

# FINAL TRANSCRIPT

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## **MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call**

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Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

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**Ken Frazier**

*Merck & Co., Inc. - EVP, President Global Human Health*

**Eva Baretto**

*Merck & Co., Inc. - VP Investor Relations*

**Peter Kellogg**

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## CONFERENCE CALL PARTICIPANTS

**Chris Schott**

*JPMorgan Chase & Company - Analyst*

**Tim Anderson**

*Sanford C. Bernstein & Company - Analyst*

**Barbara Ryan**

*Deutsche Bank - Analyst*

**Roopesh Patel**

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**David Risinger**

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## PRESENTATION

**Operator**

Good day, everyone, and welcome to Merck's second quarter 2008 earnings conference call. Today's call is being recorded.

At this time, I would like to turn the call over to Ms. Eva Boratto, Vice President of Investor Relations. Please go ahead.

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**Eva Baretto** - *Merck & Co., Inc. - VP Investor Relations*

Thank you, Cara, and good evening, everyone. Welcome to our call to review our business performance for the second quarter of 2008. We appreciate everyone's participation after a full day of news flow.

Joining me on the call today is our Chairman, President, and CEO, Dick Clark, we also have Ken Frazier, our Executive Vice President and President of Global Human Health, here to provide commentary on revenue trends on several of our key inline

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

and recently launched products, and Peter Kellogg, our Executive Vice President and Chief Financial Officer will focus in on the key financial takeaways from the quarter and provide an overview of Merck's 2008 financial guidance.

Before we get into the details, I'd like to go over some logistics. On this call, we will review the results contained in the release we issued at 4:30 today. You can access this through the Investor Relations sections on merck.com and I would remind you that this conference call is being webcast live and recorded. The replay of this event will be available this evening via phone, webcast, and podcast.

As we begin our review, let me remind you that some of the statements made during this call may discuss certain subjects that may contain forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on managements' current expectations and involve risks and uncertainties which may cause results to differ materially from those set fourth in the statements.

The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and any actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement whether as a result of new information, future events or otherwise.

Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year-ended December 31, 2007 and in any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

We will begin the call with brief remarks from our senior management and then open the call up for your questions, and expect the total call to last approximately an hour. With that, I'll turn the call over and we will begin with remarks from our Chairman and President and CEO, Mr. Clark.

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**Dick Clark** - Merck & Co., Inc. - Chairman, President, CEO

Thank you, Eva, and good evening, everyone.

Thank you for your flexibility in adjusting your schedules to the unavoidable last minute change we made this morning in the timing of our sales and earnings announcement. We felt it was important for you to first have the scientific respect of the disease results which were presented earlier today by the study's principal investigator.

In a few moments, Ken Frazier and Peter Kellogg will provide an overview of our performance in the second quarter along with updates to our 2008 guidance. But first let me make a couple of points.

It is important to understand that the results per SEAS has just been presented publicly today, and we ourselves just recently received the study results from the outside researchers. While we are moving quickly to assess the data and its potential implications for our cholesterol joint venture, it is just too early to make informed judgments about the potential impact of SEAS on our performance for 2008 and longer-term.

I know you undoubtedly have questions on SEAS, but please appreciate our scientists are working diligently to evaluate the data on this and on this call we are not in a position to add to the lengthy discussion that took place this afternoon. Also, we believe it's appropriate to take some time before we provide equity income and EPS guidance for 2008 or longer-term guidance. We will provide an update at a later time.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

While I know you dislike uncertainty almost as much as I do, I hope you understand our position. We remain fully committed to helping you understand our business and its prospects. Also, it is important to note that before these results were made available, we were within our previously disclosed GAAP and non-GAAP EPS guidance range.

Next, I want to share an update on manufacturing. Previously, we told you that Merck was working with the U.S. regulatory authorities to adequately adjust the agency's manufacturing concerns in an expeditious matter.

On July 10, Merck received a letter from the FDA closing out its recent inspection at the West Point manufacturing facility. As a result, any filed SBLAs which were held up due to the inspection can now move through the agency's normal review and approval process. As always, we will continue to work with the regulatory authorities in a cooperative manner to insure that the public health was served by the continued supply of our quality vaccine products.

In addition, the varicella supply issues which were unrelated to the issuance of the warning letter have been resolved and we have resumed manufacturing of bulk varicella. We are producing doses of VARIVAX and we don't anticipate any supply interruption of VARIVAX.

Finally, I wanted to provide you with some perspective on how our leadership team and I are thinking about positioning Merck for success now and in the future even in the face of very tough industry environment and some unexpected difficulties. These factors made for an intense review of our business at our recent annual strategy meeting. At that meeting my team and I identified opportunities and actions necessary to drive future growth.

During the session, we decided to move forward on several immediate and long-term steps designed to accelerate our revenue growth. To give you a flavor of some of these steps, emerging markets will become an even more central part of the Company's business strategy.

In addition, we will aggressively seek out the best partners in the regions outside the United States to support [in light] product acquisitions, co-marketing and promotion agreements as well as country and regional licensing opportunities. We are accelerating development programs for novel mechanisms and fixed dose combinations in some of our key therapeutic areas. All of these moves have significant incremental revenue potential.

In the meantime, it remains vital that we operate our business in a more lean and flexible manner by having the discipline and leadership to make significant but necessary changes. That means continuing to embrace both internal and external innovation to enhance productivity in the long-term sustainability of our pipeline.

We've advanced a robust research and development pipeline that contains nine late-stage breakthrough investigational candidates that address critical unmet medical needs. We are continuing to launch new medicines around the world and we are investing heavily in the life cycle management plans for those brands. We remain committed to doing what it takes to regain leadership in the pharmaceutical industry.

Now I'd like to turn first to Ken who will be followed by Peter and after their remarks we will take your questions. Ken?

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**Ken Frazier** - Merck & Co., Inc. - EVP, President Global Human Health

Thank you, Dick, and good evening, everyone.

Merck's revenue performance in the second quarter reflects continued strong growth of a number of our recently launched new products offset by challenges to key brands such as GARDASIL and SINGULAIR and the continued impact of the loss of marketing exclusivity for FOSAMAX. Overall, revenue was down 1% in the second quarter, however, excluding FOSAMAX, revenue in the second quarter increased by 6%.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

Our international business, aided by the prevailing exchange rates, continues to perform very well, increasing by 12%. As we enter the second half of the year, we believe that we have the plans in place to address a number of the challenges facing our products and we can continue to drive growth around the world as the launches of JANUVIA, JANUMET, ISENTRESS and GARDASIL rollout.

Now let's discuss some of the key drivers of Merck's business in the second quarter beginning with our HPV vaccine, GARDASIL. In the second quarter we continued to make progress in our attempt to reduce the global burden of cervical cancer with GARDASIL.

Merck sales in the second quarter were \$326 million, a 9% decrease when compared to the second quarter of last year. In addition, during the second quarter, our vaccine joint venture, Sanofi Pasteur-MSD recorded end market sales for GARDASIL of \$234 million.

Global end market sales for GARDASIL in the second quarter of 2008 increased 28% versus the prior year driven by the continued rollout of GARDASIL in Europe. Sales of GARDASIL in the U.S. were sequentially down in the second quarter as a result of three factors.

First, a decrease in second and third dose administrations. As new starts peak in the back-to-school period with the recommended dosing regimen over six months, second and third dose immunizations occurred disproportionately in the fourth and first quarters.

Second, a deceleration in the penetration rate among the 13 to 18-year-old cohort. Considering the strong cumulative utilization in this cohort since launch, continued growth requires substantially higher penetration rates among the remaining eligible cohort. The adolescent penetration rate for GARDASIL is nearly two times higher than the average cumulative penetration rate of MENACTRA and the diphtheria-tetanus and pertussis vaccine at comparable points in their life cycles.

Third, lack of significant progress in our ability to increase the penetration rate in the 19 to 26-year-old cohort. While our launch efforts achieved unprecedented uptake in the 11 to 18-year-old cohort, the penetration rate in the 19 to 26-year-old cohort have thus far proven harder to increase.

Despite our efforts to increase the penetration rates in this population, we clearly underestimated the attitudinal and behavioral barriers with both the 19 to 26-year-old females themselves as well as the doctors that treat them. Fortunately, the opportunity in this population is still very much in front of us and we remain fully committed to achieving broad vaccination in this cohort as per ACIP and physician society recommendations.

To increase the action among these women, we recently implemented programs to help reduce reimbursement concerns and assist physicians in their recommendations for these women. In addition, we recently developed and launched new DTC ads and an interactive Web portal.

In the third quarter we are planning to launch additional healthcare provider and consumer initiatives to drive increased immunization in the 19 to 26-year-old cohort. Importantly, as we look forward, we continue to anticipate that origination will peak in the third quarter based on the fact that historically, approximately 40% of adolescent well visits occur in that quarter.

As with all of our products, Peter will provide you with an update of our guidance for GARDASIL in a few minutes.

Now, turning to SINGULAIR. Sales of SINGULAIR were down 1% in the second quarter. This performance in the second quarter '08 was due to a decline in the U.S. business partially offset by continued growth outside the U.S.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

In the second quarter, U.S. prescriptions, that's TRX, were down approximately 8% versus second quarter of '07 while the overall respiratory market, which is the combined allergy and asthma market ex-ZYRTEC, was down approximately 3%. Ex-U.S. sales of SINGULAIR grew 15% driven by continued growth in Japan, the second largest market for SINGULAIR worldwide.

In Japan, the successful launch of the allergic rhinitis indication in the spring of 2008 and the introduction of the oral granules formulation for preschool-aged children since late 2007 are contributing to the growth.

Three main factors contributed to the year-over-year U.S. performance of SINGULAIR. First, the switch of ZYRTEC to OTC in January. Despite SINGULAIR's continued strong positioning on formulary, ZYRTEC OTC has clearly had an impact on the overall allergic rhinitis market including SINGULAIR.

We continue to believe that SINGULAIR offers a compelling value proposition among new and dissatisfied allergic rhinitis patients. As dissatisfied patients try multiple products to treat allergic rhinitis over time, including OTC products, we believe that they will continue to visit their physicians and seek additional alternatives including SINGULAIR.

Second, the timing of and the public reaction to the FDA early communication created uncertainty in the marketplace just as the allergy season was about to start. The October 2007 label change was based on a very limited number of post-marketing adverse event reports that Merck received.

Since that time, Merck has worked with the FDA to provide further clarity in the product label as well as to further communicate this information to physicians. Based on feedback from our sales force and Merck's proprietary research, physicians continue to rate SINGULAIR as the brand that best represents having a side effect profile similar to placebo in the asthma market. We continue to have confidence in the safety and efficacy profile of SINGULAIR.

Third, the spring allergy season was shorter and milder compared to recent years. Fortunately, recent weekly domestic performance for SINGULAIR has shown signs of improvement relative to the growth of the overall respiratory market and we are taking additional steps to further support the brand including accelerating a new asthma program, initiating expanded multi-channel promotion, and delivering compelling healthcare provider, consumer and disease awareness programs to market.

Despite these challenges, SINGULAIR continues to be the number one product in the U.S. respiratory market.

Moving to JANUVIA and JANUMET, two of our newest growth drivers. Global revenue for these two products reached \$406 million in the second quarter, up 23% sequentially versus first quarter of this year. In the U.S., JANUVIA continues to be the second leading branded oral anti-diabetic agent in terms of new prescription share.

Recent data presented at ADA, including a compelling analysis, comparing JANUVIA versus sulfonylureas, which showed treatment with JANUVIA dramatically lowered hypoglycemia compared to treatment with FFUs. Based on our post-marketing experience for JANUVIA and with over 5 million prescriptions written in the U.S. since launch, we continue to be extremely confident in the efficacy and safety profile for JANUVIA and JANUMET.

In addition, we are extremely please the ex-U.S. performance of JANUVIA and JANUMET in the second quarter. Sales outside the U.S. were \$77 million as recent launches in key markets such as France, Spain, Italy and Canada continue to progress. The recent European approval for JANUMET will provide an additional growth opportunity for our diabetes franchise in the 27 markets in which the regulatory decision is applicable.

Now, I would like to take a moment to provide an update on the revenue performance of our cholesterol JV. Before doing that, as you know, based on today's announcements and the press conference, the Company has recently received the clinical data from the SEAS study. In view of this, I am not in a position to provide an immediate perspective on the future performance of ZETIA or VYTORIN.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

We will do everything we can to insure that the data are communicated effectively and understood in the appropriate context. We continue to believe that both ZETIA and VYTORIN provide physicians with valuable treatment options to help get more patients to their LDL goals.

Worldwide sales of ZETIA and VYTORIN, as reported by the Merck/Schering-Plough joint venture, were \$560 million and \$592 million respectively in the second quarter. In the second quarter sales declines in the U.S. were partially offset by strong growth outside the U.S.

Before turning the call over to Peter, I would like to take a moment to update you on the progress we are making in terms of optimizing our cost base as we pursue a new commercial model. In the second quarter marketing and admin expenses, excluding the legal defense reserve in the base period, was up 3% versus the second quarter of 2007.

The year-over-year increase in marketing and administrative expense is solely attributable to the impact of exchange. Excluding exchange and the legal defense reserve in the base period, operationally, marketing and administrative expenses were down 3% in second quarter '08 versus second quarter '07.

As you know, in May Merck announced plans to reduce the size of its U.S. sales force by 1200 positions. The reduction in the U.S. sales force is part of our previously disclosed and continuing efforts to optimize our cost base and improve Merck's effectiveness and efficiency across all aspects of our business.

These actions are consistent with our imperative as a company to continue to look for opportunities to improve business processes and practices and to create a leaner, more cost effective and customer focused operating model.

In closing, we continue to believe that tremendous commercial opportunities exist for our inline and new products. We are confident that the plans we have in place will enable us to maximize the revenue potential of our pharmaceutical products and vaccines.

And while we have faced a number of commercial challenges in the first half of 2008, we continue to believe that our established franchises, along with our new first in class vaccines and medicines such as GARDASIL, ROTATEQ, JANUVIA, JANUMET and ISENTRESS, provide us with a diverse product portfolio well positioned to drive revenue growth. At the same time, our continued focus on efficiency on the marketing and administrative line will help drive overall margin improvement.

So with that, I'll turn the call over to my colleague, Peter Kellogg.

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**Peter Kellogg** - Merck & Co., Inc. - EVP, CFO

Thank you, Ken, and good evening.

To wrap up the call, I will discuss key elements of Q2 results not previously covered, provide an overview of the extent of our 2008 guidance, and comment on other financial matters such as our dividend. So let's get started.

Merck reported second quarter non-GAAP earnings per share of \$0.86 per share representing growth of 5% over the second quarter of 2007. On a GAAP basis, earnings per share for the second quarter were \$0.82, a growth of 6%.

For the first half of 2008 the Company recorded non-GAAP EPS of \$1.75, also up 5% versus the first half of 2007. Year-to-date GAAP EPS were \$2.34, 51% above 2007 GAAP EPS.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

Our second quarter results reflect our continued efforts to create a leaner, more cost effective and customer focused operating model as evidenced by first product gross margin that showed continued strength. There was an impact of a restructuring charge in the second quarter.

Excluding this charge, PGM was 77.2% maintaining performance at pre-ZOCOR patent expiry levels. Sequentially, PGM was down 1.8 points primarily attributable to product mix and some inventory write-offs.

Secondly, as Ken mentioned, marketing and administrative expense in the second quarter was down 7% and as he mentioned, excluding both the legal defense charge in the prior year and the unfavorable impact of foreign exchange, expenses were down 3%, great progress. This excellent result was due to the improvements that Ken walked us through and some additional efficiencies throughout our G&A organizations.

And finally, research and development expenses of \$1.2 billion increased 13%. This increase was generally attributable to several areas of clinical spending for late-stage programs.

Next, as anticipated, equity income was down year-over-year because of two factors. First, the equity income contribution from the Merck/ Schering-Plough joint venture was down 22%, or \$100 million as a result of ZETIA and VYTORIN market share losses in the U.S. The lower revenue in the U.S. was partially offset by the strong performance outside the U.S.

Additionally, the respiratory joint venture was terminated during Q2 which will result in a payment by Merck of \$105 million to Schering-Plough. Consequently, Merck's second quarter equity income contribution from the Merck/Schering-Plough joint venture includes a \$43 million expense related to this termination. The remainder of this payment will be amortized over the life of the partnership in accordance with U.S. GAAP.

Second, contribution from the AstraZeneca joint venture was \$154 million lower in Q2 versus prior year. This decrease in the equity contribution from the AZN partnership is attributable to the previously disclosed events surrounding the JV restructuring that occurred toward the end of the first quarter this year and some inherent variability of timing of payments from AstraZeneca.

As a reminder, Merck's priority return was decreased to \$55 million per quarter from \$75 million per quarter and Merck no longer receives a 10% royalty payments from the Astra USA products.

Finally, in the second quarter our effective tax rate realized a 9 percentage point benefit from various tax settlements. The reported effective tax rate was 14.1%, and excluding the impact of restructuring charges, the non-cash GAAP underlying effective tax rate was 15.2%.

Both rates reflects the impact of various tax settlements that resulted in a reduction of our corporate FIN 48 reserves. As you can appreciate we aren't in a position to disclose the details of these settlements, however, they are unrelated to the foreign tax credits that were announced in Q1.

Moving to the bottom line. As I mentioned earlier, Merck's second quarter non-GAAP EPS was \$0.86 and the GAAP EPS was \$0.82.

Now moving to guidance. As Dick and Ken discussed, we are assessing the impact of SEAS on the performance of ZETIA and VYTORIN and are not in a position to provide an immediate perspective. Therefore at this time, we are not able to provide 2008 equity income guidance, 2008 GAAP and non-GAAP EPS guidance and any long-term financial performance.

We are fully committed to helping you understand our business and its prospects and we are not stepping away from that commitment. We will provide an update at a later date.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

Now, Ken talked about a number of challenges and opportunities of the business that may change our 2008 product performance, and accordingly, we are changing several elements of our product guidance and some will be increases and some will be reductions. As always to assist your modeling, we provide a breakdown of the product revenue guidance in our other financial disclosure schedule attached to the press release issued earlier today. So let me walk through those changes.

Regarding SINGULAIR, we are lowering our full-year guidance by \$200 million and now anticipate revenue in the range of 4.4 to \$4.6 billion for the reasons Ken discussed.

For COZAAR/HYZAAR, we are raising our guidance by \$100 million and now anticipate revenue in the range of 3.5 to \$3.7 billion. This is primarily driven by strong performance in Japan and the positive effect of foreign exchange, considering the geographical segmentation of revenue for these products.

Guidance for GARDASIL revenue as recorded by Merck is now anticipated to be in the range of 1.4 to \$1.6 billion. This \$500 million reduction is due to the several factors that Ken just reviewed. Additionally, since this is full-year guidance, it also incorporates some impact for the delay in the mid-adult women indication.

Other vaccines guidance of 2.7 to \$2.9 billion has been reduced by \$200 million. This reduction is largely attributable to the lower than anticipated VARIVAX second dose penetration, which we can now take steps to address with the improved supply situation which Dick mentioned earlier.

Regarding FOSAMAX, we continue to be pleased with the performance of the domestic FOSAMAX Plus D year-to-date. And as a result, we are increasing our full-year guidance by \$100 million to 1.4 to \$1.7 billion.

Now, regarding marketing and administrative expense, we are reducing our guidance by \$300 million to 7.5 to \$7.7 billion. This reduction is possible because of the delay of MK524A in the U.S., and the domestic sales force reduction of 1200 positions announced in May, which has now become, or has now been completed, and our ongoing companywide aggressive expense management program.

Let's turn to restructuring. As part of the Company's restructuring of its operations, we anticipate the aggregate 2008 pre-tax expense related to these activities to be in the range of 200 to \$300 million.

Moving to taxes. We are reducing our full-year 2008 non-GAAP tax rate guidance range to approximately 18% to 21%. This guidance incorporates the impact of the foreign tax credit benefit recorded in Q1 and the discrete tax settlements recorded in Q2. It does not reflect the tax rate impact of the gain on distribution from AstraZeneca or restructuring charges.

Turning to other financial matters, it should be clear, though, that we have the financial strength and remain fully committed to maintaining our dividend at the current level. At the same time, we continue to fully invest in our key strategic priorities.

So let me summarize. There have been several changes to our revenue guidance but, as Ken reviewed, our inline product portfolio includes numerous young therapies that continue to show real promise. We continue to rollout and launch our eight new products globally.

We also continue to aggressively manage our overall cost structure as demonstrated by the reduction in marketing and administrative guidance, and with our robust, late-stage pipeline of nine new vaccines and medicines, we remain confident in the Company's ability to deliver strong results. We are, however, taking some time to assess the impact of today's announcements and will re-establish guidance on the equity income and EPS for 2008 and on our long-term guidance in the future.

Now, I'd like to turn it back over to Eva. Eva?

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Thank you, Peter.

We will now open the call to take your questions. We will take your questions in the order they are received and try to get through as many as possible. Also, joining us for the Q&A is Bruce Kuhlik, our Executive Vice President and General Counsel. At this point, I will turn it over to Cara, who will communicate the instructions for our Q&A format and then introduce the first question.

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## QUESTIONS AND ANSWERS

### Operator

(OPERATOR INSTRUCTIONS) Your first question comes from the line of Chris Shott with JPMorgan.

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**Chris Schott** - JPMorgan Chase & Company - Analyst

I have a couple of questions. First, just to clarify, did you mention your plan was to maintain the 2008 EPS guidance prior to the SEAS study result released today?

And then second on GARDASIL, the cuts to the guidance, what age group specifically was driving a bulk of the clients here? It sounds like the trends with the 13 through 18-year-olds was particularly surprising. Is that a fair statement?

And then are you factoring in any impact from some of the adverse event kind of media publicity we've seen kind of scattered throughout this month on GARDASIL? Thank you.

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**Dick Clark** - Merck & Co., Inc. - Chairman, President, CEO

Chris, for your first question, before the SEAS announcement, we were going to reaffirm our guidance for 2008. That is correct.

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**Ken Frazier** - Merck & Co., Inc. - EVP, President Global Human Health

And on the GARDASIL questions, the cohort I think that we've seen the most difficulty with is the 19 to 26-year-old cohort, and then that's for a couple of reasons. As I mentioned before, trying to get action among these women, even when you can drive high levels of awareness, has proven more difficult than we anticipated.

In addition, these women primarily visit PCPs and OB/GYNs who are not typical routine vaccinators and who, in many cases, have no established infrastructure for routine vaccination of this age group. In addition, there is some lack of consistency around benefit design with a portion of these women, which causes additional confusion with their physicians, despite the fact that they're high levels of these women who have some coverage if they are privately insured.

So the biggest issue for us has been with the 19 to 26-year-olds although I also mention that given the high cumulative strong utilization we have in the 13 to 18-year-olds, continued growth will also require substantially higher penetration rates among those remaining to be vaccinated.

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**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Cara, next question, please?

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

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**Operator**

Your next question comes from the line of Tim Anderson with Sanford Bernstein.

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**Tim Anderson** - *Sanford C. Bernstein & Company - Analyst*

Thank you.

Can we get an update on the ongoing SINGULAIR safety review by FDA in terms of when we might learn more and really what are the chances that something could blow up here because this is obviously a very key and high margin product for you?

And then of SINGULAIR sales, can you talk about what percent goes to a pure allergy indication versus a pure asthma indication versus concurrent disease?

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**Ken Frazier** - *Merck & Co., Inc. - EVP, President Global Human Health*

Well, we can't obviously predict what the FDA will do. We are in the process of interacting with the FDA now and providing that information to the FDA.

As for the relative breakdown of asthma and allergic rhinitis, we do not generally provide that information so I can't provide that.

I also, I noticed that in response to the last question, I did not respond to the question about whether or not GARDASIL sales were anyway impacted by the most recent publicity around adverse events. We are aware of that. We are monitoring that.

I can't say that that has not had had an impact. We hope that that impact will not be a substantial one going forward, but it certainly is an issue that we're contending with now.

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**Eva Baretto** - *Merck & Co., Inc. - VP Investor Relations*

Cara, next question, please?

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**Operator**

Your next question comes from the line of Barbara Ryan with Deutsche Bank.

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**Barbara Ryan** - *Deutsche Bank - Analyst*

Chris sort of had my question, thank you, but maybe if I can just expand a little bit. I think, Dick, when you did start out, you said that you were ready to reiterate guidance until the SEAS results came out, and I'm just wondering beyond 2008, I would imagine that the growth outlook would be somewhat impeded by the shortfall in GARDASIL, maybe that's not the case.

I can see adding up the various pluses and minuses in 2008, how the guidance on GARDASIL could be offset with tax rate, lower spending, et cetera, but on a longer-term basis, is that a fair assessment on GARDASIL?

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

**Dick Clark** - Merck & Co., Inc. - Chairman, President, CEO

Yes, first of all, Barbara, when you look at 2008, you're right. There are many other things that are going right, as Ken and Peter were able to tell you, and we continue, obviously, to surprise ourselves when we look at our new operating models for the major parts of the Company and what impact we're having on flexibility and expenses and to be able to drive that to something that meets our expectations, in many cases it exceeds it. But we also look at where we are from when putting our long-range plan together for 2008, 9 and 10 and what we had to commit to in order to get to double-digit growth and where we actually are with some of the other products, which is very, very positive.

The comment I'll make about GARDASIL it's still that although there is obviously a delay in the penetration for those cohorts, we have not lost that market share to a competitor, so it's our ability to bring that home within 8, 9, and 10. And so when you bring all of these factors into play, until we evaluate the SEAS activity, I would have been very comfortable with 8 as well as 10.

**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Okay. Thank you. Next question, please?

**Operator**

Your next question comes from the line of Roopesh Patel with UBS.

**Roopesh Patel** - UBS - Analyst

Yes, thank you. I have a couple of questions on GARDASIL.

I look at the revised guidance for this year, it implies that second half sales will decline year-over-year somewhere between 5 and 27%, and I'm curious as to when you expect the drug to resume growth and what the drivers will be.

Secondly, what's the estimated penetration that you've reach in the U.S. in the two age groups, the 13 to 18-year-olds and then 19 to 26-year-olds?

And lastly, given the challenges experienced with penetrating the 19 to 26-year-olds, what do you believe the Company will have to do differently when it gets approved for adult women 27 to 45 year olds? Thanks.

**Ken Frazier** - Merck & Co., Inc. - EVP, President Global Human Health

Okay. I'll try to get all of those, I'll try to work backwards on those.

I think that as we deal with older populations, including adult women, we obviously will be dealing with very different populations than we did with adolescent girls. What we found in the adolescent population was that our efforts to motivate the primary actors, in that case largely mothers of young girls as well as pediatricians, was something that our earlier efforts were relatively successful and that created a very large uptake in the first year.

I think as we deal with older populations we're going to have to find strategies that we are in fact defining and working on strategies that allow us to communicate what is clearly a valuable therapeutic offering to those women as well as the doctors and get people to begin acting on it when they have that level of awareness. So that is the challenge.

As for the question of what's the relative penetration in cohorts, that's not data that we provide and so I can't answer that, and so I think the last question was when and how do we expect to see growth resume later in this year. I think that goes back to

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

what I said, which is that we have a number of programs in place to address some of the primary concerns and barriers that we've experienced in the market, particularly for the 19 to 26-year-olds.

They include financial issues that affect the physician as well as actions that are intended to drive more action among our young adult females, including new consumer DTC campaigns that are aimed directly at young adult women, and we think those are the kinds of things that we'll have to do in order for us to drive greater awareness during the course of the year.

We have distributed a significant number of doses. I would say the penetration has been 30 million worldwide and 18 million in the U.S., so we have done relatively well and we continue to believe that there's a lot of opportunity out there.

As Dick said, we are the sole source for a number of these vaccines, GARDASIL, ZOSTAVAX, VARIVAX, and the fact that our current demand is less than anticipated is something that leaves us a great opportunity going forward to penetrate in the future, because you have more of an opportunity in fact because you haven't penetrated as much now. I don't say that by way of excuse. I just say that's the challenge before us and that's the challenge that we're taking on.

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**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Next question, please, Cara?

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**Operator**

Your next question comes from the line of David Risinger with Merrill Lynch.

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**David Risinger** - Merrill Lynch - Analyst

Yes, hello. I have a couple of questions.

First of all, with respect to the vaccine supply constraints in the second quarter, can you just help us understand what the sales constraints were and what level of improvement will occur as a result of the FDA okaying the facility? And I guess just to follow-on to that, are there any manufacturing overhangs ongoing? So that's my first question.

Second, can you just explain the surprising tax settlements in the second quarter that yielded your lower tax rate guidance for the full-year of '08?

And then third, with respect to going back to the manufacturing issue, I think your press release said that there won't be any limitations on filed vaccine supplements that are pending approval. Could you just run through what those filed vaccine supplements are? Thank you.

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**Peter Kellogg** - Merck & Co., Inc. - EVP, CFO

So David, first, this is Peter.

Let me take the tax item first then we'll get into the manufacturing topics. So, as you know, FIN 48 is the accounting standard referred to as accounting for uncertainty in income taxes, and what it requires is the Company to determine whether the benefits of a tax position are more likely than not of being sustained upon audit so based on the technical merits of the tax position. So for all of our tax positions around the world, we do set up for the appropriate ones, we set up a FIN 48 tax reserve and so that's on our balance sheet, and basically, as we go through and resolve certain tax positions with different authorities through audits and whatnot, either those reserves turn out to be appropriate or not.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

What happened in the second quarter was we did finish a few different tax audits and reviews at different times prior year filings and overall we came out very favorably versus what we had on our balance sheet for the FIN48 reserves. And so the way it works is once you have clarity on that and you've made the settlements and you make the payments then you go back to the reserve and if you have reserves in excess of what were called for, you release that and so that's what we got the benefit for in Q2 is the release of certain reserves that turned out, in hindsight, to be a little bit conservative but at the time we made them we thought they were appropriate but we turned out to do better under audit than we anticipated.

So that's what FIN 48, that's what the tax benefit was in Q2. It's a one-time item for those particular items. It really doesn't have any recurring nature going forward except that the way the overall effective tax rate is calculated.

So moving then to the manufacturing topics, I'll let Ken and Dick handle those.

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**Ken Frazier** - Merck & Co., Inc. - EVP, President Global Human Health

So the question was to what extent were issues in the effective quarter relative to our vaccines, the product of supply interruption. So as it relates to certain vaccines as you probably know, we've stopped taking orders temporarily for pediatric and adult vial formulations in fact as well as our (inaudible) containing vaccines.

As it relates to VARIVAX, we did have supply adequate to meet the demand in the second quarter of '08 and now that we've resolved the supply situation for VARIVAX, we're working with our customers in the private and public sector to continue to increase second dose immunizations for the catch up cohort through the rest of 2008.

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**Dick Clark** - Merck & Co., Inc. - Chairman, President, CEO

And concerning supplements we have at least two supplements with the FDA concerning GARDASIL and they will move through the process.

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**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Cara, next question, please?

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**Operator**

Your next question comes from the line of John Boris with Citi. Mr. Boris, your line is open.

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**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Hello? Next question, please?

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**Operator**

Your next question comes from the line of James Kelly with Goldman Sachs.

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**James Kelly** - Goldman Sachs - Analyst

Thank you and good evening.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

My question has to do with the progression of gross margins. In this quarter where, I'm just really interested I guess, Peter, in some of the pushes and pulls on gross margins.

I would think that given the royalty burden on a product like GARDASIL and the way that that one has been trending, one, that that could have lead to a higher set of gross margins for this quarter, but two, it could also have upward pressure on the gross margin guidance for the year. So could you give us some thoughts on some of the other important pushes and pulls and if I have that other one correct that would be great. Thank you.

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**Peter Kellogg** - Merck & Co., Inc. - EVP, CFO

Sure. So you're right. I mean, when we go to PGM, I just want to make sure, your premise is (inaudible) right there's a lot of different pushes and pulls, product mix and so forth so it is sort of a weighted average effect.

I think that, as I mentioned on the call, the PGM line had really just some product write-offs as well as some restructuring charges as well in the quarter, so there are a couple different effects. Overall, I think that PGM, we've done very well in the way we've, the team, the manufacturing organization and global operations have worked on their cost structure and, obviously, that comes into a couple different ways that one is just the overall amount of overhead that goes into our PGM, but also the efficiencies with which we manufacture.

As we provide guidance, obviously, we're always within the ranges that we're giving guidance and it's going to move around a little bit, but in general, that's what we do when we do the forecast. The team works through kind of what the pushes and pulls are, exactly (inaudible) and what the run rates are and what the trends are, so we're very comfortable with our guidance and we don't like to make it a nervous guidance so we don't move it around by 0.3s and 0.4s but we stay within that range.

But, yes, you're right. The product mix could have a slight impact over time, but at this point we feel pretty good about the guidance we have out there.

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**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Cara, next question, please?

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**Operator**

Your next question comes from Tony Butler with Lehman Brothers.

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**Tony Butler** - Lehman Brothers - Analyst

Thanks very much.

Ken, you made, at least by my estimation, some slightly incongruent comments regarding GARDASIL in that you stated that in this particular quarter, the 19 to 26-year-old population being treated by OB/GYNs who do not normally vaccinate, actually might have had an effect on the overall demand, and yet, you also stated, or perhaps Peter stated, that the change in full-year guidance was affected because the timing of the over 26 population did not occur when you anticipated. Again, I would assume that's an OB/GYN population so I guess I'm just looking to reconcile that especially when I had the impression that you were likely throwing some refrigeration units into those OB/GYNs, realizing that they're not the primary population of physicians who tend to be historically vaccinators.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

And then as a second question, I might think, you know, candidly much like myself, the JV or the VYTORIN/ZETIA sales folks are pretty battle worn and battle scarred from the full-year, so I'd be interested, Dick, if you might be able to provide a couple words on how you think about resurrecting their energy especially given a lot of the bad information that seems to be hitting them in the face going forward. I appreciate the time.

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**Dick Clark** - Merck & Co., Inc. - Chairman, President, CEO

I'll start with the VYTORIN/ZETIA joint venture question. I think you begin the discussion around leadership. We have an outstanding leadership team in place in the joint venture and it is an experienced team that's been through marketing and sales battles before with competition and we make sure that we get in the right support as a joint venture.

I know that Schering-Plough and (inaudible) do the same and they like the competition and they like the challenge, and the major reason is because they believe in the products. They are good products and they are important products in order to reduce cholesterol and to help people with cardiovascular risk moving forward.

And so with that as a part of it, it's an important mission and we've got some of our best people in there and although this is a very difficult time, I have a tremendous amount of confidence in their capabilities and when you see some of the mistruths that were spoken particularly around the ENHANCE, that makes us even more engaged in order to get the right information to physicians so they can make that decision. And so we hear a lot of passion about our products from the joint venture and certainly you heard a lot of passion on the call today from chief investigators.

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**Ken Frazier** - Merck & Co., Inc. - EVP, President Global Human Health

With respect to GARDASIL, let me start by clarifying that for the populations over the age of 26, given the original July PDUFA date and our original assumptions around the timing of an APIP vote for this cohort, we had only forecast a partial year contribution for this population. So I think that might have been what we alluded to earlier was that that contributes to some of the difference in what we thought we would do this year.

But the predominant issue coming back before is the challenge that we have with respect to the penetration rate for 19 to 26-year-olds. And what I was trying to say there is that while compared to historical norms, penetration remains high across all the established GARDASIL age cohorts that we have stronger uptake for girls 11 to 18 than we do for the 19 to 26-year-olds.

And there, the uptake is not nearly as high and the issues are more diverse and they include challenges in getting those women in translate the awareness into action, making it relevant for those people to want to come in and demand vaccines. But the other issue is getting OB/GYNs who are not typically vaccinators to adopt that as a business model and to strongly recommend this to their patients.

So we are dealing with issues with respect to the 19 to 26-year-old women, with respect to their physicians, we're dealing with financial issues that their physicians and their offices are encountering and we're trying to change the behaviors and the attitudes across there. We believe we can. As I've said, I try to be very candid in saying that we clearly underestimated the difficulty of it but we have lots of programs in place and we're going to continue to get after that.

It's a great vaccine. Physicians believe in the therapeutic promise of the vaccine. We've just now got to get them to a place where universal same-day vaccination is the standard of care for those OB/GYNs as it is with pediatricians.

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**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

Okay. And just a note. Given the time we'll take one or two more questions. Cara, please, next question?

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

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**Operator**

Your next question comes from the line of Catherine Arnold with Credit Suisse.

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**Seamus Fernandez** - *Leerink Swann & Company - Analyst*

Thank you very much.

Dick, I was wondering given the substantial focus by investors on the 11-12 horizon and despite the near-term challenges that you need to face, are you still considering giving longer-term guidance at your December analyst meeting? Is that something we can look forward to?

And on a more micro level I just wondered if you could comment on the ZOSTAVAX performance? It seems it has declined sequentially and we haven't seen that in the United States. I wondered if you could comment on that for me? Thanks.

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**Dick Clark** - *Merck & Co., Inc. - Chairman, President, CEO*

Sure. As I mentioned in my talk, we are coming out of our strategic planning meeting where we looked at several initiatives to increase revenue growth during the period particularly with SINGULAIR going off the patent and the ability to change our operating models in our three divisions, even more significantly than we did with our first "Plan to Win". So I'm not in a position yet to evaluate what impact that has giving guidance to that period we have to discuss that and certainly with have teams working on that.

What we're focused on now is to be able to get back to you as quickly as I can for 2008 and '10 guidance is my first step and that's our priority. But I can tell you I was extremely encouraged with the week strategic planning meeting we had where we focused on 11 to 16 and we're evaluating that now.

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**Ken Frazier** - *Merck & Co., Inc. - EVP, President Global Human Health*

As it relates to ZOSTAVAX, as we've pointed out, due to the supply issues that had existed with varicella containing vaccine, we prioritized VARIVAX particularly to insure that we had a supply to support the second dose vaccination recommendations. As a result, we were not in the same way publicizing or promoting ZOSTAVAX. So I think if you look at the patterns around ZOSTAVAX, they're not as reflective of the product's potential as they are the priorities being given to VARIVAX.

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**Eva Baretto** - *Merck & Co., Inc. - VP Investor Relations*

Okay. And we'll take our final question.

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**Operator**

Your final question comes from the line of Seamus Fernandez with Leerink Swann.

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**Seamus Fernandez** - *Leerink Swann & Company - Analyst*

Thank you very much.

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

So, just hoping that you could provide a little bit more clarity on maybe the elements that drove the \$700 million reduction in the equity income that you chose in the first quarter so that we have something off of which to base the incremental guidance that you are expecting to provide to us in the near future.

And then second, can you just help us better understand ROTATEQ had a strong quarter, \$178 million in global revenue. Was there any stocking in the quarter for ROTATEQ and also, how do you plan to defend against GlaxoSmithKline's Rotarix since in the second quarter, the ACIP recommended for harmonization of the two products? Thank you.

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**Peter Kellogg** - Merck & Co., Inc. - EVP, CFO

Okay. So let me, this is Peter.

Let me get started on the equity income line because there's a couple moving parts as you have indicated in the question. So, the first thing is, as I said earlier, the Merck/ Schering-Plough joint venture was down 22%. Now the one thing to remember was there was a charge of \$43 million of expense in the quarter related to the termination of the respiratory joint venture, and so that \$43 million is an expense that occurred in Q2 and then after that, we will be amortizing the balance which is \$62 million over the remaining life of the franchise of the IP for ZETIA which goes out 2016 so we won't have a charge like that as big as \$43 million going forward it'll be a lot smaller.

Obviously, I think that I am very impressed by how accurately and closely everybody tracks the VYTORIN and ZETIA scripts so I have no doubts that you can respond to that and do forecasting off of those trends as well as we see those emerge, but I don't think there's anything unusual otherwise in the joint venture performance of Merck/Schering-Plough. And as Dick said before, I think we, I just want to reiterate, we have enormous faith in that organization and that team, very seasoned team to come out fighting in the second half of this year.

Related to the AstraZeneca joint venture, which I will acknowledge is a lot more complicated, the equity income, the income was \$154 million lower than Q2 last year. And as you go back to your notes you'll certainly remember there's a lot of moving parts because of the way we went through the joint venture restructuring towards the end of the first quarter this year, and some of the pieces of that were that the priority return actually decreased to \$55 million per quarter from what had been roughly \$55 million per quarter in that neighborhood, from what had been closer to something like \$75 million per quarter, that was one change.

Another is that we used to receive 10% royalty on the Astra USA products and we don't receive that, again, going forward.

And then the third one, which I alluded to, is that there is inherent variability in the timing of how we received payments from AstraZeneca and there was a significant change to that effect in the second quarter, and that created the volatility downside in the second quarter that we don't expect to see recurring, hopefully like that, but there is always some volatility in the bouncing around of those numbers. So in terms of going forward, we think that Q2 was overall weaker because of that volatility but the other items become part of the new trend.

So hopefully that gives you enough to work up some estimate on it, but certainly, at the bigger impact was on the volatility this quarter. Ken?

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**Ken Frazier** - Merck & Co., Inc. - EVP, President Global Human Health

As it relates to ROTATEQ, in the second quarter we recorded revenue of about \$13 million that was attributable to the CDC stockpile and we do have a competitor now in the U.S., but we feel it had no real impact in the second quarter. And we continue to be extremely confident in ROTATEQ as far as how it's going to perform in the U.S, with over 75% of the U.S. birth cohort now

Jul. 21. 2008 / 5:30PM, MRK - Q2 2008 Merck & Co., Inc. Earnings Conference Call

being vaccinated with ROTATEQ, and we're also pursuing a systematic thoughtful approach to the global introduction of ROTATEQ.

So we continue to have great confidence in that vaccine going forward and we think the ACIP recommendation will be extremely positive for ROTATEQ going forward. So that would be my response.

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**Eva Baretto** - Merck & Co., Inc. - VP Investor Relations

That last question concludes today's conference call. The information from today's call, both the transcript and replay, will be available at our Web site for the next several months and Mike Nally and I will be available to take your calls and any incremental questions. Operator?

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**Operator**

That concludes Merck's second quarter 2008 earnings conference call. You may now disconnect.

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