

MYOGEN INC  
Form SC TO-C  
October 03, 2006

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## Schedule TO

Tender Offer Statement under Section 14(d)(1) or 13(e)(1)  
of the Securities Exchange Act of 1934

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### Myogen, Inc.

(Name of Subject Company (Issuer))

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Mustang Merger Sub, Inc. (Offeror)

Gilead Sciences, Inc. (Parent of Offeror)

(Names of Filing Persons)

COMMON STOCK, PAR VALUE \$0.001 PER SHARE

(Title of Class of Securities)

62856E104

(CUSIP Number of Class of Securities)

Gregg Alton

Senior Vice President and General Counsel

Gilead Sciences, Inc.

333 Lakeside Drive,

Foster City, California 94404

Tel: ( 650) 574-3000

(Name, address, and telephone number of person authorized to receive notices)

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and communications on behalf of filing persons)

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**Calculation of Filing Fee**

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**Transaction Valuation**

Not Applicable

**Amount of Filing Fee**

Not Applicable

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Check the box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number or the form or schedule and the date of its filing.

Check the box if the filing relates to preliminary communications made before the commencement of a tender offer.  
Check the appropriate boxes below to designate any transactions to which the statement relates:

third-party tender offer subject to Rule 14d-1.

issuer tender offer subject to Rule 13e-4.

going-private transaction subject to Rule 13e-3.

amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer:

**Oct. 02. 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call**

**Conference Call Transcript**

**GILD - Gilead Sciences Conference Call**

**Event Date/Time: Oct. 02. 2006 / 8:30AM ET**

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1

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**Oct. 02. 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call**

**CORPORATE PARTICIPANTS**

**John Milligan**

*Gilead Sciences, Inc. - EVP and CFO*

**John Martin**

*Gilead Sciences, Inc. - President, CEO and Director*

**Kevin Young**

*Gilead Sciences, Inc. - EVP, Commercial Operations*

**CONFERENCE CALL PARTICIPANTS**

**Meg Malloy**

*Goldman Sachs - Analyst*

**Mike King**

*Rodman & Renshaw - Analyst*

**Geoffrey Porges**

*Sanford Bernstein & Company, Inc. - Analyst*

**Thomas Wei**

*Piper Jaffray & Co. - Analyst*

**Geoffrey Meacham**

*J.P. Morgan - Analyst*

**Ian Somaiya**

*Thomas Weisel Partners - Analyst*

**Sapna Srivastava**

*Morgan Stanley Dean Witter - Analyst*

**Craig Parker**

*Lehman Brothers - Analyst*

**Tim Freedarone**

*Citigroup - Analyst*

**Eun Yang**

*Jefferies & Co. - Analyst*

**Bill Tanner**

*Leerink Swann & Company - Analyst*

**Bill Slattery**

*Deerfield Partners - Analyst*

**Michael Abramin**

*Credit Suisse First Boston - Analyst*

**Phil Nadeau**

*Cowen and Company - Analyst*

**Jim Reddoch**

*Friedman, Billings, Ramsey & Co. - Analyst*

**Maged Shenouda**

*UBS - Analyst*

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2

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**Oct. 02, 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call**

**PRESENTATION**

**Operator**

Ladies and gentlemen, thank you for standing by. Welcome to this morning's conference call to discuss the announcement made early today regarding Gilead Sciences' plans to acquire Myogen.

[OPERATOR INSTRUCTIONS]

Your speakers for today's call are John Martin, President and Chief Executive Officer, and John Milligan, Executive Vice President and CFO. I would now like to turn the call over to John Milligan. Please proceed.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Good morning, everyone. Thank you for joining us this morning on such short notice. We're very pleased to announce that Gilead Sciences and Myogen have signed an agreement under which Gilead will acquire Myogen. By now you should have received a copy of the press release issued early this morning.

On our call today, we would like to provide you with some of the highlights, rationale and financial terms of the agreement and also give you the opportunity to ask any questions you may have.

Joining me on today's call from Gilead are John Martin, Kevin Young, Executive Vice President, Commercial Operations, Norbert Bischofberger, Executive Vice President of Research and Development, Mark Perry, Senior Business Advisor, and Susan Hubbard, Vice President, Investor Relations. John Martin will begin by giving an overview of the rationale and benefits of the deal. Then I will go over some of the financial terms associated with the acquisition, which will take the form of a tender offer followed by a backend merger. We will keep the call to approximately 45 minutes. So, to that end, we will keep our comments brief in order to allow as much time as possible for your questions.

I would like to remind you that we will be making forward-looking statements that are subject to risk, uncertainties and other factors that could cause our actual results to differ materially from those referred to in any forward-looking statement. Statements in this conference call relating to the consummation of the contemplated acquisition are subject to the possibility that one or more of the closing conditions to the tender offer might not be satisfied, including the possibility that regulatory approvals might not be obtained. In addition, we are moving into a quiet period in connection with the tender offer, so we are limited on the details we can share.

Statements related to the expected benefits of the contemplated acquisition are subject to the risks that are expected to the risk that expected synergies will not be achieved and that the operations, products and employees of Gilead or Myogen will not be integrated successfully. The market for Myogen's products may not develop as anticipated and Myogen's products are not approved by regulatory authorities as well as the general risks associated with the respective businesses of Gilead and Myogen as described in the reports and other documents filed by each of us with the Securities and Exchange Commission.

Now, I'd like to turn the call over to John Martin. John?

**John Martin - Gilead Sciences, Inc. - President, CEO and Director**

Thank you, John. I, too, would like to thank everyone for joining us this morning on such short notice. We are very pleased to announce the signing of our agreement to acquire Myogen. We will now work to complete the tender offer, obtain necessary regulatory approvals and then to integrate the accomplished Myogen team and its promising product pipeline into our growing organization.

As you know, Gilead regularly evaluates opportunities to augment our product portfolio, pipeline and internal capabilities and to build under established areas of expertise to grow our company. Our planned acquisition of Myogen represents both a scientific and strategic fit. The acquisition of this acquisition allows us to build off our recent acquisition of Corus, expanding our knowledge and focus in pulmonology. We also will augment our growing pipeline with a late-stage product candidate in ambrisentan. Ambrisentan is an endothelin receptor antagonist in

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development for the treatment of pulmonary arterial hypertension.

Pulmonary arterial hypertension or PAH is a rare disease which is typically progressive and fatal and it affects approximately 50 to 100,000 Americans with 5,000 newly diagnosed cases reported annually.

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3

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The median survival of untreated PAH patients following diagnosis is estimated to be approximately 2.8 years. This debilitating disease occurs twice as frequently in females as in males and tends to be diagnosed between the ages of 20 and 50. Tracleer, a product marketed by Actelion, was the first endothelin receptor antagonist approved for the treatment of PAH and remains the only FDA-approved product in the class.

Tracleer sales worldwide sales for the first half of 2006 were \$339 million, up 49% over 2005. This represents a significant and growing commercial opportunity.

We believe that ambrisentan has the potential to be the best product in the endothelin receptor antagonist class, based on its efficacy and safety profile and lack of drug-drug interactions. Two pivotal Phase III studies, ARIES 1 & 2, in treatment-naïve patients were completed earlier this year. Positive data from these two studies will form the basis of an NDA filing in the U.S. expected prior to the end of this year, with a filing expected in the European Union early next year.

Earlier this year, Myogen signed a U.S. market agreement with GlaxoSmithKline for their product, Flolan, which was approved in 1995 for the treatment of patients with stage IV PAH. This agreement provided the strategic opportunity for Myogen to establish a small sales force of 17 individuals who are building relationships with key prescribers. To adequately promote ambrisentan after its approval, we believe we will need to grow this sales force to a range of 75 to 100 sales reps. Ambrisentan addresses an area of significant unmet medical need. Many affected individuals are diagnosed late in their disease and most do not receive adequate treatment. In addition, there is a trend towards increased combination therapies with multiple mechanisms of action. These market characteristics are consistent with the specialty therapeutic markets where Gilead has extensive commercial experience.

In addition to ambrisentan, Myogen has a compound, darusentan, in Phase III development for the treatment of patients with resistant hypertension. The first Phase III is enrolling and the second Phase III study is expected to begin in the fourth quarter of this year. In summary, we are very excited about this opportunity to expand our respiratory franchise with a very promising late-stage drug candidate addressing a growing market. We will rely on the diligence and experience of Myogen employees to rapidly advance the U.S. NDA filing for ambrisentan. We are confident that we can execute an expeditious and efficient integration of our two teams. With those comments, I would like to turn it back over to John Milligan, so that he may walk you through some of the specifics of the deal terms and then we will be then we will all be available for questions.

John?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Thank you, John. First, I need to be clear that this announcement is neither an offer to purchase nor a solicitation of an offer to sell Myogen shares. The tender offer will only be made through an offer to purchase, letter of transmittal and related tender offer material. At the time the expected tender offers commence, Gilead will file these tender offer materials with the Securities and Exchange Commission and Myogen will file a Solicitation/Recommendation Statement with respect to the offer.

The tender offer materials and the Solicitation/Recommendation Statement will contain important information. Stockholders are urged to read this information carefully before making any decisions about the tender offer. The tender offer materials, certain other offer materials and the Solicitation/Recommendation Statement will be sent free of charge to all stockholders of Myogen.

Now, I'd like to walk you through the transaction terms. Under the terms of the agreement, Gilead will pay \$52.50 per share of Myogen stock and a cash tender offer for a total deal value of approximately \$2.5 billion, including the assumption of outstanding option. This transaction includes a cash offer made directly to Myogen shareholders and a subsequent merger to cash out any shares not tendered. As Gilead has cash reserves in excess of \$3 billion and positive operating cash flow, we have sufficient cash on hand to complete this transaction. The deal is expected to be dilutive to Gilead's earnings in 2007 and 2008, neutral in 2009 and accretive in 2010 and beyond. We will provide more detailed information related to the impact of this transaction on our future financial results once we have completed the transaction.

We anticipate that the tender offer will be completed in the fourth quarter of this year, subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act, completion of the successful tender offer and other standard conditions typical of deals of this size and scope.



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As John stated earlier, we're very excited about the agreement to acquire Myogen and we really look forward to welcoming Myogen's dedicated and experience staff to Gilead in helping to bring an important new drug to patients in need.

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4

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With that, this concludes the formal part of the call. We will now begin the question-and-answer session. Operator?

**QUESTION AND ANSWER**

**Operator**

Yes, sir.

[OPERATOR INSTRUCTIONS]

And your first question comes from the line of Meg Malloy from Goldman Sachs. Please proceed.

**Meg Malloy - Goldman Sachs - Analyst**

Thanks very much. Two quick questions, following the rules here. One is, in terms of leveraging the pulmonary opportunity that you've kind of started with Corus, could you walk through how PAH would be different from CF and how you would envision sort of building out the commercial franchise. And John Milligan, I realize it's a little bit early [basic], is there any sense you can give us on what kind of magnitude of position we might expect in '07 and '08? Thanks a lot.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Hi, Meg. So, in terms of the leveraging pulmonology, the sales forces that we have put together for PAH and for cystic fibrosis are, in fact, distinct. So, we wouldn't have combined sales forces in that area. We would sell to pediatric pulmonologists in the case of cystic fibrosis and pulmonologists/cardiologists for PAH. Each has similar characteristics in that there are a set number of centers. For example, there's about 120 centers for PAH and there is some good overlap with the CF proximities to the CF centers. But in general, I would think of them as distinct sales forces. What we're looking for in terms of the long term synergies between these two organizations is the broader opportunity for the future into all sorts of pulmonology disorders and the expertise that these two respective organizations bring to us in terms of both development and discover of compounds in this area, which has a high number of diseases of unmet medical needs.

So, that's the quick answer to how we view this coming together. The second question with regard to the magnitude of the dilution, we're not yet prepared to give you the impact of dilution because it will depend quite a bit on the timing of the transaction, how many employees are retained at the site and our expectations for budgets for next year. And we're just in the process of putting those together. So, we'll update you on future calls with respect to the impact for 2007 in particular.

**Meg Malloy - Goldman Sachs - Analyst**

Thank you, John and John.

**Operator**

And your next question comes from the line of Mike King with Rodman & Renshaw. Please proceed.

**Mike King - Rodman & Renshaw - Analyst**

Good morning. Thanks for taking my question. Gentlemen, I was wondering if you could speak to the hefty premium and the thought process behind the premium offered for Myogen shares.

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**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Well, Mike, a couple things to say about the thought process here. Number one, this was a process that was being run. So, there were other organizations involved in this. That does tend to make premiums higher than they would be otherwise. There also is a scarcity value associated with products in late stage. It's very few interesting late stage Phase III studies, particularly those that have positive two positive trial and an NDA looming which become available. I think that sort of dictates the premium more than anything else in this area. We looked at this very carefully from a number of perimeters in terms of the sales potential of the product, the overall clinical potential of the product, our ability to leverage the kind of high margin products that we typically like and felt that the premium was a fair value for what we were doing here and that this was, in fact, a product that we could build a franchise around a very interesting product.

And so, as you can tell here, we're very heavily focused on ambrisentan. We also have some synergy with the product Flolan, which came in from GlaxoSmithKline. That's an attractive asset because it allows the sales forces to get out there sooner to establish the expertise in the area. I think that was an important part of the asset. And then, finally, there's darusentan, which is a product for resistant hypertension. Resistant hypertension is not an area where you would typically find us. I think it's an interesting asset. We're, frankly, not sure exactly how we will utilize that kind of product. The Phase II data were very striking in terms of the milligrams I'm sorry, millimeters of mercury drop in blood pressure. Very distinct in patients who have failed other therapies. And so, I think that's an opportunity that we could figure out how to deal with over time, but it does represent some potential interesting value for the future.

**Mike King - Rodman & Renshaw - Analyst**

Terrific. And I'm wondering I remember when the Flolan agreement was announced, the Street reacted fairly negatively to it. Do you think that was the appropriate reaction or is there something that you think the investors are missing in that regard?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Well, I think Flolan was a good opportunity for the U.S. It seemed to me that investors were somewhat disappointed in the partnership with Glaxo for Europe at that point in time. And I think European partnerships can be an advantage in certain cases and a disadvantage in certain cases and I guess the Street reacted that this was a disadvantageous relationship because it gave up worldwide rights Myogen gave up worldwide rights in exchange for that. So, I do think there was a little bit of a letdown associated with that.

**Mike King - Rodman & Renshaw - Analyst**

Thank you.

**Operator**

And your next question comes from the line of Geoffrey Porges with Sanford Bernstein. Please proceed.

**Geoffrey Porges - Sanford Bernstein & Company, Inc. - Analyst**

Great. Thanks for taking the question. Could you take us through, Kevin, your thinking about the assumptions that you used in analyzing this market. What you really see as the accessible patient population given the late presentation of some of these patients and then what you think [inaudible] in terms of potential of range of pricing and that sort of thing. Just give us a little bit more insight as to your analysis.

**Kevin Young - Gilead Sciences, Inc. - EVP, Commercial Operations**

Hi, Geoffrey. Just to comment on your last part of the question. We wouldn't be commenting on pricing at this point in time. In terms of the market, we would estimate there is circa 88,000 PAH patients in the U.S. Approximately 30% of those are actually diagnosed. 85% of that 30% are actually on all therapies of some form. So that's about 24,000 patients. And approximately 40% of that 24,000 are actually on an endothelin receptor antagonist. So, that's currently how we see the market. So, the opportunity, we think, for our new product, will be in both switching patients because of its profile as well as in the new patients. And as John said, there's approximately 5,000 new patients per annum are diagnosed

with PAH.

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6

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**Geoffrey Porges - Sanford Bernstein & Company, Inc. - Analyst**

Sorry, Kevin, but just to follow up on that, was you thinking then that the opportunity for Gilead with ambrisentan was a share gain or was it increased penetration or increased overall market? I mean, you're making the analogy back to HIV.

**Kevin Young - Gilead Sciences, Inc. - EVP, Commercial Operations**

Well, clearly, there is established competitor—a company that essentially made the market for endothelin receptor antagonists. We will be treating them with respect. We believe we have a product with a stronger profile. So, components of our entry will be share gain. But as we've done in both hepatitis and in HIV, we always consider that, as a leading company, part of our role is to develop the market and we think there is opportunity for quite significant growth in PAH just by an increase in the diagnosis of patients.

**Geoffrey Porges - Sanford Bernstein & Company, Inc. - Analyst**

Thanks. Very helpful.

**Operator**

And your next question comes from the line of Thomas Wei from Piper Jaffray. Please proceed.

**Thomas Wei - Piper Jaffray & Co. - Analyst**

Thanks very much. Just a follow-up on the last question here. In—when you've looked at the clinical data and the market opportunity, did you assume that there would utility of ambrisentan in patients who fail another endothelin receptor antagonist? And then, how does that 75 to 100 rep sales force compare to some of other competitors?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Thomas, we did look at the overall profile of the product and we think that the distinct decrease in ALTs—so distinct change in liver toxicity, the lack of drug-drug interactions would allow for switching.

So, there is a switching component to the model as well as uptake of new patients who are new to the market. So, I think those two aspects led us to the conclusion that we could make this a very significant product along with the increase of diagnosis going forward. If you look at the sales reps that we're thinking about, it's a little bit smaller than they—what I would—what I think the current Actelion sales force looks like. But so we've been looking at the geography and the types of centers that we've been focusing on. I think that's the right place for us to start.

**Operator**

And your next question comes from the line of Geoffrey Meacham with J.P. Morgan. Please proceed.

**Geoffrey Meacham - J.P. Morgan - Analyst**

Yes, it's Geoff Meacham. Given your bullish view on ambrisentan, any plans to reacquire rights to that drug in Europe from Glaxo?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

I wouldn't—those sorts of things are almost impossible to do, so I would not expect that to occur. No.

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**Geoffrey Meacham - J.P. Morgan - Analyst**

Okay. And then just a quick follow-up. With more resources behind Myogen's assets, do you guys have any initial plans to change the DAR-312 trial for darusentan or expand the ambrisentan clinical program?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

I would say we don't currently have any plans to change the darusentan trials. We are looking into additional studies for ambrisentan. Yes.

**Geoffrey Meacham - J.P. Morgan - Analyst**

Okay. Thanks.

**Operator**

And your next question comes from the line of Ian Somaiya with Thomas Weisel. Please proceed.

**Ian Somaiya - Thomas Weisel Partners - Analyst**

Thanks for taking my question. Will you have any role in the NDA filing or putting together the NDA package for ambrisentan?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

We are going to start working as soon as we can with the team at Myogen and, yes, we would like to have a role in putting the NDA together. Clearly, this NDA is going in, in the fourth quarter, which is this quarter. So, there's a lot of work on going there. But clearly, we will start to work on this as soon as possible. But even once you file there's a lot of work to do. So, I think, as you recall, with the triangle acquisition a few years ago, that application went in during the tender offer process. But we were already working very closely with the team there. And then, of course, worked very closely with them after the filing, which is where a lot of the hard work goes in terms of getting approval. So, we intend to be involved in that. Absolutely.

**Ian Somaiya - Thomas Weisel Partners - Analyst**

And just a follow-up question. On darusentan, how come there's value to moving that product forward? It seemed like there was some hesitation in terms of whether it perfectly fits within the current selling effort. Or how much incremental effort it would require.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Clearly, we place a lot of value in ambrisentan in this transaction. Darusentan does provide value to us. It's one of those areas that we're continuing to evaluate. It had very positive Phase II data. We'll have to see how the Phase III studies play out before we can before we'll know exactly where that product would fit in terms of the current regimens for hypertension and what the market potential is for that. So, I sort of put it in that category of we're going to watch and evaluate based on the data that comes out.

**Ian Somaiya - Thomas Weisel Partners - Analyst**

Okay. Thank you.

**Operator**

And your next question comes from the line of Sapna Srivastava from Morgan Stanley. Please proceed.



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**Sapna Srivastava - Morgan Stanley Dean Witter - Analyst**

Hi. So, I think just one broad [related] question. I think a lot of us are surprised by the significant substantial investment into a franchise that surely you haven't spent any time on. And maybe can you just walk us through like what all you evaluated to make this investment worth it in pulmonology. And also, where do you see the room to grow in this area? Which other product types as you go into the future.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Sapna so, two things. How we evaluated this was largely based on our ability to bring a new therapeutic product to market that met an unmet medical need. That was first and foremost for us. And ambrisentan fills that kind of product category that we were looking for. It fit in nicely with the kind of doctors that we think we can get to fairly closely. It is different than what we do in HIV, but there's a lot of characteristics to this market that are, in fact, quite similar in terms of combination in terms of it being a relatively new indication, so many people don't know they have it.

As we look more broadly, though, we look at other pulmonology indications that we've been quite interested in getting into and we do think there's an overlap, again, with the research, the development expertise we have both at Corus and now we have at Myogen. We do think there's a strong opportunity for the future to build more products products that we could potentially build off ambrisentan and products that we can fill in around ambrisentan. So, we've looked broad and hard at a lot of different areas to get into and so we've been looking at this area in particular for not a short period of time. More than a year we've been evaluating opportunities in this area and really started to focus most heavily on Myogen earlier this year.

**Kevin Young - Gilead Sciences, Inc. - EVP, Commercial Operations**

Sapna, I'd also - I think, from my point of view, the commercial organization is ready to do this. Over the last couple of years, we've worked very hard on investing in both the quantity and quality of the commercial organization and I think we're ready to take on a new therapeutic area without diverting attention from hepatitis and HIV. So, I think ...

**Sapna Srivastava - Morgan Stanley Dean Witter - Analyst**

But you have to divert some attention if you want to grow in the other areas, right? Because I mean, the cash investment that you're making in this area definitely, potentially puts a limit to what you can do in other areas.

**Kevin Young - Gilead Sciences, Inc. - EVP, Commercial Operations**

Well, as John said, in terms of the focus that we'll apply in ultimately marketing and selling ambrisentan, it certainly will be very much a dedicated focus.

**Sapna Srivastava - Morgan Stanley Dean Witter - Analyst**

Okay. Thank you.

**Operator**

And your next question comes from the line of Craig Parker with Lehman Brothers. Please proceed.

**Craig Parker - Lehman Brothers - Analyst**

Good morning. John, is there a royalty obligation to Abbott on ambrisentan and darusentan? If so, can you give us an idea what that is? And the second question is it's a I guess, a relatively short patent life for ambrisentan, if I'm right about that, to 2014. Is there a really obvious opportunity for a formulation change or perhaps even a fixed dose combination that would extend that?

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**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Hi, Craig. So, a couple things. With regard to the patent life of ambrisentan, it's actually 2018.

**Craig Parker - Lehman Brothers - Analyst**

Okay.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

So, we have a longer patent life than that. There have been some recently issued patents earlier this year, I believe, that came out and we're very confident of the patent position of this product. Your earlier question is that these were originally discovered by Knoll Pharmaceuticals which merged into Abbott, so there is a royalty obligation back to Abbott, both on ambrisentan and on darusentan. The ambrisentan royalty is the chair royalty that starts in the tens and goes up. And the ambrisentan - I'm sorry - darusentan royalty starts at 14 and goes up from there. So, that's an obligation that we'll have back to them.

**Craig Parker - Lehman Brothers - Analyst**

Great. Thank you.

**Operator**

And your next question comes from the line of [Tim Smith] with Citigroup. Please proceed.

**Tim Freedarone - Citigroup - Analyst**

Hey, this is [Tim Freedarone]. I was just wondering if you guys could talk a minute about how enrollment is proceeding in the DAR-311 trial. I mean, I know, I think accumulatively the two darusentan trials are enrolling over 1,000 patients. And if I recall, the Phase II trials, these trials do take awhile to enroll. So, just wondering if you guys could lay out some - just even a general timeline of when you expect 311 to do a complete enrollment and for 312 to be initiated.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Yes, so the 311 trial is in its very early days, so I don't think we can give a good projection other than to say it's certainly going to be more than a year for enrollment to get the full cohort and maybe significantly longer than that. It's hard to project from early days because you don't have all your sites up and running and you don't have your full run rate established at that point in time, so it's a little bit complicated for us to project from here. We may get more clarity as we dig in a little bit more closely to that one. The 312 trial would be expected to begin fairly soon. It could, in fact, begin this quarter. If not this quarter, then next quarter. But they are finishing up the protocol and getting [IRB] approval, things of that nature.

**Tim Freedarone - Citigroup - Analyst**

Okay. Great. Thanks a lot.

**Operator**

And your next question comes from the line of Eun Yang from Jefferies. Please proceed.

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**Oct. 02. 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call**

**Eun Yang - Jefferies & Co. - Analyst**

Hi. Thanks very much. In the past you guys were saying that the therapeutic areas that you were interested in are oncology and inflammation. But recent acquisitions of Corus and this today's call, it sounds like you guys are more moving into the pulmonology or respiratory area. So, my question is are you still looking into the oncology and inflammation disease areas?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

So, Eun, a couple of years ago there was quite a bit of speculation that we would move into oncology and we've tried our hardest to say that is the least likely - not the least likely, but less likely than other areas to move into because of the difficult nature of the predictability of early compounds and the scarcity of compounds that I think serve an unmet medical need there. So, we've, for the last couple years really felt that oncology is a tough area for us to move into. Inflammatory diseases is an area that we're quite interested in. There are all sorts of manifestations of that.

But also, as we started to look around for other specialty therapeutics, it became clear that respiratory diseases have great unmet medical needs and pulmonology has some interesting unmet medical needs with some really interesting compounds coming through. Especially the ERA, the endothelin receptor antagonists being a pretty neat class of compounds. And so, our interest moved over to that. At any given time, there's probably four or five different areas that we would have considered moving into depending on the data, the compounds available and the companies that were available. And at some point at time, we really started to circle into this because of the two companies and the ability that we have and the people that will join us have to build a franchise for the future.

**Eun Yang - Jefferies & Co. - Analyst**

Thank you.

**Operator**

And your next question comes from the line of Bill Tanner from Leerink Swann. Please proceed.

**Bill Tanner - Leerink Swann & Company - Analyst**

Thanks. John, just maybe some questions on the guidance. I know you probably don't really want to get a lot into specifics. But just curious how much there is - or how conservative they actually would be in terms of it doesn't sound like there's much in the way of darusentan expectations in that and that drug could perhaps be on the market in 2009. So, just kind of curious if there could be less or there could be some accretion, I guess, in 2009 and even more so in 2010. And then, your early comments about how you would utilize it, I'm guessing that also would just contemplate taking it through Phase III and then perhaps selling it to another company to actually to the marketing.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

It's very hard for us to give guidance for 2009 because there's so many different variables that far out in the future. We haven't yet determined what the spend rate is going to be on these programs for 2007 nor what the exact timelines are for darusentan. So, it's very hard for us to give a predication for that. We tend to stick with timelines for when we think we can get product approvals, which I think is the more important way to think about it. And also, accretion-dilution models are compared to what? They're often compared to idealized lines that move out in the future that are, I think, difficult to measure again. Especially because future projections almost always underestimate expenses.

So, what - so, I don't think we can give you greater guidance than that. It is clear that we will spend more money next year, but we have the opportunity for 2007 product launch, which will add some revenues because they'll be late in the year, but also significant revenues in 2008 associated with that. And remember, we have now multiple Phase III programs and I think you're right to point out that this could provide upside in the future with darusentan in Phase III, ambrisentan being filed, [Biriad HBV] in Phase III and [Caston] in Phase III. So, it's [inaudible] inhalation in Phase III. So, we have a lot of different opportunities for growth in '08.

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11

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Oct. 02, 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call

**Bill Tanner - Leerink Swann & Company - Analyst**

I mean, it just seems like if there's the expectation that darusentan is unless there's the expectation that it's not going to make it, then obviously the premium that is perceived that you guys paid for this is certainly a lot smaller. In fact, one could almost argue it's maybe fair value.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

I'll buy that argument.

**Bill Tanner - Leerink Swann & Company - Analyst**

All right. Thanks.

**Operator**

And your next question comes from the line of Bill Slattery with Deerfield Partners. Please proceed.

**Bill Slattery - Deerfield Partners - Analyst**

Good morning, John and John. In the setting of secondary pulmonary arterial hypertension, clearly a growing concern is the condition associated with HIV and certain types of hepatitis. Is there some synergy that we're failing to appreciate or is there a growing unmet medical need that you can help us better appreciate? Thanks.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

There are secondary indications for pulmonary arterial hypertension that we may consider exploring. We don't yet know if the mechanism of HIV associated or hepatic associated pulmonary hypertension is similar or if it would be treated the same way. So, we will spend some time looking at the potential to expand these indications through additional trials, but we don't yet know if there's an opportunity there and so while we'll explore it, I think the primary value is in the PAH market as Kevin described it.

**Bill Slattery - Deerfield Partners - Analyst**

Okay. Great. Thank you.

**Operator**

And your next question comes from the line of [Michael Abramin] from Credit Suisse. Please proceed.

**Michael Abramin - Credit Suisse First Boston - Analyst**

Hey guys, thanks. I've got a couple of questions on the acquisition process. The first question with multiple bidders, we have seen [inaudible] go to higher bidders than the first bidder in the past. Can you comment on your thoughts on that? And second, I understand it's difficult to make predictions for 2007. But can you talk about your revenue assumptions for later in like the 2010 and beyond timeframe that justified the price? Thanks.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

If I understand your first question correctly, I think you're asking is there a concern about somebody else coming and bidding beyond this. And I don't think we're going to make comments on this. This was a fair process, so we're fairly confident in where we are that this transaction



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12

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**Oct. 02, 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call**

will be completed. With regard to giving future revenue projections, we haven't done that for any of our products, not our HIV franchise nor anything else. We can't point to the patients' side, we can point to the class of products out there. Clearly, we think this product has considerable revenue potential and that's why we paid what we did for the transaction. But I'd be reluctant at this point to give exact guidance on that.

**Michael Abramson - Credit Suisse First Boston - Analyst**

Thanks.

**Operator**

And your next question comes from the line of Phil Nadeau with Cowen. Please proceed.

**Phil Nadeau - Cowen and Company - Analyst**

Good morning. Thanks for taking my questions. My first is just on the economics of the deal with GSK. Could you remind us what you owe on Flolan in U.S. sales and what you get on ambrisentan x U.S. sales?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

So, in Flolan, there's a fee that's paid to there's a fee paid for the calls that are made on Flolan. So, the economics basically supports the field force. So, that's the revenue from that is relatively small, but it does make the field force economically neutral right now, which I think is a good thing. With regard to ambrisentan x U.S., there is a royalty stream that starts in the 20s and goes up into the mid-30s depending on sales levels. We are not aware that Glaxo has a forecast yet for that and I wouldn't anticipate anything to come out of that until 2008 at the earliest.

**Phil Nadeau - Cowen and Company - Analyst**

Okay. And then my second question is on the dilution for specifically next year. I know you don't want to give specific guidance at this time, but it looks like, given where your stock is indicating, the market is saying that Myogen lost about \$18.5 million Q2. That's \$74 million in the year. That would translate to about \$0.15 dilution to Gilead. Is that a fair back of the envelope calculation or is there anything else that we should be considering?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

There will be the ongoing trial expenses that we'll have. There will also be, in 2007, the increase in the sales force. So, we will be increasing the number of people associated with the product. Next year there will be expenses associated with that. Those would probably build up more in the second half of the year and they'd be more fully felt in 2008. I think those two components and then, of course, there's the interest income that we don't get because the cash we're using will now go to this acquisition.

**Phil Nadeau - Cowen and Company - Analyst**

Okay. So, it sounds like \$0.15 dilutive might be a little low, if I'm interrupting your comments right?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

I'm just going to give you the input. You guys will have to do your own modeling on that.

**Phil Nadeau - Cowen and Company - Analyst**

Okay. Fair enough. Thank you.

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13

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Oct. 02. 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call

**Operator**

And your next question comes from the line of Jim Reddoch with FDR. Please proceed.

**Jim Reddoch - Friedman, Billings, Ramsey & Co. - Analyst**

Good morning. Thanks. Two questions about the competition. The first would be on the [PDE-5s]. Do you happen to know what the Viagra sales were or any other PDE-5 sales were in the U.S., kind of say last year or this year? And how much of that might have been in use with Tracleer. And then, on Tracleer itself, what exactly is suboptimal among doctors out there about that drug? That is, what might you be able to exploit competitively? Thanks.

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

So, we're looking for [inaudible]. Do we know we don't know what [inaudible] is so we don't know what the [inaudible]. So, I don't I do know. I just remember off the top of my head. So, we've got it. We'll get that to you. The second question was with regard to the suboptimal nature of Tracleer. I would say it's sort of twofold. One, it's got significant liver toxicity associated with it, so it has limitations in terms of the patients who can be dosed and the duration of dosing based on the on liver toxicity. It also has significant interactions. So, it has interactions with [Zotenophil]. So, to your question, I don't know how much was used with Tracleer. I'd be surprised if it was a lot because it's a known drug-drug interaction. There's also a drug interaction with Coumadin, which is often used in these patients as an anticoagulant and so we think that because ambrisentan has shown very low [LFP] elevations in clinical studies because it doesn't have drug-drug interaction and because it's a once-a-day product versus a twice-a-day product, it has the ability to become best in class.

**Jim Reddoch - Friedman, Billings, Ramsey & Co. - Analyst**

Okay. That's perfect, John. Thanks.

**Operator**

And your next question comes from the line of Maged Shenouda from UBS. Please proceed.

**Maged Shenouda - UBS - Analyst**

Sure. Hi. Just following up on your prepared comments for ambrisentan. What other areas beyond PAH do you plan to evaluate the product and potentially extract additional value?

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

I would say, for competitive reasons, we don't want to say that right now. We do have some plans to go into some other indications, but I'm going to wait until we get those protocols set and out there before we start to give competitive intelligence out in this area. This is an area where we're not the first one out there and so we're going to have to try to be pretty savvy about moving into this new market.

**Maged Shenouda - UBS - Analyst**

Okay. Thank you.

**Operator**

And ladies and gentlemen, at this time, we have run out of time for questions. I would now like to turn the call back over to Dr. Milligan for any closing remarks.

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14

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Oct. 02. 2006 / 8:30AM ET, GILD - Gilead Sciences Conference Call

**John Milligan - Gilead Sciences, Inc. - EVP and CFO**

Thank you, operator, and thank you for all joining us today. If you have any questions that you feel were not answered here to day, we d be pleased to speak with you by phone. If you need to reach us, please contact our investor relations department at 650-574-3000.

**Operator**

Ladies and gentlemen, thank you for your participation in today s event. This does conclude the presentation and you may now disconnect. Have a great day.

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15

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