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Conference Call Transcript

MRK - 4Q 2008 Merck & Co., Inc. Earnings Conference Call

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PRESENTATION

Operator

Good day everyone, and welcome to Merck's fourth quarter 2008 earnings conference call. Today's call is being recorded. At this time, I'd like to turn the call over to Ms. Eva Boratto, Vice President of Investor Relations. Please go ahead.

Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

Thank you, Taylor ,and good morning. Welcome to our call to review our business performance for the fourth quarter 2008. Joining me on the call today is our Chairman, President and CEO Dick Clark, Ken Frazier, our Executive Vice President and President of Global Human Health and Peter Kellogg, our Executive Vice President and Chief Financial Officer. 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 7:30 this morning. You can access this through the Investor Relations section on merck.com, and I would remind you this conference call is being webcast live and recorded. The replay of this event will be available later today via phone, webcast and podcast. As we begin our review, let me remind you that some of the statements made during this call my 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 management's current expectations and involve risks and uncertainties which may cause results to differ materially from those set forth in these statements The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and 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 10K for the year-ended December 31, 2007 and in any risk factors or cautionary statements contained in the Company's periodic reports on form 10Q or current reports on form 8K which the Company incorporates by reference We will begin the call with brief remarks from our senior management and then open the call for your

questions, and expect the total call to last approximately an hour. With that, I'll turn the call over and we'll begin with remarks from our Chairman, President and CEO, Mr. Clark.

Richard Clark - Merck & Co., Inc. - Chairman, President, CEO

Thank you Eva, and good morning, everyone. Earlier this morning, we announced results for the fourth quarter and full year of 2008. The solid financial results we reported today reflect both the challenges we faced in 2008 and the benefit of our broad product portfolio. In 2008, we improved efficiencies, managed through a dramatically changing industry environment and took actions designed to better position Merck for success. And we did so during a very difficult and unsettling time for the US and global economies. In terms of top line for the full year 2008, we recorded revenue of \$23.9 billion, 1% lower than 2007. Excluding the impact of the loss of marketing exclusivity for Fosamax in 2008, revenue increased by 5% for the full year. Our full year 2008 non-GAAP earnings per share were \$3.42 which excludes certain items. While our full year GAAP EPS were \$3.64, reflecting the excellent progress we've made in improving our cost structure and strong growth in key products, Januvia, Janumet, Isentress and RotaTeq. Today we are also confirmed our top and bottom line expectations for the full year 2009. Non-GAAP EPS we expect to be in the range of \$3.15 to \$3.30, excluding anticipated restructuring charges and for 2009 GAAP EPS, in the range of \$2.95 to \$3.17. For full year revenue, we continued to expect to be in the range of \$23.7 billion to \$24.2 billion. But based on what we see at this early point in the year, we think revenues are likely to be in the lower half of that range. Peter will be walking you through some additional details on 2009 guidance and 2008 results a bit later on today's call. Also in a few moments, Ken will review the performance of our key products as well as our expectations for them. They'll talk about Gardasil and the impact on revenue with the delay in the FDA approval in adult women indication. Now let me make a few observations about 2008. We were pleased with the stand up performance of innovative Merck medicines like Januvia, Janumet, Isentress and RotaTeq in 2008. We have designed our franchise operating models to manage the entire lifecycle of our products, and they have enabled us to maximize the value of more established products such as Cozaar, Hyzaar and Fosamax. Clearly, results for Singular and Gardasil were not where we would have liked them to be. Ken will discuss their performance and improvement actions we have underway.

Next, I'd like to share a few thoughts on the progress we've made in transforming Merck in 2008. We continued to move away from outdated commercial and business models to a new, more effective and efficient way of operating. We've moved forward with a new approach to customers through our commercial models and with reengineering our basic research global operations and our new clinical development model. Those efforts are helping to make us leaner, more agile and better positioned for the long term. By focusing on our core strengths, the new Merck we are building will maximize the value of our current product portfolio and our pipeline. That will enable us to pursue growth through initiative such as Merck BioVentures in emerging markets, as well as taking advantage of the right strategic opportunities. In 2009, we are building on the progress we've made in taking our supply chain management to the next level using Lean Six Sigma. We are on track in the United States to implement an SAT information technology system. That is the key step in fundamentally changing how we run this Company. Merck's overall financial strength, especially during these difficult economic times is an advantage that enables us to pursue the important work of transforming our Company. Let me move next to our global restructuring efforts. More than just reducing Merck's cost structure, our restructuring initiatives are creating a leaner and more flexible company that is appropriately sized and scaled for the new pharmaceutical operating environment.

In 2008, we completed our 2005 restructuring program, and we are on track to realize total cumulative savings of approximately \$4.5 billion to \$5 billion by 2010. Our 2008 restructuring plan is well underway, and we continue to expect the effective yield of cumulative pretax savings of \$3.8 billion to \$4.2 billion from 2008 to 2013. As a result of our restructuring programs, Merck had approximately 55,200 employees at the end of year 2008, a 10% reduction compared to the 61,500 we had at the end of 2005. We achieved this reduction while at the same time continuing to hire employees within the new skills and expertise we need to achieve our long term strategic goals. We've made significant progress streamlining all management layers across the Company since we announced the effort last October. At that time, we outlined plans to reduce our total number of senior and mid-level executives by approximately 25%. Those plans are on track. Let me also emphasize that lowering our cost does not come at the expense of supporting our key products in the marketplace. We are fully supportive of our key brands and are continuing to invest in our pipeline. During 2009, we expect to file NDAs for three promising candidates in Phase III that address patient needs in the treatment of migraines, acute heart failure and lipid management. In fact, Merck's pipelines includes nine Phase III programs continuing in 2009 and nine new Phase III programs anticipated to start this year.

Finally, I want to comment on vaccine manufacturing. As I mentioned in December, one of our top priorities is addressing supply issue for our vaccines. Merck is responsible for inviting many of the pediatric, adolescent and adult recommended vaccinations in the United States, and we take this job very seriously. While vaccine manufacturing is inherently complex, we are prioritizing our vaccine production based on the public health needs. We regularly communicate with customers, public health agencies, professional societies about the status of our vaccines. We make sure they know where are returning to normal shipment times as well as when we are experiencing shortages or delays. In addition, we routinely update our customer website to communicate comprehensive information on a timely basis. Finally, I want to note that we are investing nearly \$1 billion to help ensure we have consistent robust manufacturing practices and processes that meet existing demands for our vaccines as well as

expand our capacity to meet demand for the next generation of vaccines under development. While we are focused on building a Company that will be a tough competitor in the environment that is very different than the one we have known, we are being very careful to protect the values that have long distinguished Merck. Meanwhile, as these harsh economic times continue in the US and around the world, our customers, including patients, payers and health care providers are likely to feel the effects in one way or another. Just about all economic forecast data, the United States is a prolonged period of unemployment, and high unemployment means a rise in the number of people without health insurance. That's why we are already engaged with the new administration in Congress to support reform of this country's health care system. And outside the United States where most people still lack adequate access to medicine, vaccines and health care, we continue to work independently and in partnerships to improve access to our products. In closing, I want to emphasize that as we move ahead in 2009, the level of determination and energy throughout our organization remains high. Our employees are the most talented, dedicated people in this industry. They clearly understand the new era for pharmaceutical companies is here today. We strongly believe Merck has what it takes to succeed in the world that places great value on the scientific innovation that continues to be the hallmark of this Company. Now I'd like to turn the call to Ken and then Peter to summarize results. After their brief remarks, we'll take your questions. Ken?

Kenneth Frazier - Merck & Co., Inc. - EVP, President

Thanks, Dick and good morning, everyone. As we move into 2009, we must overcome the lingering effects of last year's business challenges to some of our key products, capitalize on new opportunities, all the while continuing to implement our new commercial model. As we announced today, overall revenue was down 3% in the fourth quarter 2008 and 1% for the full year. Excluding the impact of the loss of marketing exclusivity for Fosamax in 2008, however, revenue increased 5% in the fourth quarter and the full year. The increase in revenue in the fourth quarter, excluding the impact of Fosamax, was driven by strong growth for a number of our recently launched products, including Januvia, Janumet and Isentress. And we also achieved strong growth for Zostavax as we cleared the majority of back orders. Outside the United States, our reported revenue grew 5% with strong volume increases of 10% thanks to continued launches of new products and strong performance for many of our in-line brands. As we saw in the first three quarters of the year, our revenue growth internationally was offset by continued challenges for driving demand for Singulair and Gardasil in the US. Our overall US business, along with that of others in our industry, may have been effected by general slow down in prescriptions for newer medicines. In addition, supply shortfalls of some of our vaccines during 2008 and the year-over-year effect of clearing Varivax back orders in the fourth quarter 2007 also contributed to the sales decline.

Before I get into the details of the performance of some of our key products, I'd like to comment briefly on the current global economy as it relates to our business. At this point, it is difficult to determine whether, and to what extent, the economy could have impacted our 2008 performance. However, many patients, providers and payers around the world are facing difficult choices about spending which could affect health care utilization at the macro economic level and could also affect individual brands as well. We will continue to monitor these trends closely and factor them into our activities and our guidance. Now moving to performance of our key brands, beginning with Gardasil, our HPV vaccine. Sales as reported by Merck in the fourth quarter were \$286 million, a 16% decline when compared to the fourth quarter of last year. In the US, sales declined 19% and ex-US sales declined 2%. The ex-US sales decrease was attributable to a decline in Australia because a significant portion of the female population was vaccinated in previous years as part of a publicly funded vaccination program. In addition, sales of Gardasil in our SPMSB joint venture in Europe decreased by 26% versus fourth quarter '07 to \$171 million. This is due to a slow down in demand in large early adopting markets like Germany. Other later adopting markets will continue to grow and we will compete for new government tenders in 2009.

The fourth quarter decline for Gardasil in the US was effected by three factors. First, as expected, because of the broad use of Gardasil since launch, the total number of 11 to 18 year-olds who have already been vaccinated has increased. As a result, despite continued vaccination in this age group, the overall number of first dose vaccinations of 11 to 18 year-olds has declined. Second, also as one would expect, there were fewer second and third dose vaccinations in the fourth quarter because there were fewer first and second dose vaccines administered during the previous two quarters of 2008 when compared to the same period in 2007. Third, because of continuing challenges to vaccinated the 19 to 26 year-old age group, we observed a decline in total vaccinations during the past quarter compared to the fourth quarter of 2007. I'll remind you that 2007 was the first full year of launch and vaccination rates included the impact of early adopters who were not deterred by some of the barriers of vaccination for their segment. As I mentioned in December, we learned that OB/GYNs believe that they have vaccinated a significantly larger percentage of their patients than their actual vaccination rates indicate. As a result, we are implementing programs to make OB/GYNs aware of the actual vaccinations rates of their practices. Our customers appreciate this initiative as they continue to believe in the importance of their vaccine. Here are some other examples of some of the programs we have underway. Approximately 6,500 OB/GYN and primary care offices have enrolled in the dose replacement program with we launched 2Q 2008 to address their reimbursement concerns. In the first two to four months since enrollment, we've observed an 8% to 10% lift in sales at these locations versus other locations. Our in office patient outreach program for physicians and unvaccinated women and parents of eligible females has enrolled more than 8,000 offices and is distributing 2.5

million patient mailers. This program rolled out in September 2008. Lastly, more than four million enrollees in managed care plans have been informed about coverage of Gardasil.

We've learned much more about the practice related and financial challenges affecting vaccination rates, especially for 19 to 26 year-olds. The opportunity is still there. Our research indicates that most of these woman may be receptive to vaccination. In fact, less than 10% have decided not to be vaccinated. While early indications suggest that our programs are beginning to have an effect, the issues they are designed to address are complex and vary from practice to practice. We believe that is why we've not yet seen an impact on vaccination rates overall. In the 11 to 18 year-old group where high vaccination rates have already been achieved, we continue to work with pediatricians and family practitioners to reach patients -- parents, excuse me, whose daughters have not yet been vaccinated. As you're all aware, in January, we received a second complete response letter from the FDA to the application and the use of Gardasil in women age 27 through 45 and based on that letter, we now anticipate responding to the agency in the fourth quarter of 2009. As a result of the delay in the approval and the decline in vaccination rates among 19 to 26 year-olds towards the end of 2008, we are reducing our 2009 values to \$1.1 billion to \$1.3 billion. This guidance takes into account both the high level of vaccinations already achieved in the adolescent population as well as the challenges of substantially increasing vaccination rates among the 19 to 26 year-old population where the proportion not yet vaccinated is greatest. These challenges notwithstanding, opportunity remains for Gardasil, the millions of women not yet vaccinated in the 19 to 26 year-old population as well as the millions of males and adult women we expect to become eligible for vaccination with Gardasil over the next two years. I should note here that the FDA has accepted our application for use in males. We continue to believe in Gardasil's potential to drive revenue growth. We are fully investing in these programs and will invest in additional, innovative programs to drive demand for this product. Also, let me be clear that our overall cost reductions have not been, and will not be at the expense of fully funding the programs needed to help Gardasil realize its full potential.

Now, I'd like to take a moment to discuss Zostavax. Total fourth quarter sales as reported by Merck were \$162 million as we cleared the majority of back orders in December 2008. We are working with our customers to drive appropriate utilization for this novel vaccine. For example, we've implemented a patient notification service and pharmacy based outreach initiatives. Demand for Zostavax continues to be strong, and we currently believe we'll clear all existing back orders in the first quarter 2009 and that we will have normal shipping times sometime within the second quarter. Once the back orders are resolved, we expect to have adequate supply to meet anticipated US customer demand for the rest of 2009. We remain excited about the potential of Zostavax and we look forward to supplying this important vaccine to our customers. Turning to Singulair, sales in the fourth quarter were \$1.1 billion, down 3% versus the prior year. Performance in the fourth quarter reflects the decline in the US business of 11% which was partially offset by strong, 15% growth outside the US. Singulair continues to do well in Japan, for example, thanks to the successful launch of the allergic rhinitis indication and the introduction of the oral granule formulation for preschool age children. For the full year, the US performance for Singulair was effected by the availability of Zyrtec OTC, a smaller allergic rhinitis season in both the spring and the fall and the FDA early communication in March 2008. Merck is pleased that the FDA has now issued its follow up to its early communication on Singulair. Our sales force is prepared to provide appropriate information to health care practitioners about the FDA communication. Merck stands by the proven efficacy and safety of Singulair, a medicine that has prescribed to tens of millions of patients with asthma and allergic rhinitis for more than ten years. We're devoting significant resources to programs designed to improve performance and drive growth of Singulair in the US. Our sales force has new materials for use with physicians and Singulair remains a key priority as we roll out our new commercial model in the US early this year. We continue to utilize multiple channels for Singulair including new trial with coupon kits for new patients, educational materials, print, TV and online DTC, in office branded marketing programs, pharmacy programs and adherent initiatives. We have the resolve as well as the resources planned and materials to ensure Singulair remains the number one respiratory product in the US.

We are pleased with the performances of Isentress since its global launch in the fourth quarter of 2007. Sales in the fourth quarter were \$130 million, up 21 % sequentially versus the third quarter. In the US, fourth quarter sales were \$71 million and continue to exceed the last five margins in TRX market share through December. On January 30, the US Food and Drug Administration granted traditional approval to Isentress following review of the 48 week data from the benchmark one and two clinical studies. Isentress was originally approved under the FDA's accelerated approval process in 2007 with 24 week data. Isentress is currently approved in 70 countries, on six continents, including all top 10 HIV market. Overall, uptake has been strong and we look forward to continued success in 2009. Global revenues for Januvia and Janumet grew in the fourth quarter to reach \$532 million, up 11% sequentially versus the third quarter. In the US, Januvia continues to be the second leading branded oral anti-diabetic agent in terms of new prescription share. Despite the slowdown in the overall US diabetes market last year, the Januvia/Janumet franchise continues to grow in both volume and share and is the fastest growing family of products in the oral segment of that market. Januvia delivers strong once daily efficacy in a single pill without the compromises of weight gain and hyperglycemia associated with other oral diabetes therapies. Janumet combines Januvia with Metformin for powerful, unsurpassed efficacy. We have invested in new patient educational tools administered by diabetes educators around the US, and we have an innovative adherence program to help patients remain on Januvia and Janumet therapy. In addition, we were extremely pleased with the international performance of Januvia/Janumet in the fourth quarter. In the EU, these medicines are the fastest growing family of products in the oral diabetes market. Januvia is the only marketed DPP4 inhibitor that once daily for all indications. It is widely reimbursed and Janumet is gaining equally strong reimbursement status. In all markets where more

than one DPP4 exists, Sitagliptin is the market leader. Finally, India, Brazil and other emerging markets have enjoyed strong growth with this launch. Globally, more than 10 million prescriptions have been written to date, and as these products are major growth drivers for Merck in the short term as well as the long term, we were investing in them to ensure that we realize their full potential. As we mentioned at the annual business briefing, we have one new six dose combination product in Phase III development with Pioglitazone and we anticipate starting two new Phase III development programs this year, and extended release form of Janumet as well as a Sitagliptin/[Simpostantin] six dose combination. Now I'd like to take a moment to provide an update on the performance of our cholesterol JV.

Let me start by saying we are pleased that the FDA has completed its review of enhanced study and that their position remains that elevated LDL-C cholesterol is an important risk factor for cardiovascular disease. The agency goes on to say that based on currently available data, patients should not stop taking Vytorin or other cholesterol lowering medication and should talk to their doctor if they have any questions about Vytorin, Zetia or the enhanced trial. Our sales forces are prepared to provide appropriate information to health care practitioners regarding the FDA communication. Moving to performance, worldwide sales of Zetia and Vytorin as reported by the Merck Schering-Plough joint venture were \$525 million and \$549 million, respectively in the fourth quarter. Sales of Zetia were down 23% and sales of Vytorin were down 29% versus the prior year. Market share for Zetia and Vytorin in the US appears to be stabilizing. Outside the US, sales in the fourth quarter were flat relative to 2007 but were up 13% after adjusting for exchange. We continue to anticipate growth outside the US in 2009, excluding the effect of foreign exchange. We remain steadfast in our support for Zetia and Vytorin which continue to be valuable treatment options for physicians by helping to get more patients to their LDL goals.

Before I close and turn over the call to my colleague Peter Kellogg, I just want to mention that we are continuing to progress in our global rollout of new commercial models which are designed to respond directly to our individual customer's needs around the world. In the EU, many of our new models are already established. And in the US, we will expect to complete a national rollout in early 2009 after strong pilot results achieved last year. We fully expect this model will help us drive revenue growth for key franchises in markets while improving efficiency and customer value associated with all of our customer interactions. I look forward to updating you further about our progress in this important initiative in future calls. In closing, I assure you that the entire global human health organization is focused upon restoring growth in 2009 by continuing to address challenges with some of our key products and by capitalizing on opportunities with our customers. Notwithstanding the overall slow down in branded prescription growth for primary care brands in the US, Merck has a portfolio of medicine and vaccines that offer unique value to our customers, and we continue to believe that tremendous commercial opportunities exist to grow our established and our newer brands in markets around the world. We are confident that our continued focus on efficiencies on the marketing and administrative line demonstrated in 2008 will help drive overall margin improvements, and that the plans we have in place to fundamentally change our business model will enable us to better meet the needs of our varied customer base and to drive the top line for our medicines and vaccines. So with that, I'll turn the call over to Peter Kellogg.

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

Thank you, Ken and good morning. I will provide an update on the following.

Our fourth quarter and 2008 results and our 2009 guidance. Now for guidance, I will only highlight those elements of our guidance that have changed as we provide a breakdown of all the elements of our guidance in our other financial disclosure schedule attached to the press release issued earlier today. Merck reported fourth quarter non-GAAP earnings per share of \$0.87 representing growth of 9% over the fourth quarter 2007. On a GAAP basis, EPS for the fourth quarter was \$0.78. As Dick and Ken discussed, fourth quarter results reflect the blend of revenue performance, strong expense management and the favorable tax benefit. For the full year, 2008 non-GAAP earnings per share was \$3.42 representing a growth of 7% over 2007. On a GAAP basis, EPS for the full year 2008 was \$3.64. Turning to revenue, total revenue for the quarter as reported by Merck was \$6 billion. Total revenue for the year was \$23.9 billion.

Now, Ken already walked you through product performance, so I'll quickly just cover the guidance. As Ken shared with you, we are reducing our 2009 guidance for Gardasil by \$300 million to a new range of \$1.1 billion to \$1.3 billion. Moving in the other direction, we are increasing guidance for supply sale AstraZeneca by \$100 million to a new range of \$1.3 billion to \$1.5 billion, reflecting current market trends. We continue to expect 2009 revenue in the range of \$23.7 billion to \$24.2 billion. However, based on current information, it is likely that revenues would be in the lower half of that range. Our fourth quarter materials and production costs were \$1.5 billion which includes \$33 million for costs associated with the global restructuring program, primarily related to accelerated depreciation. Excluding restructuring costs in 2008 and 2007, material and production increased 1% in the quarter. Reporting PGM was 75.6%, excluding the restructuring costs, PGM was 76.2%. Just as in previous periods, these results reflect our final product mix, particularly driven by the patent expiry related declines from the Q4 US Cosopt/Trusopt expiry and the Q1 US Fosamax expiry. Marketing and administrative expenses with \$1.9 billion in the fourth quarter, an increase of 8% versus the fourth quarter of 2007. But let me provide additional perspective on that.

Included in the fourth quarter 2008 marketing and administrative expenses is an increase \$62 million to the Vioxx legal defense reserve. Included in Q4 2007 was a gain of \$455 million from insurance proceeds. Excluding these items in both 2007 and 2008, M&A expenses decreased 17% in the fourth quarter. The lower spending for the quarter and year is attributable to savings from our new commercial models Ken discussed and corporate G&A efficiency programs. We are benefiting from US sales force reductions completed in July and similar European sales force reductions during the year. We are also continuing to realize reductions in our administrative expenses as Dick mentioned earlier, particularly in some of the support functions. We have maintained a healthy amount of support behind our core and successful newer franchises. I'd also note that 2008 spending was reasonably steady throughout the quarters, highlighting consistent and steady investments. Full year M&A was \$7.4 billion, down 6% in 2007, excluding legal defense reserves in 2007 and 2008 and the \$455 million insurance arbitration gain recorded in 2007. Turning to research and development, expenses in the fourth quarter were \$1.4 billion, essentially flat versus fourth quarter 2007. When you adjust for the restructuring costs in fourth quarter 2008, Q4 R&D spending is down 7%. The fourth quarter year-over-year comparison is effected by the timing of research activities with third party collaborations. Now, if we continue to invest in late stage clinical trials and in fourth quarter, there was increased spending to support the development programs for our promising new drug candidates, among which [Ralafaline], Odanacatib 5LO, Anisotropy , as well as Januvia. For the full year, R&D expenses were \$4.8 billion. When you adjust for restructuring charges recorded in 2008 and \$325 million acquired research charge associated with the purchase of NovaCardia in the third quarter of 2007, R&D expenses grew 3%. We remain committed to fully funding core internal and external R&D, insuring the continued progress of compounds in all phases of development. Now let's turn to equity income.

In the fourth quarter, Merck recorded \$720 million of equity income. There were two major impacts in this result. First, the equity income contributions in the Merck Schering-Plough joint venture was down 30% or \$160 million as a result of Zetia and Vytolin market share losses in the US. Outside the US, sales in the fourth quarter were flat relative to 2007. However, if we adjust this international Q4 result for exchange, MSP sales increased 13%. Second, the AstraZeneca joint venture equity income was \$267 million, which is \$55 million higher in the fourth quarter compared to the prior year. This increase in equity contribution is attributable to the inherent timing variability of payments from AstraZeneca . Moving to other income and expense, that line for the fourth quarter was \$3 million of expense. This compared to \$567 million in expense in the fourth quarter of 2007, which included a \$671 million charge related to the resolution of certain civil government investigations. Excluding that charge, other income expense was \$107 million lower than the fourth quarter of 2007. The largest contributors to the year-over-year change is our balance foreign exchange translation loss and lower net income -- interest income as a result of the lower interest rates that we're all becoming accustomed to. Now moving to the tax line, Merck's fourth quarter GAAP effective tax rate was 14.7%. Excluding the impact of restructuring charges, the non-GAAP effective tax rate was 14.5%. These rates reflect first, the benefit of approximately five percentage points related to the favorable tax impact of foreign exchange rate changes during the quarter, particularly the strengthening of the Japanese yen. And secondly, a benefit of approximately three percentage points related to the US research and development credit which was enacted as part of the emergency economic stabilization act on October 3. The resulting full year benefit is recorded in the fourth quarter.

Now let's turn to other financial matters, and I'd like to take a minute to speak about Merck's overall financial strength. As you know, Merck maintains a strong balance sheet and a conservative investment policy. As of December 31, our current cash and investment portfolio totals approximately \$18 billion, which includes \$6 billion pledged as collateral for bank guarantees related to certain items including the Vioxx product liability settlement from last year. I also want to continue to emphasize that we have the financial strength to support our dividend, and we remain fully committed to maintaining it at the current level, while at the same time, continuing to fund our important investment priorities. So to summarize, in 2008, despite the loss of patent exclusivity for Fosamax and continued challenges in our Vytolin, Zetia, Singulair and Gardasil US franchises, we achieved solid EPS performance. We delivered non-GAAP EPS of \$3.42 for the year through aggressive expense management and strong growth in key products as Ken discussed, Januvia, Janumet and Isentress. However, it is clear that we did benefit from foreign exchange on a full year basis and various discrete tax items. As we look ahead to 2009, we reaffirm our non-GAAP EPS guidance of \$3.15 to \$3.30 and corresponding GAAP EPS guidance of \$2.95 to \$3.17. Please keep in mind as we think about the quarterly patterns, the Company continues to expect GAAP and non-GAAP EPS in the first quarter to be less than one-fourth of the full year EPS. In addition, the Company anticipates marketing and administrative expense and R&D expenses to be relatively equally distributed across the four quarters. We are reiterating our longer term guidance. We continue to have revenues will have a compound annual growth rate of 2% to 4% from 2005 to 2010, including 50% of the revenues from the joint ventures. Merck's GAAP reported sales, which exclude the 50% of revenues from joint ventures, is expected to have a compound annual growth rate of 1% to 3% from 2005 to 2010. Looking at non-GAAP EPS compound annual growth rate, we continue to expect it to be in the mid to high single digit range over the same time period, excluding certain items with GAAP EPS compound annual growth of double digits. Thank you very much, and I'd like to turn the call back to Eva. Eva?

Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

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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. Joining us for the Q&A session is Bruce Kuhlik, our Executive Vice President and General Counsel. At this point, I will turn it over to Taylor who will communicate the instructions for our Q&A format and introduce the first question.

QUESTION AND ANSWER

Operator

(Operator Instructions). We'll pause for a moment to compile the Q&A roster. Your first question comes from the line of Tim Anderson of Sanford Bernstein.

Tim Anderson - Sanford Bernstein - Analyst

Thank you, I have a couple questions. Just to be clear, on the revenue guidance for 2009, I'm wondering if you can rank order the elements of why that may be at the lower end of the range you gave just about two months ago. And then foreign exchange impact on total sales in fourth quarter was only a negative 1%, which I think was the lowest of all the drug companies reporting thus far, and I'm wondering why that might be the case. Last question on Zostavax, can you give us demand driven sales in the fourth quarter ignoring the filling of back orders?

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

Okay Tim, it's Peter. Let me take the first two and let me think about the Zostavax calculation here for a second. So, our comment related to the range for total revenue for the year really reflects the revisions to guidance that we provided for Gardasil, offset slightly by AstraZeneca. And then just some other trends that we're observing, and we're highlighting that as we rolled in two changes to the individual line items in revenue, we didn't change the full revenue guidance range, because we think there's actually -- it's actually very early in the year and there is a lot of -- is quite a range of healthy outcomes that could occur in light of different products. Certainly, we've gotten some good letters back from the FDA, and we've certainly gotten some interesting developments in the life cycle management as Ken has talked about. So -- but we primarily indicated the lower end because of most recent trends in some businesses, but most importantly, it is the Gardasil guidance revision. On foreign exchange, you're right. As you'll note in the attachment to four quar -- to the press release that our foreign exchange impact in the fourth quarter top line revenue was negative 1%. Now, that -- I really haven't actually checked all the other companies, but as you do know, we have a revenue hedging program at Merck that we roll in the hedges over time and obviously, as we saw the foreign exchange rates peaking, I'd say, in the first half of last year, we really wrapped up a lot of fairly good hedge positions. That has certainly helped us. I would say that we have -- that's not something that I would characterize as unusual or unique. We have an ongoing hedging program that we roll in the hedges over three years. It's based against the major currencies, and so perhaps that was the driver of why the foreign exchange rate impact for us made it appear a little bit less than other companies. I really can't comment on the other companies. Finally, for Zostavax, let me turn it to Ken.

Kenneth Frazier - Merck & Co., Inc. - EVP, President

Thank you, Peter. As I've mentioned, we're very pleased that we cleared the majority of backorders in 4Q '08, representing orders received in both 3Q '08 and 4Q '08. While we cannot estimate the amount of inventory at the provider level, we expect the volume of shipments in December will impact first quarter '09 purchases as provided resume normal order patterns. Prescriptions which represent a portion of the business for Zostavax showed 4Q '08 volumes at levels comparable to 4Q '07. And while it is difficult to estimate the total demand following the extended back order period in the second half of 2008, we consider this to be a positive sign of the demand for Zostavax. Thank you.

Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

Next question, please.

Operator

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

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Roopesh Patel - UBS - Analyst

Thank you. I've got three questions. First on the tax rate, the 500 basis points benefit this quarter due to FX, Peter, I was just wondering if you could kindly elaborate on that and clarify if this is just a one time benefit or if there is a (inaudible) 2009. Secondly, Gardasil international sales down sequentially, around 45% versus the prior quarter. Could you please elaborate on what's -- what explains this big deceleration? And lastly, on Verivax, if you could also just provide some color around its performance in the fourth quarter and what we should expect in 2009. Thanks.

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

Hi Roopesh, it's Peter. Let me take the first one on the tax, the five points of impact from the yen strengthening. So to summarize very quickly, I would view that -- I would anticipate that to be a one time event. We do see sometimes foreign exchange impacting our net monetary assets on our balance sheet. And sometime when certain movements occur, they can create a gain or a loss. And sometimes that loss, on a tax basis, does create a deduction on our tax return, so generally tends to be only in periods when the currency, such as the yen, a big currency such as the yen moves that significantly in a short period of time and creates a noteworthy gain or loss. In this case, it was a loss that was on a tax basis deductible. For the performance of Gardasil versus prior quarter, it was down 45%, so Ken, why don't I turn that to you?

Kenneth Frazier - Merck & Co., Inc. - EVP, President

So I think there are a couple of things. As we mentioned, it was the fulfillment of the Australian program and the product impairs, that's one issue. The Canada program was implemented in the third quarter of '08, but I think the real issue here that we're pleased about is that we see continued strong uptake in markets across Europe as well as reasonably good uptake as it relates to the comparison of market share. And I'll remind you that in those countries where both vaccines are reimbursed by the government and physicians have a choice, Gardasil has a share of 90% or greater in those markets. So we continue to be pleased with that. With respect to Varivax, in the fourth quarter '07, significant amounts of back orders for Varivax, about \$75 million were cleared. And when you adjust for those back orders, sales in 4Q 2008 were actually up 56%.

Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

Next question please.

Operator

Your next question comes from the line of David of Banc of America.

David Risinger - Banc of America Securities - Analyst

Thanks very much. I have operating, financial and R&D questions. First on the operations, can you discuss the SAP systems implementations? For many, many companies, they're often quite problematic, and can you explain your assumptions for being able to operate seamlessly despite the implementation? Second, in terms of your sequential quarterly outlook for the first quarter of '09, is there anything that you'd like to call out versus what you just booked in the fourth quarter of '08 that we should be sensitive to? And then third, with respect to Isentress once daily, can you talk about the registrational trial timeline including when you're disclose the interim look? Thank you.

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

I'll take the SAP question. We're really confident in what we're accomplishing with SAP, probably for several reasons. One is that we have spent a great deal of time in making sure that the planning takes place, that we have line executives involved in it, that we really do our homework in making sure that we're putting the right systems in. Quite frankly, we put a roll in place that we'll do no customization, and any customization that takes place with our SAP system has to be approved by me, and a lot of the systems that haven't worked as well as in the past have a lot of customization where it is very difficult to implement, but it's also very difficult to get kind of savings you're talking about. But probably most importantly, what we've been able to do so far is that we have run a significant pilot -- our first pilot in Mexico, and that went extremely well. We learned a lot from that pilot that we made improvements as we go to our next market. And we just completed at the end of last year a major pilot in Puerto Rico which included manufacturing and finance in our global human health from Puerto Rico. So it was a much larger project and pilot

than just Mexico, and that was just spectacular. In fact, the feedback we're getting is that may have been one of the best pilots ever in SAP to go live, and Ken and I and Peter spent a great deal of time in Puerto Rico celebrating with our team. So I think we have enough confidence that we've done two major pilots that work well, we've made improvements and the fact that we have line people involved and a significant amount of line people involved to go live in the United States gives us the confidence that we need.

Richard Clark - Merck & Co., Inc. - Chairman, President, CEO

So David, let me take the second question, which was your -- I think it was your financial sequential quarter question and you -- I think you asked basically, were there any items I'd like to call out going from Q4 to Q1. As I think about it, actually, yes. Probably quite a few. So let me rattle through a few that I would think about. First of all, last year, Fosamax went off patent in February in the US. So we did have some sales in the beginning of Q1 last year with prepatent expiry sales volumes and levels. Likewise, Cosopt, Trusopt went off patent in October of this year, so you should look at the impact of that in the fourth quarter and think about that for the first quarter this year. Obviously, some of that was in the fourth quarter already, and I think the same can be true about Fosamax, but as you look year-over-year, that would be important to think about. I mentioned several times that we are anticipating to see our expenses, both in R&D and sales and marketing, or SG&A, relatively be flatter as we go quarter-to-quarter and through the year. In the past, we've seen spikes in the fourth quarter, and we don't anticipate seeing those -- we didn't see them in 2008, we don't expect to see that again next year. I would highlight that if you look over time, clearly there has been seasonality in our revenue. We tend to see January as our weakest revenue quarter, so I would highlight that that would be something to factor into your thinking, although I'm sure your models already have that. We did indicate also that we're working through the PGM trends right now. PGM was a little softer in the fourth quarter, if fact, it was softer in the second half, but on a full year basis, next year, we expect to it return. That may not pop right back into place in the first quarter, but these are all things to think about. I think equally importantly, we did see tax benefits in the first half of this year as well as in the fourth quarter that I just discussed, and we would expect to return to the normal tax range that we would guide to on a full year basis in the fourth quarter. Those are things that come to mind. Obviously, I can't go through and give specific guidance, but those are things to -- factors to think about.

Kenneth Frazier - Merck & Co., Inc. - EVP, President

As it relates to Isentress in the once daily study that's underway, as you know, it started in the fourth quarter 2008, I can't say when we will be able to provide any data as it relates to that at the completion on (inaudible), but we do anticipate filing in 2011.

Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

Next question, please?

Operator

Next question come from the line of John Boris of Citi.

John Boris - Citigroup - Analyst

Thanks for taking the questions. Dick, I think you mentioned you'd like to take advantage of the right strategic opportunity going forward. Can you give some commentary or your thoughts on your appetite for large transformative deal versus smaller strategic type tuck-in acquisitions and what you mean by right strategic opportunity and then your commitment based on the amount of cash flow that you are throwing off your commitment to the dividend going forward. And then on Singulair, when do you anticipate that the FDA is going to come back to you on the review of your clinical data and on then on the litigation side on Singulair, I think you will be entering the courts litigating the patent on Singulair with Tava. How confident are you that the judge will issue an opinion by the 30 month stay expires?

Richard Clark - Merck & Co., Inc. - Chairman, President, CEO

I'm talking about strategic opportunities. As I mentioned over the previous few weeks, we are still very focused on strategic opportunities. Obviously, they would have to have shareholder value as we move forward. So it's not an event, just from an event standpoint. Concerning large scaled transactions, as I said before, I wouldn't rule anything out. I don't think in today's world any CEO can categorically rule out any type of

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transaction. There are opportunities across the whole spectrum that we look at, and the critical point again is the transaction has (inaudible) financial to deliver a value to our shareholders. So I think we're looking at the entire spectrum and quite frankly, an important part of how we look at them is the importance of the dividend and to make sure we continue to sport a strong dividend which has part of Merck's reputation.

Kenneth Frazier - Merck & Co., Inc. - EVP, President

On Singulair, as you know, we're pleased with the FDA statement today relating to suicidality and the absence of any real evidence of a connection based on this clinical data related to Singulair and suicide or suicidal behavior. We can't say or speculate on when the FDA will come forward with additional analysis of the data that's underway with respect to the entire class.

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

And this (inaudible), with respect to the patent trial, we still are scheduled to go to trial on February 23, and both parties have asked for a decision from the court before the stay expires on August 20, and based on the judge's history of decisions, we've got every expectation that he'll issue a decision before then and obviously, we would not expect that that would delay beyond the 30 month stay, and we have contingency plans in place in case it does.

Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

Given the time, we have time for about one or two more questions. Next question please?

Operator

Your next question comes from Chris Schott of JPMorgan.

Chris Schott - JPMorgan - Analyst

Great, thank you. Just a question on Gardasil. Sequentially, should we expect a step-up in US Gardasil sales relative to 4Q, which I'm thinking is relative to the patients getting their first and second doses over the summer, returning for the third shot? Second question on Gardasil, by your estimates, roughly what percentage of 11 to 18 year-olds at this point have received at least one dose of Gardasil at this point? And maybe just a final question with regards to a larger-- within a large M&A transaction as to this space, just two points on that. First, do you see further opportunity on the cost side as we see what appears to be an accelerating trend towards cuts across the industry? I know you've done a lot, but is there more opportunity? And then when you say large transactions and you're looking at everything, would that include another major pharma company? Thanks.

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

Starting with Gardasil. At the current point in time, I don't think we're in a position to give specific guidance on the quarter-to-quarter patterns that we expect to see. As it relates to the 11 to 18-year-olds, without getting specific, it is significantly higher in that population than it is, for example, in the older population. We've gotten much quicker penetration in the adolescent population with pediatricians and general practitioners than we have with the 19 to 26-year-olds.

Richard Clark - Merck & Co., Inc. - Chairman, President, CEO

From an M&A standpoint, as I said before, anything we do must make sense from a shareholder standpoint, and as you've heard me say before, I think there is overcapacity in the industry, and I think the important thing that Merck is doing is that we are recreating a new business model. So we are not only taking class out of the system, we're completely looking at a different way of running the company and researching manufacturing and how we support our customers. And so there's certainly, in my opinion, if you do that the right way, there's a lot of costs that still need to come out of the system.

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Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

Okay, we'll take one more question.

Operator

Your final question comes from the line of Steve Scala of Cowen.

Steve Scala - Cowen & Company - Analyst

Thank you. Two questions on the cholesterol franchise. Merck said on its third quarter call that two thirds of patients would have access on second tier in 2009, and that was down from 75% in 2008. That was prior to certain formulary changes and also a positive study from a competitive product late in the year. So has there been any change in that two-thirds figure that you were looking at for 2009. And secondly, Schering said on its conference call earlier today that it was investing for future growth in this franchise. Do you think growth until the US and in 2009 is likely? Thank you.

Kenneth Frazier - Merck & Co., Inc. - EVP, President

Let me start by saying that the two-thirds figure that we anticipated continues to be what we see for Vytorin and Zetia. That is that it will be reimbursed without restrictions on second tier for about two-thirds of patients in commercial and Medicare Part D plan. As it relates to future growth, let me start by just saying that prior to last year, these were products that had been well received in the marketplace as a result of those controversy, we have seen a slight change in how these products work -- significant change in how these products are actually used. We continue to believe in these products. The FDA's recent statement underscores the importance of LDL lowering. The guidelines that exist in the US and that are coming online in Europe underscore those. So I can say without predicting when the growth will resume, we fully expect that as people begin to reflect upon the importance of getting large numbers of patients to their cholesterol lowering goals, they will realize that Zetia and Vytorin are important ways of achieving that objective and we continue to invest competitively behind these brands with the hope and the expectations that over time, they will be restored to growth in the US.

Eva Boratto - Merck & Co., Inc. - VP of Investor Relations

That last question concludes today's conference call. The information from today's call, both the transcript and the replay will be available at our website for the next several months, and Carol Ferguson and I will be available to take your calls with any further questions. Taylor?

Operator

Thank you , this concludes today's Merck's fourth quarter 2008 earnings conference call. You may now disconnect.

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