FINAL TRANSCRIPT

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MRK - Q3 2008 Merck & Co., Inc. Earnings Conference Call

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PRESENTATION

Operator

Good day everyone, and welcome to Merck's third 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.

Eva Boratto - *Merck & Co., Inc. - VP of IR*

Thank you Taylor and good morning. Welcome to our call to review our business performance for the third quarter of 2008. Joining me on the call to review our business performance for the third quarter of 2008. Joining me on the call today,as always 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 that this conference call is being webcast live and recorded. The replay of this event will be available later today via phone, webcast and podcast. 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 the statements.

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 management's current expectations and involve risks and uncertainties which may cause results to differ materially from those set forth in the statement. 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 10-K for the year ended December 31, 2007 and any risk factors or cautionary statements contained in the company's periodic reports on form 10-Q or current reports 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 for all your questions and we expect the total call to last about an hour. Given the other earnings calls today, we will be mindful of our time and we'll finish up by 10:00 a.m. With that, I'll turn the call over and we will 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 Merck's third quarter results and updated our 2008 and 2010 long term values. With this morning's call, we can provide more detail about our most recent performance and our near-term outlook and answer your questions.

Today we reported another solid set of quarterly results including growing non-GAAP EPS and revenue from key products. We delivered those results even in the face of a slow down in sales of our Merck/Schering-Plough joint venture and the continued impact of the loss of market exclusivity for Fosamax in the United States. Since 2005, Merck has anticipated and aggressively prepared for the changing industrial environment by restructuring our business and transforming the way in which we discover, manufacture and market our products. All this is part of the plan to win strategy that I introduced shortly after becoming CEO. For three years, Merck has clearly seen our share of positives and negatives as the industry has overall. In terms of growth and new product introductions, in 2006 and 2007, were outstanding years for Merck.

This year thus far has been a more complicated story. We faced an unusual set of challenge,s some of them expected and others unexpected. Some of them unique to Merck and others affecting many in the pharmaceutical industry. And of course global economic conditions are very dynamic at this time and could potentially continue to disrupt many industries for many times to come. We've made good progress on many fronts since 2005, however, our most recent sales transfer of key products, compounded by known industry and emerging economic factors has led us to reassess the environment in which we expect to be operating between now and 2010. In light of these considerations, we have decided to lower our financial guidance over this period. As we look at our business today, we expect adjusted full year 2008 EPS to come in at the lower end, but still within our previously disclosed range with 2008 non-GAAP EPS of $3.28 to $3.32 excluding certain items. We now anticipate reported GAAP full year 2008 EPS of $3.45 to $3.55. And for the longer term, we expect revenues will have a compound annual growth rate of plus 2% to plus 4% from 2005 to 2010 including 50% of the revenue from our joint ventures.

Looking at non-GAAP EPS compound annual growth, we now expect it to be at the mid- to high-single digit range over the same period, excluding certain items. I take delivery on our commitments to you very seriously and are proud of Merck's track record in that regard. That is why I am disappointed about the changes we needed to make today in our short and long term guidance. We've always been straightforward and realistic when speaking to investors about Merck's business and intend to continue to communicate openly and candidly about where we stand and what we plan to do to accomplish moving forward. The experiences and events of 2008 have been instructed to me and the leadership team and we'll be proactive in addressing all challenging facing our business. One of the factors that has led to moderate our outlook is the manufacturing challenges that have affected availability of certain of our vaccines. Let me provide some context on this critical aspect of our business as a prelude for the results and guidance discussions we will have later on this call.

As we have previously discussed, vaccine manufacturing is inherently complex. The process is complicated so it can take many months to manufacture a batch of vaccine from start to finish, and it can also take several months to complete the necessary testing before the vaccine is ready for the distribution to customers. From time to time, issues arise where there's a need to make a change in the manufacturing process. Due to the complexity involved, each issue has its own unique circumstances and can affect vaccine availability. We have recently encountered some of these issues and as a result, availability of certain vaccines will be delayed from the dates previously communicated. We now anticipate having enough supply Zostavax to clear the current back orders by the end of this year, an ongoing supply to enable return to full promotion of Zostavax in the United States. Launching ProQuad and Zostavax outside the US beyond 2009 and relaunching our HIV containing vaccine in mid 2009. While these delays are frustrating, we are making encouraging progress. We have revolved the issues regarding our Varicella production. Also, we have recently added an additional Varicella manufacturing facility which has been approved by the FDA. To support our long term plans and to ensure we have consistent robust processes and practices that meet increasing demand, both of our existing vaccines for the next generation of vaccines and development, Merck is investing approximately $1 billion to expand our capacity and to make improvements to existing processes and infrastructures. That includes two new plants, one in Durham,North Carolina. which we dedicated last week, and another in Carlow, Ireland where we have just begun construction.

Despite the business challenges we face, I continue to believe that Merck has the right strategy focused on the core pharmaceutical business. We have a broad portfolio of products that include many first invested class products with marketing exclusivity that extends well into the next decade. Januvia, Esentious, Gardasil, Doctavax and RotaTeq. We have a best in class research and development capability and our early (inaudible) pipeline includes breakthrough investigational candidates that address critical unmet medical needs. In addition, our industry leading R&D capability helps make Merck the partner of choice with new external scientific collaborators to discover, develop and distribute important new therapies. Lastly, we are moving forward on several immediate and long term steps designed to accelerate our revenue growth including significant investment in expanding our presence in emerging markets, broadening our business development focus to include deleveraging of opportunities in regions and countries outside of the United States and accelerating development programs for novel mechanisms and fixed dose combinations in some of our key therapeutic areas. In addition, we are leveraging our acquisition in Quipify to pursue (inaudible) biologics actively in multi therapeutic areas with the goal of becoming a leading player. All of these moves have significant incremental revenue potential. We expect to provide greater details concerning these key growth levers at our December analyst meeting. In the meantime, it is vital that we continue to ensure that we are operating our business in the most lean and flexible way. As we move through the process, we must gain a significant but necessary changes in our business.

Earlier this year, I explained how we would accelerate efforts in 2008 to further optimize our cost space, transform our business model and maximize performance across all of our products. Today we are moving ahead with the next step in our restructuring efforts. Like its predecessor, this program is focused on continuing to transform our business model, lower our fixed costs, eliminate redundancies and increase the speed at which we make decisions, especially when it comes to taking advantage of growth opportunities. So for example, Merck is accelerating the rollout of a more customer centric selling model that we believe will yield a meaningful competitive advantage to Merck and will help physicians, patients payers improve patient outcomes. Merck's research laboratory is deploying a new operating strategy for basic research which will improve the company's ability to manage increased research program complexity, expand its access to worldwide external research and relocate resources to translate to late stage clinical success. Merck's manufacturing division will further focus its capability on core products and outsourcing non-core manufacturing needs. And Merck will make greater use of outside technology resources, centralize common sales and marketing activities and consolidate its streamline its operations. We expect that 2008 restructuring program to yield cumulative pre-tax savings of $3.8 billion to $4.2 billion from 2008 to 2013. These cost savings are in addition to the accumulative $4.5 billion to $5 billion which the company announced in 2005 and remains on track to achieve the 2010 target. As part of the 2008 restructuring plan, we expect to eliminate approximately 7,200 positions worldwide across all areas of the company by the end of 2011.

Streamlining Merck to make the demands of ever-changing business environment includes the painful reality of losing employees whose contributions have helped our company accomplish so much throughout the years. But no matter how difficult the decisions are today, we know our long term strategy is right. We took a leadership position in the industry and began reshaping

our company ahead of our competitors. I am confident that we can overcome Merck's short-term challenges and continue to position this company for success in the future. I recognize the change to guidance is not what our investors expect, nor what we wanted to deliver. That is why we remain committed to doing everything we can to improve this outlook. We are determined to deliver to our investors and we believe our 2008 restructuring program announced today will help us do so. In closing, let me acknowledge that we are in the midst of an extraordinary time for the business world and the world economy. Uncertainties and volatility in all areas of the market abound. However, I have full confidence in the fundamentals of Merck's business, our strong balance sheet and cash flow, our product portfolio, our deep strength in research and development, our great people and an excellent management team across the globe. Now I'll turn to Ken who will provide an overview of the performance of our product portfolio during the quarter. Ken?

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

Thank you Dick and good morning, everyone. Merck's revenue performance in the third quarter reflects continued strong growth of a number of recently launched new products including Januvia, Janumet and Isentress. This growth was offset by, as Dick discussed, supply shortfalls of some of our vaccines and continued challenges to driving demand for Singulair and Gardasil. Overall revenue was down 2% in the third quarter. Excluding the impact of the loss of marketing exclusivity for Fosamax, revenue in the third quarter increased by 5%. Our international business showed strong growth with an increase of 13%. This was driven by volume increases of 6% as a result of the continued rollout of our new products as well as the prevailing exchange rates. Let me provide you with some prospectives on our top line results this quarter focusing on our key brand.

Beginning with our HPV vaccine Gardasil, reported Merck's sales in the third quarter were $401 million, a 4% decrease when compared to the third quarter of last year. In the US, sales declined 16% while ex-US sales increased 37%. Ex-US sales were aided by the adoption of school based programs in all Canadian provinces, which resulted in a $34 million increase in sales in Canada compared to the base period. We are very pleased that the provinces have adopted this approach for an annual back to school based vaccine routine. The US third quarter performance for Gardasil was driven by three factors. First, we observed a consistent monthly vaccination rate among 19 to 26 year old women over the past year. While we have implemented many programs to increase vaccination in this age group, it will take time to address the barriers and significantly change behaviors of physicians and consumers. I will provide an update on the status of some of our key efforts in a moment. Second, while the annual vaccination rate of the remaining 13 to 18 year olds increased, the overall number of first dose vaccinations declined because of the early success in vaccinating this age group following launch. Considering the strong cumulative utilization of among 13 to 18 year olds since launch, continued growth requires substantially higher rates among the remaining eligable population. The vaccination rate for Gardasil among adolescents remained higher than the average vaccination rates for Menactra and TDAT in comparable points in life cycle. And third, utilization during back to school season was tempered somewhat by negative media coverage over the summer on safety misperceptions which dampened consumer acceptance.

As mentioned on the second quarter call, we have implemented a number of programs aimed at driving utilization among 19 to 26 year old women. I'll share a few early results. More than 5,000 OB/GYN and primary care locations have enrolled in the dose replacement program that we launched and first discussed last quarter to address reimbursement concerns. We've already observed the approximate 8% to 10% lift in sales at these locations versus other locations in the first two to four months since enrollment. Our in-office patient outreach program which helps physicians reach out to unvaccinated females and mothers rolled out during September. In the first few weeks of enrollment, more than 1,000 locations enrolled and more than 200,000 patient mailers were ordered in those locations. Our outreach through managed care organization to inform eligible patients about coverage of Gardasil has reached more than 2 million enrollees in those plants. And finally just this month, we launched two programs to reach young adult females, a multichannel consumer disease awareness campaign and a patient program for OB/GYN offices. While we are encouraged by the initial programs, we recognize that it will take time to have a significant impact on the overall vaccination rate of this important 19 to 26 year old group.

I would like to take a moment now to discuss the performance of our two other recently launched vaccines, Zostavax and RotaTeq First, despite significant demand, Zostavax performance was hindered by the lack of bulk Varicella supply. Looking

forward, we expect to have enough supply to clear the current back orders for Zostavax by the end of the year. As new orders are received, we will fill them as quickly as possible, but it is possible that depending on demand level, some new orders will be back ordered and filled in early 2009. Throughout this period of constrained supply, we have focused our marketing efforts on reducing many of the logistical and reimbursement barriers to vaccination with Zostavax We remain extremely excited about the potential of Zostavax and we look forward to ensuring adequate supply of this important vaccine for our customers. Next, underlying demand for RotaTeq continues to be strong. More than 75% of US infants have now been vaccinated with RotaTeq, which was the only rotavirus vaccine available in the US until the middle of this year. When you adjust for the $50 million stock pile purchased by CDC in third quarter 2007, sales in the third quarter '08 were up 11%. As you model future performance, you should keep in mind that our fourth quarter '07 results included a CDC stock pile purchase of $26 million. RotaTeq continues to perform well in the US market and we have not seen a significant impact to date from the recent introduction of competition.

Turning to Singulair, sales in the third quarter were up 1% versus the prior year. Singulair performance in 3Q '08 was driven by strong growth in Europe, Middle East and Africa and Asia, and offset by a decline in the US business. Ex-US sales of Singulair grew 12% as a result of continued growth in EMEA and Asia. US prescriptions for Singulair, that is total prescriptions, were down approximately 8% in the third quarter versus third quarter '07, similar to the decline in the overall respiratory market. The combined allergy and asthma market without Zyrtec, which was down approximately 6%. As I've mentioned in previous quarters, the US performance for Singulair continues to be affected by the switch of Zyrtec OTC, the weak spring allergy season and the FDA early communication this spring. We are determined to improve the performance of Singulair in the US in the fourth quarter, and we have significant resources and plans underway to grow Singulair during the fall allergy season and the end of year asthma season. Our sales force has new material to use with physicians including very specific patient profiles, messaging on efficacy and safety, new trial and coupon kits for new patients and educational material for patients. We are using a multichannel approach with customers which includes print, television and online DTC including digital banners and e-coupons, in office branded marketing programs, pharmacy programs, adherence initiatives and an updated website. Looking outside the US, Singulair continues to show strong performance for the year so far. Singulair grew 20% outside the US in Europe and other markets such as Japan ,which illustrates the strong positive perceptions about Singulair held by physicians around the world.

Moving to two of our newest growth drivers, global revenue for Januvia and Janumet reached $479 million in the third quarter, up 18% sequentially versus second quarter '08. 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, the Januvia/Janumet franchise continues to grow in both volume and market share. In addition, we are extremely pleased with the ex-US performance of Januvia/Janumet in the third quarter. In the EU, Januvia is the only DPP4 inhibitor approved for dual and triple therapy with a sofanaria or a sofanaria plusmet foreman and remains the only marketed DDP for that is once daily. Worldwide, more than 8 million prescriptions have been written to date, and we consider these two benefits to be major growth drivers for Merck in the short-term and in the long term, and we are investing significantly in them to ensure that we realize their full potential.

Now I would like to take a moment to provide an update on the performance of our cholesterol JV. Worldwide sales of Zetia and Vytorin as reported by the Merck/Schering-Plough joint venture were $534 million and $567 million, respectively in the third quarter. Sales of Zetia were down 12% and sales of Vytorin were down 18% versus the prior year. Sales declines in the US were partially offset by continued strong growth outside the United States. Market share for Zetia and Vytorin in the US appears to be stabilizing post ESC. Although we have seen an 8% decline in new prescriptions since the initial release of the C's results, the rate of volume and share decline for the JV has slowed throughout the year. However, the overall cholesterol market growth has been slower than expected. And while we expect that the JV brands will remain competitive in terms of managed care positioning in 2009, we anticipate a reduction in formulary coverage from 2008 levels. We remain steadfast in our support for Zetia and Vytorin which continue to be valuable treatment options for physicians by helping to get more their patients to their LDL goals.

Before turning the call over to my colleague Peter Kellogg, I would like to take a moment to update you on the progress we are making on our efforts to evolve our commercial models and to optimize our cost base to better position Merck to grow the top line. With Merck's portfolio both in line in new medicines and vaccines and with the number of people around the world who can still benefit from our products, we have ample opportunities for future growth. The challenge to us is to create approaches

that can go after these opportunities in an effective and efficient way. We have already changed our headquarters and sales leadership structure to prepare for the full implementation of the new commercial model in the US in March of next year. The results from our year long pilot gives us confidence that the new customer centric model provides the right level of support for our new products and can drive revenue and margin improvements. As Dick mentioned, we've continued the efforts that we started back in 2005 to optimize our cost base and improve Merck's effectiveness and efficiency. In Q3, we started to realize the savings of the US sales force actions we announced in May of this year.

Overall for the quarter, marketing and administrative expense, excluding the legal defense reserve in the base period, was down 8% versus the third quarter of 2007, but I should note that promotional spending was up, which is a reflection of the support that we continue to put behind our growth brands and our growth markets. We are also realizing savings outside the US as we begin implementing our new commercial models and streamline our sales and marketing operations. What we are doing with these actions is reducing our fixed cost base so that we have the flexibility to invest in growth brands and growth markets around the world, and I believe that we have made a great deal of progress here.

Turning to our long term revenue guidance, as Dick mentioned, we have reduced our 2010 compound annual revenue guidance including 50% of our joint ventures to 2% to 4%. As we work through our bottoms up planning process, we needed to assess our underlying product trends as well as project future challenges and opportunities in a rapidly changing external environment. Based on our assessment, the key drivers for the reduction in revenue guidance since July are as follows. First, since we last gave guidance in July, there has been a 10%to 15% reduction in the Euro to dollar exchange rate. Because 40% of our sales are from outside the US, the decline and exchange significantly dampens our outlook. Second, supply shortfalls for some of our vaccines will affect our ability to meet market demand, and as you know, we are investing heavily in our manufacturing capacity for our vaccines to address this key issue. As Dick said, we remain confident both in the ultimate resolution of our supply issues and the important benefits provided by these unique vaccine products to our customers. However, the supply issues will affect our future performance. Third, we continue to anticipate that we will have challenges to driving increased demand trends for our joint venture cholesterol medicine, Gardasil and Singulair. While we have comprehensive plans in place to address these challenges and return these products to higher growth trends, our overall expectations for performance over this period are now lower.

In closing, while we are disappointed in the reductions to our long term revenue guidance, I assure you that the entire Merck organization is focused on improving that picture for the top line as well as the bottom line. We continue to believe that tremendous commercial opportunities exist for our established franchises along with our new first in class vaccines and medicines such as Gardasil, RotaTeq, Januvia/Janumet, Zostavax and Isentress. We are confident that our continued focus on efficiencies on the marketing and administrative line demonstrated throughout 2008 will help drive overall margin improvement and that the plans we have in place fundamentally to change our business model will enable us to drive the top line for our medicines and vaccines for years to come. So with that, I will turn the call over to my colleague, Peter Kellogg.

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

Thank you Ken and good morning, everybody. Before we start the Q&A portion of the call, I just want to touch on three items very quickly. First, discuss the other key elements of our Q3 results that haven't been previously discussed. Secondly, provide an overview of our 2008 and 2010 guidance and then finally, provide an overview of some other financial matters. Let's get started.

Merck reported third quarter non-GAAP earnings per share of $0.80 per share which represented a growth of 7% over the third quarter of 2007. On a GAAP basis, EPS for the third quarter was $0.51 per share. Both the GAAP and non-GAAP third quarter results include the impact of $88 million of recognized losses losses in the company's investment portfolio. Now, Ken just walked you through the key elements of revenue performance for the quarter, so I'd like to now cover the other elements of the P&L beginning with product gross margin or PGM. Our third quarter PGM was 76.1% excluding restructuring, a decrease of 1.1 percentage points versus the prior quarter. The sequential reduction in PGM is primarily attributable to product mix and

secondarily discards. In the third quarter, sales of Singulair and Fosamax, both high margin products were lowered than in Q2 of 2008 while sales of Garasil, a lower margin product ,were higher than prior year. In addition, PGM was negatively affected by discards associated with vaccines.

Moving to research and development, R&D expense for the third quarter was $1.1 billion. When you adjust for the $325 million of acquired research, which is a charge that was associated with the purchase of NovaCardia in the third quarter of last year and the 2008 restructuring cost, R&D expenses were up 2%. Turning to restructuring, our 2005 restructuring program is nearing completion at year end, but we continue to transform Merck into a lean and flexible company, appropriately sized and scaled for the future pharmaceutical operating environment. Accordingly, the company announced a new 2008 restructuring program. Included in our Q3 results were total restructuring charges of $847 million. Now, that is made up of $720 million for the new 2008 program and $127 million for the 2005 program that is winding down. In the aggregate, the cost of the 2008 program is expected to be $1.6 billion to $2 billion and is expected to be substantially complete by the end of 2011. Now as Dick has already mentioned, this effort is expected to yield cumulative pre-tax savings of $3.8 billion to $4.2 billion from 2008 to 2013. This is a critical next step in our journey to establish a more variable cost structure. Next, in the third quarter, we continue to face pressure on the equity income line as a result of two factors. First, the equity income contribution for the Merck/Schering Plough joint venture was down 17% or $81 million as a result of Zetia and Vytorin market share losses in the US. The lower revenue in the US was partially offset by strong growth outside the US. Secondly, the equity income contribution from the AZN joint venture was $42 million lower in the third quarter compared to the prior year. The decrease in equity contributions from the AstraZeneca partnership is attributable to the previously disclosed events surrounding the JV restructuring that occurred towards the end of the first quarter of this year, and we've discussed that previously, and as well, as always, we had inherent variability in the 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 received the 10% royalty payment from the Astra USA product.

Moving to the other income and expense line, net for the third quarter was $62 million expense, which declined $243 million versus Q3, 2007. The year-over-year decline is attributable to first, recognized losses of $88 million in our investment portfolio as I mentioned earlier, and that is a result of Merck's exposure, primarily the Lehman Brothers and AIG in Q3 2008. Secondly, there were balance sheet translation losses of $52 million in Q3, 2008 due to foreign exchange movement and how they impact our balance sheet. And thirdly, income of approximately $100 million occurred last year from a one time net gain that resulted from the settlement of certain patent disputes that is we discussed last year.

Now moving to our 2008 guidance, our 2008 non-GAAP EPS guidance is for $3.28 to $3.32, as Dick covered earlier. This guidance is at the low end of the previous range. Our corresponding 2008 GAAP guidance is now $3.45 to $3.55. Now as always, to assist your modeling, we have provided a breakdown of the product revenue guidance in our other financial disclosure schedule attached to the press release that we issued earlier today. But let me briefly walk you through the changes that occurred there. On the revenue line, Singulair had its full year lowered by $100 million, so the range now stands at $4.3 billion to $4.5 billion. Other vaccines also had their full year range lowered by $100 million, so that range now to $2.6 billion to $2.8 billion and as Dick mentioned, that is largely attributable to delays in supply. Finally, the Astra component was increased on a full year basis by $200 million. So that now stands at $1.5 billion to $1.7 million, and that is due to strong Nexium performance that we have seen year-to-date. Now regarding marketing and administrative expense, we are reducing our guidance by $100 million to $7.4 billion to $7.6 billion. This reduction is possible because of our ongoing company-wide aggressive expense management that Ken covered a few minutes ago. Entering the restructuring as a result of the charges associated with the additional restructuring program that we announced today, restructuring guidance for 2008 is increased to $1.3 billion to $1.5 billion. Now turning to the 2010 guidance, as Dick and Ken mentioned, a number of factors have led to the revised 2005 to 2010 guidance that we issued this morning. Since we last provided long term guidance in July, foreign exchange rates have clearly moved against us, and that, coupled with the manufacturing supply issues and product specific changes that have led to the change in outlook. As an organization, we are committed to maintaining focus on cost control, and the restructuring program announced this morning will help us move toward a variable cost structure. We have a clear plan in place to enable us to achieve the long term guidance we provided this morning.

Now moving to share repurchases, Merck has been actively repurchasing shares. During the third quarter, the company continued its stock buy-back program and purchased approximately $1 billion of treasury stock, and during the first nine months of 2008, we have now purchased $2.5 billion of treasury stock. This program will continue in Q4. The company considers a variety of factors in share repurchase decisions including our strategy for long term capital structure, market conditions, the impact of actual and anticipated employee stock option exercises and EPS implications of repurchases. As of September 30, the company has $2.6 billion remaining under the July 2002 treasury stock purchase authorization.

Now let's turn to some other financial matters, and I would like to take a minute to speak about Merck's overall financial strength. As you know, Merck has always had a strong balance sheet and a conservative investment philosophy. As of September 30, our current cash and investment portfolio totals $19 billion including $6 billion pledged as collateral for bank guarantees related to certain items including the Vioxx product liability settlement. The portfolio contains a diversified mix of high quality, short-term, less than 90 days and medium term, less than five years, fixed income, government agency, corporate asset backed agency guarantee mortgage backed and municipal securities. Our investment philosophy has served shareholders very well. Since 2001, our benchmark investment portfolios have earned 1.4% per annum more than a treasury bill portfolio, providing the company with incremental interest income in excess of $1.2 billion over this period. Merck's strong financial profile as indicated by our AA-minus credit rating provides Merck with a distinct advantage in accessing funding during difficult markets.

In the current market environment, we continue to have more than sufficient access to the commercial paper markets at attractive pricing and across all maturity spectrums. We have 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 and our pipeline. So in summary, Q3 was a solid quarter. Januvia, Janumet and Isentress continue to perform very well globally. We also continue to aggressively manage our overall cost structure as demonstrated by the reduction in marketing and administrative guidance, and we believe that our 2008 restructuring program will enable Merck to continue to drive toward a more lean and flexible model. Thank you, and now I'll turn the call back to Eva. Eva?

Eva Boratto - *Merck & Co., Inc. - VP of IR*

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'll turn the call over to Taylor who will communicate instructions for our Q&A format and then introduce the first question. Taylor?

QUESTIONS AND ANSWERS

Operator

Thank you. (OPERATOR INSTRUCTIONS) Your first question comes from the line of Tim Anderson of Bernstein.

Tim Anderson - *Bernstein - Analyst*

Hi, thank you. A couple of questions. Dick, I'm hoping you can talk about the notion of having a so-called established products group like one of your competitors has recently been talking about whereby a higher level of marketing resources are dedicated off patent drugs. I'm wondering if this makes sense and if Merck has a similar effort underway, and if not, does Merck plan in doing anything differently? And then Ken, when you say you expect Vytorin and Zetia to continue to have competitive formulary positioning going into 2009, how do you define competitive? Because it sure looks like Vytorin and Zetia would be disadvantaged relative to other products, much more often than not based on the data that CMS has on their website.

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

So let me start with the second question, which is what we believe would be the case for our managed care access. As you know, right now we believe that we remain competitive in 2008 as it relates to our managed care placement, especially as it relates to unrestricted access and second tier and major plans. As we move forward into next year, in 2009, we believe that we'll continue to be competitive, but we actually believe that we will have somewhat less access than we have during this year. So next year we believe that Vytorin and Zetia will be reimbursement without restriction for about two-thirds of patients in commercial and Medicare Part D. I don't know exactly what you are referring to, but some of the most recent decisions made in Medicare Part D have been not as positive for Vytorin and Zetia, but it's also important to keep in mind that they represent only 20% of the book of business.

So today, we are reimbursed without restriction on about 75%. Next year, we believe it will be about two-thirds. The other question as it relates to how we are thinking about a established products group. We are looking overall at our entire business, including how we should apportion funds between all of our products. We have a number of very strong growth drivers that are early in their life cycle, and our primary focus is ensuring that those products get off to a very fast growth curve. On the other hand, we have plans that are in place, which we'll talk in greater detail in December for our emerging market strategy, and in those markets as you know, somewhat more established products, including products that don't enjoy patent protection continue to be valuable contributors to portfolios in that part of the world, and we are certainly looking at our entire portfolio including established products across various geographic markets and looking at how to actually maximize the return of the entire portfolio to Merck's shareholders.

Eva Boratto - *Merck & Co., Inc. - VP of IR*

Next question please.

Operator

Your next question comes from the line of Chris Schott of JP Morgan.

Chris Schott - *JPMorgan - Analyst*

Great, thank you. If we look at the cost savings outlined under the new restructuring program, can you give us any more color of the segmentation between COGS, SG&A and R&D on that one? And maybe just a little bit more clarity on the timing of some of these headcount reductions that are laid out with this plan, and a final question on Gardasil, the dose replacement program that began during the quarter, can you quantify how many doses have been provided to physicians under that program? Thank you.

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

Hi Chris, It's Peter Kellogg. Let me quickly recap some of the dimensions of the restructuring program and then I'll pass the Gardasil question over to one of my colleagues. In terms of where the cost will occur, because a good portion of this restructuring is related to real cash items and they're primarily headcount related, probably about 65% of the cost that you'll see will go to the restructuring line and then the rest of the cost will be split between cost of goods and R&D. In terms of where the benefit will flow, we haven't broken that out in great detail but in general, probably about 70% or so of the benefits will come through the -- what we call the M&A line, the SG&A area. And because a lot of the impacts are primarily headcount related, the benefits of this program are fairly evenly spread over time, so our expectation is we'll get about a third of the benefits in this program through 2010 and the balance after that. So hopefully that gives you some dimensions of the restructuring and then for Ken for Gardasil?

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

I think it's important to recognize that we are still very early in the dose replacement program's life. It's been in place for about two to four months. As I mentioned, we are pleased that there's been a reasonably strong uptake in terms of participation by OB/GYNs and primary care providers. We see in the early days, an approximate 8% to 10% list. So those are all things that all go well for this particular approach to that barrier around reimbursement. We don't, however, provide the actual number of doses that we have provided in those locations, but again, we are pleased that we are seeing where there is participation an impact on Gardasil use.

Eva Boratto - *Merck & Co., Inc. - VP of IR*

Next question please.

Operator

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

Roopesh Patel - *UBS - Analyst*

Thanks for taking my questions. Just a couple of questions. First on the cholesterol franchise, given the pushes and pulls, US versus international, could you please clarify if you expect overall global Vytorin and Zetia revenues to grow or decline in 2009? And then secondly, on the vaccines business, if you could kindly elaborate on the progress of resolving manufacturing issues for the hepatitis vaccines Vaqta, (inaudible)and also for ProQuad? Thank you.

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

Okay. So I will start with the first question. As I said, we are seeing very strong growth outside the US for Zetia and Vytorin. We are experiencing difficulties in the US. As you know, we saw an 8% decline in NRX trends, we are seeing an issue with respect to the overall market growth of the cholesterol franchise, but netting those out, at this point in time, I'm not in a position to say whether the franchise will grow globally next year. All I can say is that we continue to provide investments behind Zetia and Vytorin in the US where we have seen the greatest declines and we continue to believe that the products will have the right kind of support going forward. As it relates to the other vaccines that you described, PVAC and Comvax they should be available again in mid 2009, and as it relates to Vaqta, based on the latest information, we expect the adult formulation --

Eva Boratto - *Merck & Co., Inc. - VP of IR*

Q1. -- to be here on Q1 2009 and the pediatric in the fourth quarter of 2008. Next question please.

Operator

Your next question comes from the line of John Boris of Citigroup.

John Boris - *Citigroup - Analyst*

Thanks for taking the questions. Dick, just a question on investment and R&D. You've obviously had Tredaptive delayed a while back. You had to discontinue a relatively expensive program on Taranabant, the obesity compound. Then you've announced

recently that the Hepatitis B vaccine, obviously, also has issues. Can you just talk about what is going on with -- at least you believe with the FDA currently from a safety standpoint? You obviously have eight other assets in phase 3 clinical development. How can we be assured that you have adequately designed those to meet a much more rigorous FDA from a safety standpoint? And second question, on licensing and business development for Dick and Peter. Over the last couple of years, the velocity of your licensing and business development activity has been extremely robust. Can you highlight what that activity has been year-to-date in '08 and how that contrasts with '07 and '06? Thanks.

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

Thanks for the questions. Certainly concerning some of the challenges we've had with our late stage pipeline, I always put it in perspective that this same agency that we are discussing was able to approve nine products over the past two years or so, and these have been first in class differentiated products, unmet medical needs, and it truly is going to be the foundation for the company from a revenue standpoint moving forward throughout the world, and with products like that, we are getting fair and reasonable prices globally as we speak. I think that is the good news. I have a lot of confidence in our scientific capabilities within Merck. It think it is our strong point as a company and I think we have the ability to interact and communicate with the agency to make sure we understand that if there are any changes or signals that we are receiving, that we are able to make sure that we proactively answer those questions, and I think we've been able to do that. I think the reason Januvia is on the market is that we proactively thought through the questions that they were going to ask and we were able to accomplish those, and the fact that Gardasil is on the market allows us to do that. So there's no doubt that we have to continue to look at clinical development and make sure that we communicate and we listen to what any potential signals or standard changes could exist. But we're well equipped to do that, we've done it in the past. We have got outstanding scientific leadership, and I think that puts us in a, quite frankly, competitive position in relationship to our colleagues in the industry.

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

Just wanted to take the question if I can on the business development front, the question specifically I think John asked was, is our pace in '08 comparable to what we did in '07 and '06. Obviously, the year is not done yet, but at this point, absolutely, we've been very active in the business development front. As you are well aware, we did in the neighborhood of roughly 50 or more deals in each of the last prior years. We have done a good number this year. We have announced quite a few of them that you've already heard and we remain very active as we speak today. Our focus is to look at always doing deals, whether they be in licensing or collaborations and also a truly innovative and novel mechanism that could really add to our portfolio. We tend to look at biotech companies that also bring different kinds of mechanisms into the play, and we obviously think about it from a franchise standpoint ,so our business development activity is very well integrated with the R&D organization and their franchise team. So increasingly, you'll see us stepping up that activity.

I think you will also see us broadening perhaps some of the scope of what we have done in the past, not only to do the classic pipeline and licensing deals, but also include as we discussed in the last earnings call more activity on the business development front with commercial products and global companies that may have only regional presence, but where they can add to our international portfolio. So I think this will be another robust year. We have full expectations. I know it's one of our corporate goals and certainly one of our finance and R&D goals to have a very strong licensing activity and I think increasingly, you will see more of Ken's organization really diving in as well. So I think it's a big opportunity for us.

Eva Boratto - *Merck & Co., Inc. - VP of IR*

Next question please.

Operator

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

Dave Risinger - *Merrill Lynch - Analyst*

Thanks very much. I have three questions. First, regarding Vytorin and Zetia, how do you define unrestricted? Do you mean tier 2, or are you talking about tier 2 and tier 3? The second question is, I'll just read from your press release the second bullet that I don't understand, so I'm hoping that you can explain it. It says cumulative savings of $3.8 billion to $4.2 billion expected from 2008 to 2013 and pre-tax costs of $1.6 billion to $2.0 billion through 2011. Can you just reconcile those two? And then finally, and I may have missed this, but where does Gardasil for 27 to 45 year old females stand? Thank you.

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

So Dave, this is Peter. I can start off with your specific question on the bullet point. So, when we look at restructuring, we tend to try and use the exact same vernacular and time frames that we've used in the past, so our cost that will go through the P&L as restructuring charges, we expect to be in the range of $1.6 billion to $2 billion cumulatively between now and 2011, and obviously, we'll be incurring those costs as we go along as different activities are taken.

As I mentioned earlier, more than half of those costs will be headcount related, and so those will be severance program charges and so forth. And the rest will be probably either accelerated depreciation for facilities that are being closed or other related costs of exiting different investment areas or whatever. So that is the cost side, that's the $1.6 billion to $2 billion. From that, from those restructuring moves, we will then realize savings in the operations of our P&L, and what we look for is in the range of $3.8 billion to $4.2 billion of operating savings that will flow through the P&L on a cumulative basis over the next five years, and that's the '08 to 2013 time frame. As I mentioned on an earlier question, we expect those savings to come through on a fairly steady basis as we go along because of the size of the program changes we are making right away. So we, as I mentioned, we would expect about a third of those savings to come in in the 2009 and '10 time frame. Let me hand over to Ken next.

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

First of all, I apologize for any lack of clarity in my previous response. What I was talking about our access to managed care formularies, I was referring to tier 2. So when I said that we have 75% access with no restrictions this year, I was referring to tier 2 and when I made my comments about two-thirds next year, they also related to tier 2 access without restriction. With respect to your other question, as you know, we have responded to the FDA's complete response letter in July. The agency has informed us that the response was a class 2 response, so typically, those responses take about six months to work through.

Eva Boratto - *Merck & Co., Inc. - VP of IR*

Next question please.

Operator

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

Barbara Ryan - *Deutsche Bank - Analyst*

Good morning and thanks for taking my question. Most of them were asked, but maybe Dick I wonder if in the targeted cost cutting that you have and specifically the 12% headcount reduction through 2013, if within that you've assumed any kind of

what I would call fundamental changes in the marketing model of the company. It's probably not the right form to go into all of those things, but just in a generic sense.

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

Yes. I'll let Ken answer that in a minute, Barbara. But I think one of the important distinctions that I want to make that Merck is doing with their restructuring program that we put together today, this is not a reaction to having challenges in 2008 or a reaction to 2010. What this is is taking a look at our basic strategy and saying, we need a new fundamental business model in global human health marketing and sales. We need to take a look at our manufacturing and supply strategy. We need to take a look at what we can do better in basic research and clinical development and based on that, the new models that we are putting in place, what is the outcome of those? So, it's much more strategic in nature, it's more process in nature versus just a reaction that we've had a concern in 2008, therefore we have to reduce cost by $2 billion. That is not the way we run Merck, and that doesn't put us on the path of regaining our leadership. This is very strategic. It's driven from a business model change that we know we have to be responsible from an innovation standpoint in these new business models because if you don't change these business models, we are not going to survive as an industry, let alone a company. It's much more than a reaction and I think we are doing it differently than other companies are, and I'll let Ken make a comment about the marketing part of it.

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

I'll join what Dick just said. We are able to accelerate our US new commercial model because we learned a lot from the pilot that we've had in place and what we've learned has given us a lot of encouragement that we can do that in the US, in Europe and other mature markets. At the same time we will be adding head count in some of the emerging markets because we see the growth opportunities there, and this frees up resources to invest behind our key growth drivers. For example, Singulair in the fourth quarter, we're able to put even more money behind our DGC campaign.

Eva Boratto - *Merck & Co., Inc. - VP of IR*

We have time for one more question, please.

Operator

Your final question comes from the line of Tony Butler from Barclays Capital.

Tony Butler - *Barclays Capital - Analyst*

Good morning and thank you very much. Two brief questions. Number one, and apologies for going back to Vytorin and Zetia, but can -- as you look at the equity income from affiliates of 2.3 to 2.5, the guidance. It is not necessarily changed from that -- that I -- only marginally at the top end from that given back in Q1, and I guess as we look out, and I realize we are a few weeks into the fourth quarter, at the American Heart there will be a presentation that AstraZeneca will make around the trial called Jupiter with Crestor, and I'm curious if you have a view -- and clearly, because the trial was stopped, it must have some positive benefit, but I'm curious of the view that you may have on its effect for not only the overall cholesterol market, but more importantly, how that might affect Vytorin and Zetia and if you are prepared for how your message should change should it need to change post that meeting. And the second question, a little more mundane, and forgive me if it was stated before, but what exactly is the issue with the manufacturing hang ups for Cordaptive in Europe? Thanks very much.

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

So very briefly with respect to Jupiter, we are aware of the fact that that trial was stopped early and that there is going to be a presentation at AHA. I can only tell you that we continue to believe that Vytorin and Zetia will be important to physicians. We are looking at that particular trial and developing competitive responses to that trial, and I can't go into further detail about those right at the moment. As it relates to the Cordaptive delay in Europe, all I can say is that we have encountered a delay in the availability of Cordaptive to support our pending launches in Europe and other markets due to a manufacturing related issue. We will continue to work quickly to fix that issue by continuing testing and analyzing the commercial product supply. And the last thing is, I want to underscore that this is not a safety related issue. It's a manufacturing issue that we hope to resolve quickly.

Eva Boratto - *Merck & Co., Inc. - VP of IR*

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 Mike Nally and I we will be available to take your call and any incremental questions.

Operator

Thank you. This concludes today third quarter 2008 earnings conference call. You may now disconnect.
