Event Transcript
AMGN - Q3 2003 Amgen Earnings Conference Call

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OVERVIEW
In Q3, AMGN's business continued to demonstrate strong performance both domestically and internationally in the key therapeutic areas of oncology, inflammation, and nephrology. Adjusted Q3 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.
Good afternoon ladies and gentlemen. 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.

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

Thank you, Paul. Good afternoon and welcome, everybody. Before we start, I need to make a cautionary statement. When we estimate revenues, operating margins, capital expenditures, cash and other financial metrics and discuss legal, arbitration, political and regulatory or clinical results such as 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 10-K 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 Barill 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.

Thank you, 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; and the rest of the management team and the financial team. My name is Paul and I’ll be your conference facilitator for Amgen’s Third Quarter Earnings Conference Call.

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

In the third quarter, our business continued to demonstrate strong growth 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 acceleration of both internal discovery and outreach efforts. Amgen's management team is focused on ensuring that we have sufficient pipeline productivity to provide sustained 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 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 ensure 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 new small molecule for the treatment of type two diabetes and certain other metabolic disorders. This agreement is the result of a strong pipeline of new molecules in these areas. Amgen will provide additional information 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 Neulasta (ph) that combined have economic value in protective and cycling use of growth factors in appropriate risk assessment of patients treated with Neupogen. Complications of chronic kidney disease patients whose risk factors include chronic kidney (renal) disease in patients with secondary hyperparathyroidism who are at risk of significant bone disease and cardiovascular complications.

I would like to congratulate our oncology team for all their hard work and thank the management team for their efforts on the commercial growth, the market dynamics release products. We get closer to the date, we have expanded our efforts 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 ensure that Amgen is the partner of choice for acquisition and licensing opportunities.

Adjusted earnings per share in adjusted net income for the third quarter exclude certain expenses related to the acquisition of Immune and some-time expenses of $47 million related to the legal settlement associated with the company's lawsuit with Jon Nen, which we regard as 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 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 the beneficial foreign exchange, this quarter, international sales would have grown 91%. Combined aggregate worldwide Amgen 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 worldwide worldwide Amgen demand.

Epogen sales were $660 million for the third quarter, an increase of 12% versus the same quarter last year. The third quarter year over year growth is principally due to favorable revised estimates of dialysis demands were slower for prior

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the our reported even general sales and inscription is spill over.

Once again, please refer to our form 10-K for a more detailed discussion of this relationship and its impact on the reported even general sales and inscription is spill over. Even Jan 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 day-to day growth in the 4% to 5% range will primarily drive even Jan sales.

Worldwide Aranesp sales in the third quarter were $458 million, versus $114 million in the third quarter last year. This growth was driven by demand worldwide, reflecting their entire addition of Aranesp in Europe. Third quarter U.S. Aranesp sales were $384 million versus $377 million last year, and international sales were up $54 million versus $37 million year-to-date. 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 Jan sales and expect sales to range between $3.4 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 $857 million, an increase of 51% versus the same quarter of the prior year. U.S. Neulasta sales were $204 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 $214 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 conferencecall, Neupogen conversion to Neulasta has slowed in the U.S. George will cover the additional growth opportunity 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 51% increase over the third quarter of 2002. Sales reported by Amgen of $168 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.

Sites for the current year were driven by demand, fueled by new patients in both rheumatoid 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 acquisition to moderately 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 $291 million in the comparable quarter of 2002, primarily due to increased sales. Cost of sales as a percentage of sales increased from 49% in the third quarter of 2002 to 18.1% in the third quarter of 2003, reflecting a greater proportion 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 increased R&D headcount, 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 the expense of embrel, the worldwide 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 traditionally has the highest spending quarter due to normal second spending patterns which occur as a result of the immune acquisition close date of July 15 last year.

This year in the fourth quarter, an additional $65.5 million up front payment associated with the licensing of betnum 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 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 $1.65 to 1.95 per share for 2003.

On a GAAP basis, EPS was 40 cents per share in the third quarter of 2003. We believe that adjusted earnings provide useful
supplementary information to investors. We do recognize
the importance of earnings computed in accordance with GAAP
and since 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 website.

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 $608
million versus $529 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
$3.1 billion at the end of the third quarter. We'll provide financial
guidance for 2003 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 an operating update
for the quarter. George.

George Morrow - Amgen Inc. - EVP, Global Commercial Operations
Thanks, Kevin. I'll start with the newest 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 it's importance of risk factor, relative to well-known
factors such as hypertension, diabetes and lipaemia.

Next is anemia 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 was prefilled syringes 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
cancer induced anemia patients currently receive an
cytopenic agent.

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

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

Turning to enBrel 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. Enbrel is the
leading term of inhibitors in terms of numbers in sort of virus
The outstanding results of the temp of study such as arthro
the profile. Just as reminder of the temp study involved
enBrel in combination with methotrexate with RA and P's frong will
have several words to say about that and this will be
highlighted at ACR. During the third quarter trial was expanded to include improved physical function, inhibition of
progression of structural damage and so (inadequate) riders and
most recently approved for once-weekly dosing in all patients.
Down the road, of course, is the opportunity to serve patients.

Along these lines, we have had an exceptional response to the
portals 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 abject word about
the preparation for the clinical trial launch. We believe it provides
amendable and effective way to treat secondary (inadequate)
peripheral disease. Our primary challenge commercially will be to
facilitate reimbursement and coverage for a broader group of

Kevin Sheriff - Amgen Inc. - Chairman and CEO
Now, I will provide a marketing update for the quarter.

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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 a small molecule therapeutic and representing 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 a smaller molecule 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 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 therapy in early rheumatoid arthritis in this study, 30% 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 be slowed provided that appropriate embrel based therapy is administered. Amgen is also approved for treatment of angioedema.

And as means of improving physical function in patients with RA in all 80 abstracts including 21 presentations in for the will be presented at the Ethereum 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 phase 2, 15 inhibitor program through a licensing agreement with Jian med. These new programs add additional strengths 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 postmenopausal osteoporosis.

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, immobilization 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.

Robert Goldman - Buckingham Research - Analyst

Thank you. I'm curious if you have asked the FDA specifically for a previous indication. Second, you mentioned about reimbursement. 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 diabetes 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.
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 Hankey article published in Lancet last week, supporting the view that there is 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 radiotherapy.

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 positin beta in this case and those who did not.

There are other differences in terms of eligibility criteria. There were patient mix limitations and there were some 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 from being afire 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 (indefeasible) in improve survival.

The weight of evidence, I think is that there's potential for benefit, and it is also possible that understanding some of the prior evidence and conclude anything on the basis of the single trial.

I'll let Ralph Bigh [sic] comment on the TTKT article on roach's product.

First of all, it's important to note that there is a very strong preclinical 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 normocytic or normochromic tissue being less sensitive to adjuvant 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 some overwhelming data associated with the quality of life.

Eric Schmitt - S.G. Cowan - Analyst

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

George Morrow - Amgen Inc - EVP, Global Commercial Operations

As far as we know, no indication that we have. It's not a market that we have really looked at.

Eric Schmitt - S.G. Cowan - Analyst

Thanks
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 an 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 much worse. In the legislative area it's pretty open process and there is 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 it's going to be good for the country, and AWP reform of one kind or another will probably happen apart 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 Proctor. 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 see 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.

Mark Schoenebaum - Piper Jaffray, Analyst
Should we be expecting data for Astra? Is that something that you could answer for us?
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, like androgens (androgens) to active hormone occurs in the peripheral tissues to an extensive extent. This is mediated by an enzyme 11 beta HSD 1. Innovation of a 11 beta HSD 1 inhibitor is expected to be associated with an increase in the peripheral exposure to active androgenic and enhanced insulin sensitivity and also a variety of beneficial effects on other metabolic parameters. The kind of observations have been demonstrated predominantly 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 we've accumulated to that point, and keep in mind that if we have the opportunity to study significant number of people exposed to their renal molecules, we believe that an early 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, EVP, Research and Development

We can hear you.

May Kin Ho - Goldman Sachs - Analyst

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

Roger Perlmutter - Amgen, EVP, Research and Development

The rules for what, May Kin?

May Kin Ho - Goldman Sachs - Analyst

History of going basically change the AWP system?

Roger Perlmutter - Amgen, 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 code, and they have shown willingness in the past to be aggressive. So who knows.

May Kin Ho - Goldman Sachs - Analyst

Thank you.

Craig Parker - Lehman Brothers - Analyst

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

George Morrow - Amgen, EVP, Global Commercial Operations

We don't give specific numbers in fact. I don't have one in my mind. The vast majority of sites 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 whether an area where you would contemplate building any large sites 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 gout in a way that will provide a dramatic difference to patients that will be commercially successful and we will do what it takes to bring those kinds of molecules to market. If in fact we have molecules that have the characteristics that require large sites forecasts to bring them to market, we will 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, at which this early stage would be a hallucination phase, early phase molecules, the investment would sure be worth it. We're going to invest against the molecule characteristics, and go where those take us. Now, you know, I'm not saying that we wouldn't consider another molecules, partnering with somebody in distribution, but we're going to do what it takes for the molecule to be successful.
I am a helpful assistant. Do you have a question or need assistance with something else?
Ellie 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 Amgen 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. We're not going to change that position. We need to get—gain critical mass and market share. 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 advantage they have in the marketplace right now is more convenient dosing. We still think we have the high ground in terms of efficacy and the tempos there, once upon is really unparalled. We're certainly driving that hard in the marketplace, because it is first and foremost, an efficacy driven market.

Mike king - Banc d’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 that I can give you about that. And with respect to ah, you know, we have a large number of presentations with Abbott, 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 d’America Securities - Analyst

Thank you.

Operator

Your next question is from Matt Geiler with CIBC world markets

Matt Geiler - 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 convention 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 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
I'll take the second one first. This is George. What we're seeing is--I wouldn't say the whole switch is being made. What you are seeing is many rheumatologists using both products, and what they're reusing with HUMIRA is a 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 that doctors are still very much in the experimental mode with HUMIRA.

Richard Nanula - Argent 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 any criticism set represents an evolutionary 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 Copithome with Morgan Stanley.

Caroline Copithome - 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 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 Vetrum expense and I was curious whether we've seen expenses reverse back down to the lower run rates when we got in the first quarter in addition to the seasonal change.

George Morrow - Argent Inc. - EVP, Global Commercial Operations

I don't want to comment about the first quarter of 2004. We'll do that in degrees ber. The bulk of the operating expense guidance change can be explained by the bio Vetrum license deal that we did. In terms of product sales it's another year of approaching near the end of the year, and having a $300 million sort of land around total revenues which 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.
Your next question is from Mark Auffer with Wachovia.

Mark Auffer - Wachovia - Analyst

Thanks for taking my question. Could you comment a little bit on the effectiveness of the proposed AWP reform and 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 a second question, could you talk a little bit about how if drug reimbursement becomes standardized and allowable practice in the future, 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 than not make good decisions, even though the process to get there is pretty darned messy and there is a lot of concern. My hunch is that the AWP reform will make it tougher for us, but not in some significant way.

Reimbursement 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 responsible and appropriate and that the FDA Commissioner has been very outspoken about this issue. And so, I'm not worried about it from an AWP perspective.

Mark Auffer - Wachovia - Analyst

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

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

I think that -- let me 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--

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

I think I just speculated on what might happen is not constructive. I think they just speculated on what might happen. And I think the best we can say is it's not going to be negative for the company.

Operator

Your next question is from Joel Sandek with Lazard.

Joel Sandek - Lazard - Analyst

Did I hear you correctly that Roche's Sierra 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 Sandek - 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 swing for the company. At that level.

Unidentified

Can we take the last question now, please.
Operator

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

Jeffrey Porjis - Sanford Bernstein - Analyst

Thank you for taking my question. I have a question on cynics specifically could you comment on the distribution of patients with high and low burn turnover disease in the Phase III 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 the FDA has requested on burn biopsies for patients with low burn turnover disease.

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 analyses that we have done for cynics specifically. I have indicated the full analyses of the Phase III studies in the American Society of Nephrology. I haven't had an opportunity to dig into the details. I'm assuming dataset. I encourage you or your colleagues to take a look at it.

Jeffrey Porjis - Sanford Bernstein - Analyst

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. Will 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 does conclude today's conference. You may now disconnect.