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## **SGP - Q3 2009 Schering-Plough Earnings Conference Call**

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## CORPORATE PARTICIPANTS

**Janet Barth**

*Schering-Plough - VP, IR*

**Fred Hassan**

*Schering-Plough - Chairman, CEO*

**Tom Koestler**

*Schering-Plough - EVP, President, Research Institute*

**Bob Bertolini**

*Schering-Plough - EVP, CFO*

**Raul Kohan**

*Schering-Plough - SVP, President, Global Animal Health*

**Carrie Cox**

*Schering-Plough - EVP, President, Global Pharmaceuticals*

## CONFERENCE CALL PARTICIPANTS

**Tim Anderson**

*Sanford Bernstein - Analyst*

**Jami Rubin**

*Goldman Sachs - Analyst*

**Catherine Arnold**

*Credit Suisse - Analyst*

**Chris Schott**

*JPMorgan - Analyst*

**David Risinger**

*Morgan Stanley - Analyst*

**Seamus Fernandez**

*Leerink Swann - Analyst*

**Steve Scala**

*Cowen and Company - Analyst*

## PRESENTATION

**Operator**

Good morning. I'll be your conference Operator today. At this time I would like to welcome everyone to the Schering-Plough third quarter earnings conference call. All lines have been placed on mute to prevent any background noise. After the speakers remarks there will be a question and answer session. (Operator Instructions) Thank you.

I would now like to turn the call over to Ms. Janet Barth. Ma'am, you may begin your conference.

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**Janet Barth** - *Schering-Plough - VP, IR*

Thank you. Good morning everyone and thank you for joining us to review our 2009 third quarter results. We know we are among several companies reporting today so we plan for our call to run about 30 minutes. After some brief remarks we will

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open up the call to Q&A. But before we begin, I would like to note that some of the comments made today may contain forward-looking statements about Schering-Plough's business and prospects.

As you know our actual results may differ from these forward-looking statements. Schering-Plough does not assume the obligation to update any forward-looking statements. Please refer to the Company's Securities and Exchange Commission filings including Item 1A, risk factors in the Company's 2009 second quarter 10-Q for additional information about the things that could cause our actual results to differ from our forward-looking statements. The Company's SEC filings as well as today's earnings release and tables are available at Schering-Plough.com. I would also note that during the call, we may refer to non-GAAP measures including adjusted net sales or adjusted top line sales, which is a non-GAAP measure that we define as our GAAP net sales plus an assumed 50% sales contribution from our cholesterol JV. We will also refer to as reconciled amounts or amounts on a reconciled basis as reconciled amounts exclude purchase accounting adjustments, acquisition related items and other specified items. Please refer to the non-U.S. GAAP reconciliation tables for a reconciliation of adjusted figures to our reported GAAP results. These can be found under financial highlights in the investor relations sections of our website. Now I'd like to introduce our Chairman and CEO, Fred Hassan.

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**Fred Hassan** - Schering-Plough - Chairman, CEO

Good morning. I am pleased that today we're again reporting a solid quarter. This quarter, we delivered operational top line growth, reconciled bottom line growth, and major pipeline successes. The ongoing business is robust. Our people are executing with excellence, and a powerful R&D engine is driving a strong pipeline forward. This is a tribute above all to the professionalism, the tenacity, and the resilience of our people. They're powered through continuing pressures related to currency and the global economic environment. They've also powered through the challenges of integration planning. For example, we achieved 18% sales growth with Remicade excluding currency and solid growth of other key products such as Temodar and Nasonex. In fact, six of our top 10 largest selling prescription products delivered sales growth this quarter with and without the impact of currency.

We also continued to see the benefit of our geographic expansion strategy coming through with strong growth ex-US especially in the newer markets. Meantime the powerful R&D story continues to unfold. You heard about our Five Stars in our R&D pipeline last November. Less than one year later, three of those stars, Simponi, Saphris and Bridion are launched or being launched in major markets.

Earlier this month, Carrie Cox and I were with our new field force for the Saphris launch meeting in Dallas. It was an exciting event and a very satisfying moment. Back when we announced our planned acquisition of Organon BioSciences in March of '07, we said we believed Saphris was one of the underappreciated jewels in that acquisition. Today, we can see that the OBS acquisition has been a great move strategically, scientifically, financially, and today, we continue to see Saphris as a jewel. We're also gratified to see the clinical trials of our other late stage stars progressing well.

As we approach our merger with Merck, I'm proud that our colleagues are maintaining their focus and that Schering-Plough is firing on all cylinders. With those comments I'll now turn it over to my other management colleagues to round out the picture of our business as we approach day one of our combination with Merck. In addition to Bob Bertolini and Carrie Cox you'll be hearing from Raul Kohan about our Animal Health business and Tom Koestler will expand on my comments about our powerful R&D story. We'll start with Tom.

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**Tom Koestler** - Schering-Plough - EVP, President, Research Institute

Thank you, Fred. I'd be happy to elaborate on the recent successes within our advancing late stage pipeline. As Fred mentioned, less than a year ago we began highlighting the Five Stars within our research pipeline, which includes Simponi, Bridion, Saphris, our thrombin receptor antagonist or TRA, and Boceprevir. Now, three of the five have been approved and launched in at least one major world market. During the past three-months, Simponi was granted approval in Europe and Saphris was approved in the US. We continue to study Simponi for ulcerative colitis in Phase III and we also plan to study and file for additional uses



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with Saphris including in a maintenance setting as well as to treat negative symptoms. We are also submitting a supplemental application for use as an adjunctive therapy in bipolar disorder.

Our third star, Bridion or Sugammadex was approved last year in the EU. In response to a complete response letter we received from the FDA, we recently initiated a healthy volunteer study in the US and Europe. This is a hypersensitivity study being conducted in about 450 healthy volunteers. The study sites have recently been opened and patients are currently enrolling, the study should complete in the first half of 2010.

Our two other stars, our thrombin receptor antagonist or TRA and Boceprevir also continue to progress in their respective Phase III clinical programs. With TRA, our first and best-in-class PAR-1 receptor antagonist, I'm happy to report that we currently have a total of more than 32,000 patients enrolled in both the TRA-2P or TIMI-50 and TRACER studies. You may also have seen that the TRA Phase III methodology papers for both of the studies were published last month in the American Heart Journal.

Now, Boceprevir, our investigational best-in-class protease inhibitor for the treatment of Hepatitis C is also progressing. We have two ongoing Phase III studies in both treatment experience and treatment naive patients. Back in January, we announced that these two studies were fully enrolled. The Phase III program remains on track and scheduled for completion in 2010 and we anticipate filing for regulatory approval by the end of 2010. We're also very excited about Narlaprevir, our Next Generation once a day protease inhibitor. There will be a presentation of interim Phase II data at the upcoming AASLD meeting in Boston at the end of the month. We will also have presentations on Boceprevir and data from our Ideal trial with PegIntron.

As Fred said earlier the powerful Schering-Plough R&D story continues to unfold. Over this past year, we filed for regulatory approval of three new entities in either the US or EU, Corifollitropin alfa, mometasone formoterol or Dulera and NOMAC/E2 and we also filed a new version of Implanon, meanwhile for Vicriviroc, we plan to have a key FDA meeting this quarter before we initiate the rolling NDA process. In Japan, we introduced eight new products over the past two years and we recently received an endorsement for the approval of Sugammadex by the Japanese Committee on Drug. By any measure these are major accomplishments for any pharmaceutical Company. For Schering-Plough it also reinforces the culture of development excellence and high throughput clinical that we've built here.

In addition to the Five Stars, we have a constellation of programs in various stages of research development. Now let me update you about a few of our earlier stage programs that we're pretty excited about. First, Preladenant which is our Novel first and best-in-class adenosine 2A receptor antagonist currently in Phase II for the treatment of Parkinson's disease. Based on feedback from FDA and the European Medicines Evaluation Agency, we have recently developed a Phase III program to include use in both the monotherapy and adjuvant settings. These Phase III studies are in the planning phase for initiation in 2010. While we remain very excited about the near term potential of Simponi, for inflammatory disease, we also have additional shots on goal including our first and best-in-class opportunity for anti-IL-23p19 monoclonal antibody which is currently in Phase I testing. We're encouraged by the emerging proof of concept data in psoriasis.

We're also very excited about the progress of our early development program for BACE or beta secretase, a first and best-in-class treatment for Alzheimer's disease. Our preclinical data in primates which we shared with you last Fall was pretty exciting because it showed that BACE produced a greater than 90% reduction in A-beta 42 peptide upon continuous dosing. This Novel once a day treatment that can penetrate the blood-brain barrier is now in the clinic. Now we've seen in Phase I that with a single dose administration, we are observing a 58% reduction of A-beta peptide in the cerebral spinal fluid.

In closing we've worked hard over the past six years to build a robust late stage pipeline. We are gratified by these recent R&D successes and we remain focused on delivering the promise of these new medicines to the patients who need them most. I'll turn the call over to Bob.



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**Bob Bertolini** - Schering-Plough - EVP, CFO

Thanks, Tom, and good morning. Let me now take a few minutes to review the highlights of the quarter. As Fred mentioned, as we near the anticipated close of our merger with Merck, we're pleased that we've delivered another solid quarter, with operational sales growth of 4%, that's growth excluding the impact of exchange. Despite the pressures from a currency headwind and tough global economic conditions, we also increased earnings to \$0.40 per share on a reconciled basis. In fact, starting in 2005, we delivered year-over-year reconciled earnings growth each year and we've done it again each quarter this year. We're very proud of this long term performance.

On a GAAP basis, our third quarter net sales were \$4.5 billion, down 2%. This reflects 4% operational growth and an unfavorable impact from currency of 6%. Within our global prescription business, operational sales grew 6% offset by an unfavorable impact from currency of 6%. On an operational basis, our growth was led by solid performance from key global brands such as Remicade, Temodar, Nuvaring, Nasonex and Zetia in Japan. Consumer Healthcare sales were roughly in line with the prior year quarter at \$282 million. Higher sales of MirraLAX and other OTC products offset lower sales of OTC Claritin and sun care and foot care products. Raul Kohan will talk about our performance in Animal Health in a few minutes.

Now let me review our operating performance during the third quarter. On a reconciled basis, our gross margin was 65.9% lower than the prior year period. The decrease in the quarter was primarily due to an unfavorable impact from foreign exchange partly offset by favorable mix and manufacturing cost savings.

Before turning to SG&A, I want to briefly review our progress on PTP, our productivity transformation program. For just the first nine months of 2009 we achieved more than \$1 billion of PTP savings, so we remain well on track to achieve our annual \$1.5 billion PTP target by 2012. SG&A expenses in the third quarter decreased 9% to \$1.5 billion benefiting primarily from favorable currency and PTP actions. Excluding a favorable impact from exchange, SG&A was about 5% lower.

Moving to R&D, as you just heard from Tom, we continued to invest in R&D and advance our pipeline including our Five Stars. In the third quarter, our R&D expenses increased 2% to \$913 million. Excluding a favorable impact from currency, R&D spending increased 4% in the quarter.

In closing, our continued focus and execution on our core strategies helped drive solid performance in the quarter. This is a testament to the hard work and dedication of our Schering-Plough colleagues around the world. As we move closer to the anticipated close of our merger with Merck, we remain confident about the contribution that our people are making to the business. Thank you, and let me turn it over to Raul.

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**Raul Kohan** - Schering-Plough - SVP, President, Global Animal Health

Thank you, Bob and good morning, everyone. We continue to be excited about the potential of our Animal Health business. Our combination with Intervet has created a stronger Animal Health Company with a broad product portfolio and an innovative research pipeline. We are working together as one team and our long term fundamentals are strong. Now, I'd like to briefly comment on the performance of our business in the third quarter.

Sales declined 12% reflecting an operational decrease of 5% and an unfavorable impact from currency of 7%. On a global basis, our results were unfavorably impacted by a few factors. First, the Animal Health market continues to be impacted by tough global economic conditions; second, we also had unfavorable comparisons related to the 2008 launch of our bluetongue vaccine; and in addition to that our results were affected by back orders on certain products, primarily due to the ongoing integration of Animal Health manufacturing practices and quality standards.

On the positive side, our underlying business remains strong, and we continue to bring new and innovative products to market. For example, during the third quarter, we continued the successful launch of our new vaccine in Europe for circovirus in Swine. We also strengthened our companion animal offering with several new interactions in both Europe and the United States

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including the launch of a first in class vaccine for canine influenza in the United States. These new products help position us well for future growth and that is why we have confidence about the long term performance of our Animal Health business. Thank you, and I'll now turn the call over to Carrie.

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**Carrie Cox** - *Schering-Plough - EVP, President, Global Pharmaceuticals*

Thanks, Raul. Good morning. I'll take just a few minutes to provide some perspective on our strong third quarter results. We've continued to work hard to capture the value in our product portfolio and we're pleased to have driven solid operational growth across many of our top brands and in most major markets. Products like Remicade, Temodar, Nuvaring, and Nasonex have been important growth drivers. Their strong third quarter performance and their positive momentum maintained throughout the year provides another example of the strength of our global teams.

Leading the way is Japan delivering strong double digit growth ex-exchange. The September launches of Remeron and Asmanex, as well as the continued development of Zetia and Nasonex help to transform our performance in this critical market. In fact, year-to-date sales in Japan have more than tripled since 2003.

I also want to comment on how we are delivering on the pipeline, especially the Five Stars. As you know, Simponi was approved in Europe in October for the subcutaneous treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis and it has already been launched in Germany. Market feedback from Canada where Simponi launched this past June shows that Simponi is delivering on its unique promise of powerful efficacy and once monthly dosing.

Finally, I want to talk about the US introduction of Saphris. You heard Fred mention the launch meeting and we are absolutely delighted in the team's energy, execution and excitement. Saphris is now available in the US and the early feedback our sales team has received from psychiatrists is quite encouraging. We believe Saphris can make a difference for the millions of patients living with schizophrenia or bipolar disorder. Its combination of competitive efficacy and demonstrated metabolic safety make it an important treatment option for new and switch patients alike.

In closing, back in March, we asked our team for their continued commitment to our business and our goals. They have more than delivered and have remained focused on driving performance. A very special thank you to all of our Schering-Plough colleagues for never losing sight of what matters most, our customers and their patients. Now, let me turn the call back to Fred.

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**Fred Hassan** - *Schering-Plough - Chairman, CEO*

Thank you, Carrie. As you've heard, our people are doing a remarkable job keeping up our strong forward momentum. Thanks to them, we will be delivering a powerful engine to the new combined Company with Merck. We look forward to what we can achieve together and now, let's turn to your questions.

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**Janet Barth** - *Schering-Plough - VP, IR*

We're ready to begin the Q&A session. In the interest of time we would appreciate if you could limit yourself to one question so that we can get to as many of you as possible.

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) Your first question comes from the line of Tim Anderson with Sanford Bernstein.



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**Tim Anderson** - Sanford Bernstein - Analyst

Thank you. I actually have two questions. First off I wanted to wish you, Fred, and others well in your next endeavor whatever that's going to be. And the first question is whether you can give us an inkling when and where we'll see you next? The second question is a product question on your cholesterol franchise. Can we get an update on when FDA will come out with its analysis of SEAS? It seems very much behind schedule and I wonder if the FDA could be waiting on Arbiter 6 to say anything on SEAS, so what are the updated expectations here?

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you, Tim, for those kind comments and as you know, I'm very focused on Schering-Plough results and very proud of the results we're achieving and as I've said earlier, I love this industry, I'm passionate about this industry and I'm very very confident about the future of this industry. So you will see a very active Fred Hassan as we go into the future. And Tom Koestler, would you answer the question on cholesterol, please?

**Tom Koestler** - Schering-Plough - EVP, President, Research Institute

Yes, Tim, we have not heard anything back from the FDA, so I would assume that it's still under review. I don't really see a relationship to Arbiter 6. It's not clear when we expect to hear from FDA and I really can't offer much more than that.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you, and next question please?

**Operator**

Your next question comes from the line of Jami Rubin with Goldman Sachs.

**Jami Rubin** - Goldman Sachs - Analyst

Hello. Apologies for the nitpicky question. The equity income number from the cholesterol joint venture came in below our expectations and represents a yield to revenues of about 33%. Can you explain what's going on because it does seem to be slipping? Is this a reflection of increased promotional expenses when I actually thought you were sort of pulling back given how much the market has shrunk? Thanks.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Bob?

**Bob Bertolini** - Schering-Plough - EVP, CFO

Yes, Jami, it's Bob, Jami, how are you?

**Jami Rubin** - Goldman Sachs - Analyst

Good.

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**Bob Bertolini** - Schering-Plough - EVP, CFO

So the equity income as reconciled came in around \$387 million compared to roughly \$415 million last year and I would say you're right, the actual promotional spending is down so we're actually pretty pleased with the performance we've seen on equity income line.

**Jami Rubin** - Goldman Sachs - Analyst

Okay, even though as a percentage of sales it's below where it was in the previous quarters?

**Bob Bertolini** - Schering-Plough - EVP, CFO

It's really a function of the top line, Jami.

**Jami Rubin** - Goldman Sachs - Analyst

Okay, thank you.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you, next question, please?

**Operator**

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

**Catherine Arnold** - Credit Suisse - Analyst

Thanks, and I have to also take the chance to say Fred, congratulations to you and your team for all you've accomplished with this Company since you took the reins and you're leaving it in a very different place so good for you.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you very much, Catherine.

**Catherine Arnold** - Credit Suisse - Analyst

The question that I have for you is going back to Tom's review of some of the sort of mid stage pipeline and the specific question about that is I just want to clarify, is the BACE program in Phase II and if you could just sort of speak to what he expects the timeline of that Phase II program to be, and then what are the Phase II programs that will be in line for a go, no go decision on Phase III in 2010 that we should be watching out for? Thanks.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Tom?



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**Tom Koestler** - Schering-Plough - EVP, President, Research Institute

Yes, Cathy, thanks for the call. As far as the BACE program is concerned as I just reported we're in Phase I and we're moving into Phase II probably within the next three to six months. It's in the rising multiple dose phase of that study so it's early so I really can't offer too much more than that and in terms of phased transitions for the pipeline going from Phase II to Phase III, certainly for Narlaprevir which is the compound that I mentioned a few minutes ago which we're pretty excited about our Next Generation protease inhibitor, that is currently in Phase II so I think some time later in 2010 we may get some news about transitioning that program and we will have some pretty interesting results that will be presented at the AASLD. So Boceprevir is already in Phase III, Viciviroc is on late Phase III as well. We also have a treatment naive program for Viciviroc that's in the Phase II setting so that could also transition going forward. We also have some interesting programs with Anacore which is this topical product that we have for Onychomycosis which is in late Phase II testing as well and we have a few others that are in the pipeline. So I would just sort of highlight those right now, Catherine, and we'll see what the future will bring for us.

**Catherine Arnold** - Credit Suisse - Analyst

Okay.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you very much Catherine and next question, please?

**Operator**

Your next question comes from the line of Chris Schott with JPMorgan.

**Chris Schott** - JPMorgan - Analyst

Great. Thank you. I just was hoping you could elaborate a little bit more on gross margin we saw in Q3. I guess specifically if you can quantify the impact from currency on gross margins this quarter and at current exchange rates should we expect another hit from currency in the fourth quarter? Thanks.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Very good question, Chris. Bob?

**Bob Bertolini** - Schering-Plough - EVP, CFO

Thanks, Chris. Yes, the gross margin came in about 65.9 this quarter on a reconciled basis and that compares to 66.9 in the prior year period so it's down about 100 basis points. We would estimate that the impact from exchange was about 190 basis points actually. So excluding the impact from exchange, our gross margin would have actually improved primarily due to mix and so we're seeing, Chris, some manufacturing cost savings. I think going forward, it depends on the volatility of the currencies. As you can see they are extremely volatile and really this is related to the inventory as they move through our international networks so it's hard to predict going forward what that impact would be given the volatility we're seeing in the currencies.

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**Fred Hassan** - Schering-Plough - Chairman, CEO

I think the reason I think it's a good question is last year at the R&D day we got asked a question about currency and we are heavy with our outside business and when you compare the spot rate today versus the spot rate this time last year, there's quite a good difference and it should be good for companies with large businesses overseas, and next question, please?

**Operator**

Your next question comes from the line of David Risinger with Morgan Stanley.

**David Risinger** - Morgan Stanley - Analyst

Thanks very much. I just was curious if you could provide an update on Improve-It including where the enrollment stands and then also if you could please comment on the next steps for the steering committee and the others leading the study with respect to the look at the lipid levels in both arms and also the look at when the study hits 50% of events? Thank you.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Tom?

**Tom Koestler** - Schering-Plough - EVP, President, Research Institute

Yes, David. The Improve-It product trial right now we're pretty pleased with the enrollment, we have exceeded 15,000 patients to date. As you pointed out, there will be continuous review as outlined in the methodology paper by the DSMB and the lipid panel. I really can't predict for you exactly when the interim analysis will take place because that's dependent upon the event rate but we would probably point to some time next year for that particular analysis and I do fully expect that the program will continue to the full 18,000 patients that we're attempting to enroll for the program.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you, and next question, please?

**Operator**

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

**Seamus Fernandez** - Leerink Swann - Analyst

Thanks very much and congratulations, Fred, and everybody from the Schering-Plough management team moving forward. I'm sure we're all excited to see where everybody ends up. My question actually is on just two quick questions. On TRA, can you just update us on where enrollment stands in the TRA 2P study and the timing of when enrollment is expected to complete in that study? And then the second question with regard to Improve-It, Tom can you just tell us whether or not there would be a futility analysis incorporated into this study and if there isn't a futility analysis can you just explain why? Thanks.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you for those kind comments and Tom, if you can answer?

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**Tom Koestler** - Schering-Plough - EVP, President, Research Institute

Yes, Seamus, for the TRA program I would expect that for 2P, the TIMI-50 trial, I think I previously reported this has been the fastest enrolling trial ever in the history of TIMI, and I would expect very soon that the enrollment will be complete for that 2P-TIMI-50 trial. As far as improvement is concerned, Seamus, I think the best thing for you to do is to really look at the methodology paper that will outline in more detail the types of analyses that will be occurring going forward here.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Thank you very much. And one more question.

**Operator**

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

**Steve Scala** - Cowen and Company - Analyst

I also have a question on TRA. Schering has been saying a filing was possible in 2010 or '11. Is there a scenario where 2010 is still possible based on current enrollment, treatment duration, data analysis and NDA preparation? Thank you.

**Fred Hassan** - Schering-Plough - Chairman, CEO

Very good question, Steve.

**Tom Koestler** - Schering-Plough - EVP, President, Research Institute

Steve, again it's difficult to be absolutely precise because as you know, this is an event -- these are event driven trials, but we're very pleased with the enrollment on 2P and TRACER as well. Both of these trials have really really been hitting the mark in terms of enrollment. So as I just reported a few minutes ago, in response to the other question, we would expect that the enrollment for 2P to be complete fairly soon and the trial is designed and the methodology paper is now available, it was published in the American Heart Journal, it's designed such that it's based on event rates and it also has a one year follow-up. So you can kind of do the math and we're still cautiously optimistic, 2010, 2011 is where we're still netting out.

**Fred Hassan** - Schering-Plough - Chairman, CEO

So in closing I'd like to just thank everybody for your good wishes. We have actually a very very strong Company but the Company is a result of the good people we have in our Company and we look forward to our individual futures as we go forward. We're proud that our people continue to drive high performance in the face of major challenges and it's rewarding to see that the Schering-Plough R&D story continues to unfold with new product launches and a very rich late stage pipeline. And thanks to our six year transformation journey at Schering-Plough. We will now be delivering a very powerful engine into the combination with Merck. This is a great legacy created by our people. Thank you very much for joining our call this morning.

**Operator**

This concludes today's conference call. You may now disconnect.

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