114 million in the third quarter last year. This growth was driven by demand worldwide, reflecting the mid year, 2002 approval of Aranesp in the United States for the treatment of chemotherapy induced anemia and the strong acceptance of Aranesp in Europe. Third quarter USA Aranesp sales were \$284 million versus \$77 million last year, and international sales were up \$54 million versus \$37 million versus last year. International Aranesp sales were aided by a \$19 million due to the weaker U.S. dollar.

As a result of our strong first three quarters, we are raising our estimate for combined Aranesp and even Jen sales and expect sales to range between \$3 and 4 billion for 2003 versus the previous estimate of between \$3.7 and \$3.9 billion. Combined worldwide Neupogen and Neulasta sales for the third quarter were \$657 million, an increase of 39% versus the same quarter of the prior year. U.S. Neulasta sales were \$304 million in the third quarter versus \$142 million for the third quarter last year. Neulasta has been available in certain European countries for a short period, and international sales in the third quarter were \$23 million. Worldwide Neupogen sales in the third quarter were \$330 million, a slight decline versus the third quarter the prior year, reflecting U.S. conversion to Neulasta offset by Neupogen sales growth in international markets

On a geographic basis, third quarter Neupogen sales were \$228 million in the U.S. versus \$241 last year, and international were \$103 million versus \$91 million last year. The growth in international Neupogen sales was driven by currency exchange rates. As we pointed out in the second quarter conference call, Neupogen conversion to Neulasta has slowed in the U.S. George will cover the additional growth opportunities for the franchise.

We continue to believe combined Neupogen Neulasta sales will be in the range of \$2.4 to \$2.6 billion for 2003. Embrel sales were \$342 million in the third quarter, a 116% increase over the third quarter of 2002 sales reported by Amgen of \$158 million. Prior year sales were impacted by supply shortages of embrel and to a lesser extent reflect two weeks fewer sales as a result of the immune acquisition close date of July 15 last year.

Sales for the current year were driven by demand, fueled by new patients in both rheumatology and dermatology. For 2003, we continue to expect embrel sales to be in the range of \$1.2 and \$1.4 billion. With three quarters of the year now complete, we feel we are in a position to more closely predict 2003 product sales. As a result, we are narrowing the range of our 2003 worldwide product sales guidance, to between \$7.6 and \$7.9 billion versus the previous range of \$7.5 to 8 billion. Total revenue guidance is also revised to a range of \$8.1 billion, and \$8.4 billion versus the previous range of between \$8 and \$8.5 billion.

Turning to some expense items, which I'll also discuss on an adjusted basis for both periods. Cost of sales increased to \$336 million in the third quarter of 2003, from \$201 million in the comparable quarter of 2002, primarily due to increased sales. Cost of sales as a percentage of sales increased from 14.9% in the third quarter of 2002 to 16.1% in the third quarter of 2003, reflecting a greater portion of embrel, which has higher manufacturing costs and royalties in the product sales mix. R&D expenses for the third quarter were \$400 million, versus \$304 million in the third quarter of 2002. This increase was primarily due to additional R&D head count, increased clinical trial and clinical manufacturing activity as well as higher licensing and milestone fees associated with collaborations.

SG&A for the third quarter were \$479 million compared to \$377 million in the third quarter of 2002. This increase was primarily due to support of embrel, the wide profit share and a higher staff related expense to support new products and competitive markets. The fourth quarter's historically is the lowest margin quarter of the year and this year will be no different. The fourth quarter's traditionally the highest spending quarter due to normal seasonal spending patterns which occur as spending on discretionary programs are held until the latter part of the year as planned sales targets are met. Additional promotional activities concentrated in the fourth quarter are associated with major medical conferences, including ECR, and ash.

This year in the fourth quarter, an additional \$86.5 million up front payment associated with the licensing of betrum will be expensed in R&D impacting both adjusted and GAAP earnings. As a result we are revising adjusted operating expense guidance for 2003 to a range of \$4.7 to 4.9 billion from the previous range of between \$4.6 and 4.8 billion. We continue to expect adjusted EPS to be in the range of \$1.85 to \$1.95 per share for 2003.

On a GAAP basis, EPS was 46 cents per share in the third quarter of 2003. We believe that adjusted earnings provide useful

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3

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FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

supplementary information to investors. We do recognize the importance of earnings computed in accordance with GAAP and as we do every quarter, we provide a full reconciliation of GAAP versus adjusted EPS in the press release issued today and it's also posted on our web site.

In the third quarter, we repurchased approximately 5 million shares spending \$323 million to do so. Through nine months, we have repurchased approximately 20 million shares at a cost of \$1.2 billion. Third quarter capital expenditures were \$388 million versus \$209 million in the third quarter last year. This increase was principally related to the Puerto Rican manufacturing expansion, the building of our Seattle research center and the continued construction of the new Rhode Island manufacturing plant. Our cash in marketable securities were \$5 billion at the end of the third quarter. We'll provide financial guidance for 2004 on a conference call in December, and additional details will be provided as we get closer to that date.

Unidentified

Thanks, Richard. Now George will provide a marketing update for the quarter. George.

George Morrow - Amgen Inc - EVP, Global Commercial Operations

Thanks, Kevin. I'll start with the earnest nephrology performance in the U.S. We continue to gain share in CKD or predialysis market due to the longer dosing interval. Increasingly, however, our focus is on expanding this market where less than 20% of anemic CKD patients receive an agent. Our anemia counts campaign, for example, highlights the clinical significance of anemia and its importance of risk factor, relative to well known factors such as hypertension, diabetes and lipid epidemia.

Next is earnest oncology in the U.S., here we continue to gain market share and are encouraged that many of the nation's largest and most prestigious cancer centers have selected Aranesp as the preferred agent and are doing so every week. Introduction in the third quarter of the prefilled syringe for Aranesp has provided another area for it in this market. We are not yet satisfied with the market share in oncology, we have focused more resources on raising awareness among our customers than only 40% of chemo induced anemia patients currently receive an orthopaedic agent.

Next is Aranesp EU. Aranesp continues to gain share in all European markets powered by the Oncology indication. IMS

that revealed that the earnest oncology launch in Europe has been the most successful launch in this market during the last ten years. Turning to even Jen, again this is U.S. only, the core of Jen business remains strong driven primarily by patient growth. We continue to work with our customer, signing anemia management goals for the best outcomes for patients. Next is Neupogen and Neulasta. Neupogen and Neulasta continue to perform well in the chemotherapy induced neutropenia market.

By the end of 2003, we will more than have doubled our franchise sales from 2001 to over \$2 billion in the U.S. given the rapid conversion of Neupogen to Neulasta and the tougher baseline comparisons level franchise revenue growth will eventually slow in the U.S. going forward. Significant market growth opportunities still exist as evidenced by the fact that only about a third of the patients at risk for neutropenia (ph) receive Neupogen or Neulasta as first cycle therapy. In Europe, we have now launched Neulasta in all countries except Portugal, Belgium and Italy and sales are on track.

Turning to emBro in North America. While the 8% year over year growth benefited last year, we view the 12% sequential growth for the quarter as a solid trend. EmBrel is once again the leading team of inhibitors in terms of numbers in sort of virus. The outstanding results of the tempo of study such as reinforce the profile. Just as a reminder of the tempo study involved emBro in combination with methotrexate with RA's Roger will have a few words to say about that and this will be highlighted at ACR. During the third quarter by label was expanded to include improved physical function, inhibition of progression of structural damage and so (inaudible) riders and most recently approved for once weekly dosing in all patients. Down the road, of course, is the opportunity to serve psoriasis patients.

Along these lines we have had an exceptional response to the psoriasis connection educational DTC campaign, which you may have seen on TV. This will help us know who to target at launch. Finally, I wanted to conclude with a brief word about the preparations for the cynical set launch. We believe it provides anovel and effective way to treat secondary (inaudible) perithyroidism. Our primary challenge commercially will be to facilitate reimbursement and coverage for a broader group of patients.

Kevin Sharer - Amgen Inc - Chairman and CEO

Now, I will provide R&D update for the quarter.

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4

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

George Morrow - Amgen Inc- EVP, Global Commercial Operations

Thanks, Kevin. Let me highlight key events that occurred in the third quarter in development and regulatory affairs. As Kevin mentioned we submitted a new drug application with the FDA, seeking approval of cynical set with the treatment of primary and secondary hypothyroidism. This is the company's first small molecule therapeutic and represents an important novel for Amgen. We are proud of the data for the filing. Much of which will be presented at American society of nephrology being held in San Diego in November and we are hopeful that the agency will review our application on a priority basis. I'm also pleased to announce that we have filed for approval of cynical set in Europe as well. On the regulatory front, we just announced approval of the once weekly dosing regimen for embrel, which George mentioned.

This offers enhanced screens for patients with rheumatologic disease that can benefit from the every efficacy of the therapy. The meeting this weekend will provide a forum for review of important new data with the use of embrel with methotrexate as therapy with early rheumatoid arthritis. In this study, 80% of patients treated with the combination therapy, experienced no radiographic progression in one year compared with 68% of patients treated with embrel alone and 67% of patients treated with methotrexate alone. This is the hope that the joint destruction with beloved prayed provided that appropriate embrel based therapy is administered. Amgen is also approved for treatment of ankylosing spondylitis.

And as a means of improving physical function in patients with RA in all, 80 abstracts including 21 presentations in for the will be presented at the exhibitors including their lead compound which is now in phase two trials for the treatment of type II diabetes and related metabolic disorders. We gained access to a phase 2, III 15 inhibitor program through a licensing agreement with Jen med. These new programs add additional strength to our whole letting variable robust pipeline. Indeed, in the third quarter we introduced three molecules into human trials and also began clinical studies of AMG 162, which is a potential treatment for both metastatic bone disease and post menopausal osteoporosis in Japan.

As Kevin indicated, we have almost 40 active development programs today. Included in the group are molecules that promise improved oncology supportive care, targeted therapy of malignancy, better pain control, improved management of inflammatory disease, immolation of at least some degenerative

diseases, control of bone turnover and improved management of metabolic disturbances. We will review the pipeline in greater detail at a research and development conference, which we plan to hold in the first quarter of next year.

George Morrow - Amgen Inc- EVP, Global Commercial Operations

Thanks, Roger. Now we'll take your questions.

QUESTIONS AND ANSWERS

Operator

[operator instructions]

Your first response is from Robert Goldman with Buckingham Research.

Robert Goldman - Buckingham Research - Analyst

Thank you. I'm cynical set, a couple of things. First, I'm just curious if you have asked the FDA specifically for a previous dialysis indication. Second, you mentioned about reimbursement. As an oral, do you hold any hope that in fact, Medicare will reimburse the drug? And finally, could you give us some help on how we might quantify the dollar market size. Thank you.

Kevin Sharer - Amgen Inc- Chairman and CEO

First of all, with respect to our filing for the agency, the filing is for secondary hyperparathyroidism, which is of course in association with renal disease and additionally update and primary and hyperparathyroidism. That's what the filing is directed towards. It includes data primarily from the dialysis community. But it's secondary thyroidism associated with renal disease.

Roger Perlmutter - Amgen Inc- EVP, Research and Development

Regarding Medicare reimbursement, there will be no reimbursement at launch. But part D Medicare, which is part of the Medicare reform, obviously, will provide a benefit here that I think will really help us drive this product. We don't quantify market sizes for people.

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

Robert Goldman - Buckingham Research - Analyst

OK. Thank you.

Operator

Your next question is from Eric Schmitt with SG. Cowan.

Eric Schmitt - S.G. Cowan - Analyst

Good afternoon. Congrats on a nice earnings period. Let me ask the two obvious questions both concerning roach and what your thoughts are first on the Sra product and the its potential to compete with you in the U.S. And second, on the study coming out of Lancet last week on -what you are pleading and conjunction with head and neck radio therapy.

Kevin Sharer - Amgen Inc - Chairman and CEO

We have known about the roach product as most of you have for along time. We take roach seriously. They're a smart company, tough competitors. Obviously, we're not going to comment on our strategy, but we're confident in our patents. We'll defend them vigorously. We have historically, we will again, and I think that the -retro-play the franchise around the world is so large, fast-growing and valuable, that we will see essentially for ever one assault on the franchise or another from some place, and this is the latest. As we wrap up TKT, we'll get ready for these guys if that's what it takes. All of that Roger -- I'll let Roger or Beth comment on the Lancet article on roach's product.

Beth Seidenberg - Amgen Inc - SVP, Clinical Development

Yes. Let me just say a few words about the study that was published in Lancet. I don't intend to go through a detailed critique of the study. There will be many, many, many publications, I suspect going forward.

First of all, it's important to note that there is a very strong pre-Lynn Cal rationale for believing that survival might actually be improved or that cancer therapy would be more effective if anemia were treated. This relates to the fundamental problem of anoxic or hypoxic tissue being less sensitive to additive therapy. A variety of clinical studies have demonstrated this over the years. In addition there's a lot of clinical data that supports the view that treatment with an imPoe tin to improve anemia will actually result in a benefit. First of all, there's overwhelming data associated with the quality of life.

I think everyone agrees that quality of life is improved when the anemia that is typically encountered in the context of therapy for cancer is treated. But secondly, there is also clinical data which was cited by the Hanks article published in Lancet last week, supporting the view there is at least a trend and in some cases a significant improvement in survival in studies of imPoe tin that have been provided in the context of chemotherapy or chemotherapy, radio therapy.

In this study, it's important to emphasize what actually was found. That is, if you look in particular at the study at those individuals who are treated per protocol, with correct radio therapy, there is no difference in terms of survival, with respect to those who received the poe tin beta in this case and those who did not.

There are other differences in terms of eligibility criteria. There were patient mix imbalances and there were a variety of other trial related difficulties and interpreting the study. It's difficult to look at the study particularly in the face of all the prior evidence and conclude anything substantive. Indeed, the authors of the study were very careful to note that the potential limitations of their analysis. So, I think far from being a fire drill based on publication here, we should put it in its appropriate context and say, you know, we really don't know whether treatment of patients with malignancy with an (inaudible) in improve survival.

The weight of evidence, I think is that there's a potential for benefit, and it is also possible that under some circumstances that one won't see that benefit, but we certainly cannot conclude anything on the basis of the single trial.

Eric Schmitt - S.G. Cowan - Analyst

And as a follow-up, could you comment on what percent of Aranesp bus might be in radiation therapy only treatment setting?

George Morrow - Amgen Inc - EVP, Global Commercial Operations

As far as we know, none indication that we have. It's not a market that we have really looked at.

Eric Schmitt - S.G. Cowan - Analyst

Thanks

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

Operator

Your next question is from Mark Schoenebaum with Piper Jaffray.

Mark Schoenebaum - Piper Jaffray - Analyst

Hello, guys. Congratulations before I ask my question to follow up, I'd like to congratulate my former boss, Matt Geller on his recent marital engagement. I'd think everyone would be happy to hear that. I found the previous question about cynical set in the predialysis a little vague. Will you or will you not apply for a label that includes the predialysis for example the way the indication section read on the Aranesp label. The follow-up question, could you comment on the timing of the Aranesp versus prokred head to head study that is being done out of UCLA.

George Morrow - Amgen Inc - EVP, Global Commercial Operations

So, just to be clear on the issue of cynical set the label is, of course, for the treatment of secondary hyperparathyroidism in association with renal disease. There are data in the label for patients with end stage renal disease and patients with chronic renal insufficiency. At the end of the day, what the agency decides in terms of the indication is going to be part of a negotiation process. I cannot tell what the label will look like exactly. I'm sorry, the question with respect to Dr. Glasby (ph) and the ongoing study.

Mark Schoenebaum - Piper Jaffray - Analyst

Yeah, could you comment on the timing of how that trial is progressing and when you may actually see data?

George Morrow You know, we are not providing updates on a quarterly basis on these trials. As data becomes available, we try to make everybody aware of them and make sure that everyone understands where we are. We are not prepared to provide an update on that.

Mark Schoenebaum - Piper Jaffray - Analyst

Should we be expecting data at Ashe. Is that something that could you answer for us?

George Morrow - Amgen Inc - EVP, Global Commercial Operations

Yes, we are just not going to provide an update on that.

Mark Schoenebaum - Piper Jaffray - Analyst

OK. Thanks very much.

Operator

Your next question is from May Kin Ho with Goldman Sachs.

May Kin Ho - Goldman Sachs - Analyst

Hello, can you comment on a little bit about what's happening in Washington? I know there has been a lot of negotiation on the AWE forum and other things there. And then also, Roger, maybe you can comment about the video vitrum molecule, because I understand that's a very attractive pathway. Can you tell us why you are excited about it?

George Morrow - Amgen Inc - EVP, Global Commercial Operations

The situation in Washington may be fluid. There are activities in a variety of forums, executive and legislative. You probably know by reading the press about as much as we do. In the legislative area, it's a pretty open process and there's a variety of things in play. We suspect that the bill will pass. We hope it will. It's far from sure. If it does, I think that's going to be good for the country, and AWP reform of one kind or another will probably happen as part of it. We favor what's in the senate version and hope that will happen.

With respect to the executive branch, CMS is considering the rule, this year's rule regarding the hospital outpatient sector with respect to (inaudible). And Procrit. We have had very complete, lengthy, intense, dense discussions with them over the year. The past year on this subject. We're confident it was a good dialogue, but we just don't as a matter of course predict what the government is going to do on any specific issue, but we did have a good dialogue. I'll let Roger comment on the beta molecule and our interest.

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

Roger Perlmutter - Amgen - EVP, Research and Development

May Kin, it is indeed an extremely interesting pathway. During the last several years, information has accumulated from a number of academic researchers indicating that the conversion of inactive steroid hormones, glucocorticoids (ph) to active hormones occurs in the peripheral tissue to an extensive extent. That's mediated by enzyme 11 beta HSD 1. Innovation of a 11 beta HSD 1 It is expected to be associated with a decrease in the peripheral exposure to active glucocorticoid and enhanced insulin sensitivity and also a variety of beneficial effects on other metabolic parameters. Those kind of observations have been demonstrated preclinically in rodent models. We simply don't know whether or not the same thing will be observed in humans. Based on our analysis of the information that beta Vee trum had accumulated to that point, and keep in mind they had the opportunity to study significant number of people exposed to their lead molecule, we believe there's a real opportunity here to have a beneficial effect both in type 2 diabetes and also in the metabolic syndromes that are associated with insulin resistance.

May Kin Ho - Goldman Sachs - Analyst

Hello?

Roger Perlmutter - Amgen Inc - EVP, Research and Development

We can hear you.

May Kin Ho - Goldman Sachs - Analyst

Certainly as skill has indicated they don't think that CMS has the authority to do the changes. And do you think that the CMS will actually issue the rules at the beginning of November?

Roger Perlmutter - Amgen Inc - EVP, Research and Development

The rules for what, May Kin?

May Kin Ho - Goldman Sachs - Analyst

History of To go basically change the AWP system?

Roger Perlmutter - Amgen Inc - EVP, Research and Development

I don't -- I don't have a point of view. I will say CMS is an agency with broad authority, and they're rewriting the check, and

they have shown a willingness in the past to be aggressive. So who knows

May Kin Ho - Goldman Sachs - Analyst

Thank you.

Operator

Your next question is from Craig Parker with Lehman Brothers

Craig Parker - Lehman Brothers - Analyst

Good afternoon. I wonder if George, you could first comment on the contribution to U.S. Aeronaut sales from the oncology market versus CKD?

George Morrow - Amgen Inc - EVP, Global Commercial Operations

We don't give specific numbers in fact, I don't have one in my mind. The vast majority of sales are from the oncology market.

Craig Parker - Lehman Brothers - Analyst

Okay. And second question is on the bio-- the court sole inhibitor. That's really a strategic question for Kevin, which is is that an area where you would contemplate building a very large sales force, if you had a-- an active molecule in type two diabetes. Let me try to answer the question within the question. Our strategy is to seek molecule molecules that will treat grievous illness that will make a dramatic difference to patients that will be commercially successful and we will do what it takes to bring those kind of molecules to market. If in fact we have molecules that have those characteristics that require a large sales force to bring them to market, we'll do it. That obviously would need to be contained within an economic analysis that said it was worth it, but if you wanted to hallucinate a little bit, and imagine that this molecule was a great big success, which at this early stage would be a hallucination phase, early phase molecule, the investment would sure be worth it. We're going to invest against the molecule's characteristics and go where those take us. Now, you know, I'm not saying that we wouldn't consider another molecule, partnering with somebody in distribution, but we're going to do what it takes for the molecule to be successful.

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

Craig Parker - Lehman Brothers - Analyst

OK. Great. Appreciate your candor on that.

Operator

Your next question is from Jennifer Chao with RBC Capital Markets

Jennifer Chao - RBC Capital Markets - Analyst

Thanks for taking the question, just a couple here. First on Neupogen Neulasta. You can maybe give us a sense of what portion of Neulasta during the quarter was due to Neupogen conversion, and whether we're seeing inventories being maintained at normal levels or if we're seeing any disequilibrium there. The second is if you could just give us an update on the Puerto Rico manufacturing expansion and if we're seeing progress ahead of schedule and when we should expect to see material tax benefits there.

George Morrow - Amgen Inc - EVP, Global Commercial Operations

Richard, why don't you talk about the tax consequences of Puerto Rico and George, you can handle the Neupogen, Neulasta

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

We are already seeing substantial tax consequence from the increasing activities in Puerto Rico. We have formulation finish and fill in Puerto Rico now, the tax rate I think has declined several points in the last several years and a point-and-a-half in fact in 2003. Inventory is back to I think question number two or at normal levels for all of the products

George Morrow - Amgen Inc - EVP, Global Commercial Operations

OK. And the Neupogen, Neulasta conversion, the data on that is from an audit, and that lags by at least a quarter, if not a little bit more, so I wouldn't have any data on that for the third quarter, and there was really no appreciable change in inventory in the third quarter.

Jennifer Chao - RBC Capital Markets - Analyst

That's helpful. One follow-up on the Puerto Rico site, should we expect to see any further acceleration here in the next two years as you wrap up on expansion?

George Morrow - Amgen Inc - EVP, Global Commercial Operations

No, I think we have disclosed that as we open up bulk manufacturing for some of our products down in Puerto Rico, later in the decade, our tax rate will decline further. We haven't said to exactly what, but we have indicated that that investment will make pretty good financial sense.

Jennifer Chao - RBC Capital Markets - Analyst

OK. Thanks

Operator

The next question is from Elise Wang with Smith Barney.

Elise Wang - Smith Barney - Analyst

Thank you, I just wanted to follow up on the ABX/EGF program for Roger, as to what are the next steps that will be taken given the refinement in the agreement. Clearly, you're now in full control of development. What are the next steps in terms of studies that we may expect in terms of timing as well as design?

George Morrow - Amgen Inc - EVP, Global Commercial Operations

Hello, Elise. I just want to emphasize that the reason for this clarification of the agreement is that Ray, Lithy and I of Genex had agreed, really right from the beginning that the product must absolutely come first and we clarified this agreement because we wanted to make sure that we could accelerate move of this molecule to the marketplace. We have been actively in discussions with the agency about information that would be required, ultimately, for filing in a cold rectal cancer setting and we are pursuing that as well as pursuing other indications for this molecule. As I indicated, we are quite pleased thus far with the results with respect to safety and certainly getting phase I data, some of which were presented at VACO. We are accumulating more data in all of these settings.

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FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

Elise Wang - Smith Barney - Analyst

OK. Then, a follow-up for George. Could you speak to the competitive environment right now in terms of what you're seeing J&J doing in the EPO market and also on the rheumatoid arthritis area what you are seeing on the Abbott front and what kind of steps are you taking to counteract that?

George Morrow - Amgen Inc- EVP, Global Commercial Operations

On the Aranesp front, J&J has been more aggressive with their contracting. I guess our position is as follows -- we have positioned this product as a better product by virtue of the every other week dosing and very slightly less expensive. That's a position in the marketplace that has driven our success and will continue to drive our success. It's working. We're not going to change that positioning. We need to get -- gain critical mass and market share. Elise, once we gain critical market share, then we can invest more money in growing the marketplace and we don't feel we're there yet, but I do believe there's plenty of room for both products to grow given the growth potential of this market.

Regarding Abbott's HUMYRA product, it has a reasonable foothold in the marketplace, it's pretty much what we predicted a couple of years ago when we had the road show and talked with the Immunex acquisition. I think the first step towards getting once weekly dosing will do a lot to neutralize the only advantage they have in the market right now is more convenient dosing. We still think we have the high ground in terms of the efficacy and the tempo there, once again is really unsurpassed. We're certainly driving that hard in the marketplace, because it is first and foremost, an efficacy driven market.

Operator

Your next question is from Mike King with Banc of America Securities

Mike King - Banc of America Securities - Analyst

Thank you for taking my question. Most of my questions have been answered. I wondered if we could get a status on the survival studies in CKD, and would we have in presentations of note that you would want to draw our attention to at aH?

George Morrow - Amgen Inc- EVP, Global Commercial Operations

I'm sorry, you're interested in survival studies in -

Mike King - Banc of America Securities - Analyst

Treat study.

George Morrow - Amgen Inc- EVP, Global Commercial Operations

The treat study, which is a study of very long duration, as you know. And so, Mike, I don't think there's not any particular information I can give you about that. And with respect to aH, you know, we have a large number of presentations at aH. I don't want to compromise the abstract publications that will take place. I can't put myself in that position, but surprised it to say, we're going to be extremely active at aH in December.

Mike King - Banc of America Securities - Analyst

Thank you.

Operator

Your next question is from Matt Geller with CIBC world markets

Matt Geller - CIBC World Markets - Analyst

Thank you. Couple of questions. Can you talk a little bit about the -- why is the Neupogen Neulasta conversion slowed down, is there anything that you can do about it. On the pipeline front, can talk about OPG, KGF, DGNF and what progress you are making there.

George Morrow - Amgen Inc- EVP, Global Commercial Operations

Starting with the Neupogen, Neulasta conversion. If you look at the clinics, our conversion rate is very, very high and so it's just a matter of there's just not that much opportunity there. The people who haven't converted probably have a different point of view and we continue to work on them. In the hospital sector, there's a lot of less -- less lower use of Neupogen in terms of days and that becomes a little bit harder to convert, but over time, I think it's just a matter of chipping away. We think about

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

the half of the Neupogen business today is susceptible to being converted over time. These are people that probably have a different point of view and probably use Neupogen a little less aggressively in terms of number of days.

Roger Perlmutter - Amgen Inc - EVP, Research and Development

And Matt it's Roger, with respect to the pipeline issues, as indicated in the OPG access area AMG 162, we're continuing to study it everywhere, really, and we recently began studies in Japan for KGF, as we indicated before. It's our intention to file for the treatment of chemotherapy, radio and chemotherapy induced leukocytes in the immunologic transplant setting, which we are on track for next year. For GDNF, we are conducting a randomized, blinded study that enables us to tell precisely what the effect of GDNF will be. I have been encouraged by the enrollment in the study, because of the nature of the intervention, we are expecting the study to take some time to enroll, but clearly the demand in the Parkinson's disease population is high and enrollment has gone extremely well.

Matt Geller - CIBC World Markets - Analyst

Thanks alot.

Operator

The next question is from Dennis Harp with Deutsch Banc.

Dennis Harp - Deutsh Bank - Analyst

Congratulations on a strong quarter the questions on cynical set, has FDA granted that priority review, and if so, what is the FIDUFA deadline. And then a follow-up question on HUMIRA in the marketplace, are you seeing switchers from HUMIRA to Enbrel due to the fact that some percentage of those patients cannot get a good response on the once weekly dosing?

George Morrow - Amgen Inc - EVP, Global Commercial Operations

I'll take the second one first. This is George. What we're seeing is-- I wouldn't say this wholesale switching back. What you are seeing is many rheumatologists using both products and what they're experiencing with HUMIRA is some breakthrough and dose escalation and when they dose escalate, they go from 40 milligrams every other week to 40 milligrams every week. I believe what's happening is a number of managed care

organizations are getting concerned about literally doubling the cost. They're putting some restrictions on the product, but otherwise, I think dock doctors are still very much in the experimental mode with HUMIRA.

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

Dennis, certainly on cynical set, we filed for priority review. We believe there's significant medical need here, and is cynical set represents a revolutionary new therapy and we're hopeful that the agency will review the application on a priority basis and I cannot provide any information beyond that.

Operator

Your next question is from Caroline Copthorn with Morgan Stanley.

Caroline Copithorne - Morgan Stanley - Analyst

Thank you. I had some questions about the guidance. I was curious about the lowering of the top end of the product sales guidance in total revenue guidance. Given the increase in the Aranesp EPO franchise increase and -- the guidance and all of the other product categories unchanged and what caused you to be less optimistic with the upside there and secondly on the operating expense guidance increase, it seems like it was just about equivalent to the amount of the bio Vee trum expense and I was curious whether we would see that, reverse back down to the lower run rates when we got in the first quarter in addition to the seasonal change.

George Morrow - Amgen Inc - EVP, Global Commercial Operations

I don't want to comment about the first quarter of 2004. We'll do that in degrees bar. The bulk of the operating expense guidance change can be explained by the bio Vee trum license deal that we did. In terms of product sales it's a matter of approaching near the end of the year, and having a \$500 million sort of band around total revenues which is I think about the right level for a company our size to start the year with, but with one quarter, I think we're able to call it tighter and thought we would share that with you.

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11

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Operator

Your next question is from Mark Aufter (ph) with Wachovia

Mark Aufter - Wachovia - Analyst

Thanks for taking my question. Could you comment a little bit on the effective of the proposed A.W. reforms on how it would affect your business in terms of -- is it going to impact maybe the growth of the EPO market or is it going to affect pricing in the future, and then as a second question, could you talk a little bit about how if drug reimportation becomes a standard and allowable practice in the few foot, how could that impact the EPO franchise as well?

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

It's tough to speculate. There's so many AWP possibilities floating around, who knows, and so I'd rather not speculate. I would say that the people who ultimately make decisions more times than not make good decision, even though the process to get there is pretty darned messy and there's a lot of concern. My hunch is that the AWP reform will make it tougher for us but not in some significant way.

Reimportation is basically a challenge for the traditional pharmaceutical companies our products have shipping, temperature issues I don't see the EPO franchise being meaningfully affected, in fact not at all. I also note that a number of the larger companies have taken the steps to only give Canada what product Canada can consume. I think that's a responsible and appropriate step, and the FDA Commissioner has been very outspoken about this issue. And so, I'm not worried about it from an EPO specific point of view.

Mark Aufter - Wachovia - Analyst

That's very helpful. Could you maybe give me more insight on the AWP reform issue, as far as which parts of the EPO franchise, which parts of the growth of the franchise are most sensitive to pricing and maybe to physician spread on -

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

I think that -- let's explain here. The EPO franchise is dialysis. That's covered by the end stage renal disease act, and that's not probably what people think about in the broad AWP sense.

That would be products in the physician office, and so George, you might want to comment, but as far as I understand, the EPO franchise and dialysis is -

Mark Aufter - Wachovia - Analyst

Sure. I'm sorry. I meant the whole retro product franchise incorporating Procrit.

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

I think just speculating on what might happen is not constructive

Operator

Your next question is from Joel Sendek with Lazard

Joel Sendek - Lazard - Analyst

Did I hear you correctly that Roche's Serra compound may infringe on your issued patents?

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

We're quite certain it does

Joel Sendek - Lazard - Analyst

OK. And on cynical set, will that contribute positively or negatively to your current gross margins. Could you comment on that?

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

Cynical set is not going to be a major swinger for the company. At that level.

Unidentified

Can we take the last question now, please.

FINAL TRANSCRIPT

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Operator

Yes, sir. Our last question is from Jeffrey Porjic(ph) with Sanford Bernstein.

Jeffrey Porjic - Sanford Bernstein - Analyst

Thanks for taking my question. I have a question on cynical set, specifically could you comment on the distribution of patients with high and low burn turnover disease in the phase three studies and what, if any, information the FDA has requested on burn biopsies for patients with high and low bone turnover disease in Phase III studies and what if any information SGA is requested on run biopsies for patients with low turn of abundantly in renal osteodystrophy.

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

I tell you, I really don't want to get into the details of all of the studies that we have done for cynical set. I have indicated the full analysis of the Phase III studies in the American Scientists of nephrology. I haven't had an opportunity to dig into the details. It's a stunning dataset, I encourage you or your colleagues to have a look at it.

Jeffrey Porjic Thanks very much.

Richard Nanula - Amgen Inc - EVP, Finance Strategy and Communications and CFO

OK, Thank you very much for joining us for this conference call. We'll talk to you again next quarter. If anybody has any questions, please call my office. Thank you.

Operator

Thank you, Ladies and Gentlemen, for participating. This concludes today's conference. You may now disconnect.

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13

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