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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.

FINAL TRANSCRIPT

AMGN - Q3 2003 Amgen Earnings Conference Call

CORPORATE

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Kevin Sharer
Amgen Inc - Chairman and CEO

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

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PRESENTATION PARTICIPANTS

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,

Roger Perlmutter, Executive Vice President, Development and Beth Sidenberg, 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 area 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, Aon es continues to do well by penetrating the oncology and nephrology markets.

Neupogen and knew lass (ph) that combined have economic value in protective and cycling use of growth factors in appropriate risk assessment for patients threatened by Newtripinic complications. Emrel will continue to expand it's already broad use of the series of regulatory approvals. In addition, our renatology and dermatology sales forces, each has new label claims to demonstrate Emrel's value to rheumatologi$ and sorry ya Research his 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 hypo perathyroidism 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 increased 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 Nen tech 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 epgeneral 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 worldwide Aranesp demand.

Epgeneral 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

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 it's 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 US 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

supplementary information to investors. We do recognize that 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 it's importance of risk factor, relative to well known factors such as hypertension, diabetes and list 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 was 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 orethropautic agent.

Next is Aranesp EU. Aranesp continues to gain share in all European markets powered by the Oncology indication. IMS data reveals 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 epJen business remains strong driven primarily by patient growth. We continue to work with our customer, aligning 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 neuro penia 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 expense as evidenced by the fact that only about a third of the patients at risk for knew Tro penia (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 teams of inhibitors in terms of numbers in sort of virus. The outstanding results of the temp of study such are inforce 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 it 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 os structural damage and so (inaudible) riders and most recently approval 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 a novel 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.

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 day it with the use of embrel with methotrexate as therapy with early rheumatoid arthritis. In this study, 80% of patients treat the 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 be slowed prayed provided that appropriate embrel based therapy is administered. Amgen is also approved for treatment of anglospondylosis.

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, I'll 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 inflamatory 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 reimburse 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.

Robert Goldman - *Buckingham Research - Analyst*

OK. Thank you.

Operator

Your next question is from Eric Schmitt with S.G. 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 Sera product and the its potential to compete with you in the U.S. And second, on the study coming out of de lance 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 -aretro-play the franchise around the world is so large, fast-growing and valuable, that we will see essentially for ever one assault on that franchise or another from someplace, 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 lancette 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 lancette. 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 ablative 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 Hanky article published in Lancette last week, supporting the view there is at least a trend and in some cases a significant improvement in survival in studies of imPoe tins 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 poetin 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 understand 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 aradiation 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.