Shire to acquire Dyax conference call transcript

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Company Participants
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Jeff Poulton, CFO
Gustav Christensen, Dyax's President and CEO
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Other Participants
Ken Cacciatore, Cowen
David Amsellem, Piper Jaffray
Jason Gerberry, Leerink Partners
James Quigley, JPMorgan

MANAGEMENT DISCUSSION SECTION

Operator:

Ladies and gentleman thank you for standing-by. Good afternoon and welcome to “Shire to acquire Dyax” webcast. Through this webcast, all participants will be in a listen-only mode, and afterwards there will be a question-and-answer session. Should you wish to ask a question please press 01 on your telephone keypad to enter the queue. Should you wish to cancel that request you may press 02.

Just to remind you, this webcast is being recorded. And today, I'm very pleased to present Matthew Osborne. Please begin.

Matthew Osborne:

Good morning and good afternoon, everyone. Thank you for joining us to discuss Shire’s acquisition of Dyax announced earlier today. Please visit our website, at Shire.com, to view the slides that will accompany today’s call.

Our speakers today are Shire’s Chief Executive Officer, Dr. Flemming Ornskov, Shire’s Chief Financial Officer, Jeff Poulton, and Dyax’s President and Chief Executive Officer, Gustav Christensen. Present for the Q&A session is Dr. Phil Vickers, Shire’s Head of Research and Development, and Mark Enyedy, Shire’s Head of Corporate Development.

Before we begin, I would refer you to slide 2 and 3 of our presentation and remind you that any statements made during this call that are not historical statements will be forward-looking statements and, as such, will be subject to risks and uncertainties which, if they materialize, could materially affect our results.

Following our presentation today, we will also open up the call to your questions. We will also be available to follow up with you after the call.

I will now hand the presentation over to Flemming.

Flemming Ornskov:

Thank you, very much, Matt. Let's go to slide number four. Well, first of all, good morning and good afternoon, everyone and thank you, so much for joining us on this call.

We are thrilled to be able to speak with you today regarding the proposed acquisition of Dyax and the rationale for the deal.

First, the proposed transaction aligns with and accelerates our strategy to build a leading biotech company focused on rare and specialty conditions. This acquisition adds to our portfolio of best-in-class therapies addressing significant unmet needs in our core therapeutic areas. Shire has a proven track record of integrating and accelerating the performance of acquired rare disease and orphan products. Shire's significant M&A expertise will enable rapid and effective integration following closing, with delivery of significant synergies.

It is a clear strategic fit with our domain expertise in hereditary angioedema, extending and expanding our leadership position within this important therapeutic category. As you know, we have built a strong commercial leadership position and deep research and clinical expertise in this area with Cinryze and Firazyr, and with development programs to complement these commercial products.

Dyax's lead program, DX-2930 is a Phase 3-ready, long-acting injectable agent in development for HAE prophylaxis, with the potential for improved efficacy and improved convenience. Shire is well positioned to leverage its HAE leadership to advance the development, registration, and commercialization of DX-2930. If approved, DX-2930 could generate global sales of up to $2.0 billion annually in hereditary angioedema.

The proposed transaction can bolster our pipeline of truly innovative programs. Shire will benefit from the talent and expertise within Dyax, including a deep understanding of complement biology and immunology to strengthen Shire's ongoing efforts in this area. This could further bolster Shire's pipeline of innovative programs, of which 75% are already focused on rare diseases. The acquisition will add Dyax's proven and productive phage display platform, which could be applied to a range of rare disease targets being explored by our research team.

Additional revenues will come from existing Licensing and Funded Research Portfolio programs, which include Eli Lilly's approved product CYRAMZA, as well as additional product candidates by licensees in various stages of clinical development for which Shire would receive development and commercial milestones and royalties. We estimate peak revenues from these royalties and milestone payments to reach several hundred million dollars per annum.

The transaction is expected to deliver substantial value to both Shire's and to Dyax's shareholders following closing and to offer Shire enhanced top- and bottom-line growth following the expected approval and subsequent launch of DX-2930.

Let's now turn to slide number five.

We are building a leading biotech company focused on best-in-class therapies addressing significant unmet needs. Before diving into the specifics of this transaction, we wanted to remind everybody of our strategy to build a leading biotech company focused on rare and specialty conditions in our core therapeutic areas. Within each of our focus areas, we look to build our portfolio with innovative best-in-class products which address significant unmet needs. Today's acquisition fits squarely with this strategy as we will describe in the following slides and text.

Let's now turn to slide number six.

As we have mentioned before, we view the complement system as a key area in the rare diseases landscape. HAE is just one out of a wide range of diseases and conditions in which the biology of this complex system plays an important role. For many of these diseases, current therapies are quite limited and unmet needs are quite great. We have built considerable capabilities and expertise in this domain through the development and commercialization of both Firazyr and Cinryze. This acquisition enhances our ability to pursue further innovations to improve the lives of patients suffering from these conditions.

Please now turn to slide number seven.

I would now like to focus for a few minutes on our hereditary angioedema leadership position before giving a brief background on Dyax and then on DX-2930.

Our presence in HAE began in 2008, with the acquisition of Jerini and the launch of Firazyr in Europe. Firazyr represented a new acute treatment approach to HAE treatment. Shire contributed to the early development of the HAE market by focusing on patient and physician support, and committing to drive innovation in HAE.

In 2009, Cinryze, the first prophylactic therapy specifically designed for HAE, was launched by ViroPharma in the U.S. Over the ensuing years, treatment approaches advanced that emphasized the use of both acute and prophylactic therapies, tailored to the individual needs of HAE patients, and we identified Cinryze as a leading product in this evolving treatment paradigm.

Following our acquisition of ViroPharma in January 2014, Shire accelerated the growth of CINRYZE. Our deep experience and innovation in patient identification and post-marketing and support programs, combined with expertise integrating and accelerating the approval, launch, and market uptake of rare diseases assets, contributed to the growth of both Cinryze and Firazyr.

In fact, combined, Cinryze and Firazyr are approaching one billion dollars in annual revenues today, with each product generating close to 30% growth in the most recent quarter compared to the prior year and at constant exchange rates.

And we continue to invest in Cinryze to expand in areas beyond HAE. We recently initiated a phase 3 study in adults with antibody-mediated rejection in renal transplant patients, and further plan to initiate a Phase 2/3 study next year for the treatment of patients with neuromyelitis optica.

Please go to slide number eight.

Now, turning to Dyax specifically. Founded in 1995, Dyax completed an IPO in 2000, and in 2003, began to focus exclusively on the discovery and development of biotherapeutics, most notably treatments for HAE. In our view, the company has assembled a world-class team of highly talented and highly focused individuals. Their 150 employees have proven to be efficient and incredibly productive with capabilities to discover, develop and commercialize highly innovative programs in rare diseases.

In addition to its commercial and development programs, Dyax has a portfolio of product candidates being developed by licensees using its proprietary phage display technology and referred to as the Licensing and Funded Research Portfolio.

Please, now turn to slide number nine.

Hereditary angioedema is, as many of you may know, a rare and potentially life-threatening genetic disease characterized by recurrent sudden attacks of swelling of the skin or the mucous membranes which can be disfiguring, painful and potentially life-threatening in the case of laryngeal attacks. Patients often have bouts of excruciating abdominal pain, nausea and vomiting that is caused by swelling in the intestinal tract. Airway swelling is particularly dangerous and can lead to death by asphyxiation.

Let's now, go to slide number 10.

We see HAE as a growth opportunity, with DX-2930 driving that growth. Its potential profile of more convenient dosing and greater efficacy could potentially improve the control of currently treated HAE patients as well as expand the market to patients not currently treated with prophylaxis therapy today.

Based on a 1:40,000 prevalence, approximately 40,000 patients or people in the world suffer from HAE. In the well-established markets of the U.S. and EU, we estimate that 30-40% of patients are still undiagnosed. Prophylactic treatment may be underutilized in these regions, as 40% of treated patients still only treat their attacks acutely, on an “as-needed” basis. This represents a compelling opportunity for DX-2930.

Please now turn to slide 11.

Dyax’s lead program, DX-2930, is a Phase 3-ready, long-acting injectable agent for HAE prophylaxis, with the potential for improved efficacy and convenient every-other-week subcutaneous dosing, and with patent protection and anticipated regulatory exclusivity beyond 2030.

DX-2930 is a fully human monoclonal antibody inhibitor of plasma kallikrein also called pKal, with kallikrein inhibition representing an expanding area of Shire’s focus and scientific expertise. DX-2930 has Fast Track, Breakthrough Therapy and Orphan Drug designations by the FDA, and has recommended for Orphan Drug status in the EU. It is produced using standard recombinant manufacturing technology.

The compelling Phase 1b data generated earlier this year have yielded FDA support to allow Dyax to soon enter into Phase 3 trials.

The Phase 1b study was a multi-center, randomized, double-blind, placebo-controlled, multiple-ascending dose study to assess the safety, the tolerability and pharmacokinetics of DX-2930 in 37 patients with HAE. Patients in the two highest dose groups at baseline had at least 2 attacks in the 3 months prior to the study.

After a single subcutaneous injection of DX-2930 at the start of the study and another one at day 14, and during the 6-week interval that patients were observed, DX-2930 resulted in a 100% reduction in weekly attack rate in the 300 mg dose group, and an 88% reduction in the 400 mg dose group, both compared to placebo. During this 6-week interval, 100% of patients in the 300 mg group and 82% of patients in the 400 mg group were attack-free compared with 27% of patients in the placebo group.

In terms of safety, subcutaneous injections with DX-2930 were well tolerated with no serious adverse events in patients treated with DX-2930 and no evidence of dose-limiting toxicity.

Please now go to slide number 12,

Importantly, a subgroup of four patients who participated in the Phase 1b study with the 300 mg and 400 mg cohorts with severe HAE defined as 9-36 attacks in the prior 3 months had no breakthrough attacks on DX-2930 during the observation period of Day 8 to 50.

Let's go to slide 13,

If these results are replicated in planned phase 3 trials, and if approved, we believe that DX-2930 represents a very attractive next-generation agent with the potential to significantly improve the therapeutic options for currently treated HAE patients as well as expand the market to patients not currently treated with prophylaxis therapy today. Soon, Dyax plans to initiate a global phase 3 trial with every-other-week dosing and explore even once-monthly dosing regimens.

Please now turn to slide 14.

The Shire team has done extensive due diligence on the Phase 1b data and the commercial opportunity for DX-2930. Our patient and physician market research indicates high demand for a long-acting, next-generation agent such as DX-2930. Physicians and patients consider routes of administration and frequency of dosing to be the key unmet needs in HAE prophylaxis. In addition, improvements in efficacy rates beyond the current 50-60% reductions in attacks are also desired. Key safety concerns among existing treatments include venous access issues, long-term safety of androgen usage and potential for thrombotic events. And the profile of the current prophylactic treatments relegates their use primarily to more severe patients.

Please now turn to slide 15.

This transaction offers the potential for other opportunities that overlap with our therapeutic areas of interest including another potential indication for DX-2930, with a novel mechanism of action in so called diabetic macular edema. DX-2507, for the treatment of antibody-mediated autoimmune diseases, and finally DX-4012, an anti-factor twelve-A antibody for thrombosis.

Let me now turn the call over to Jeff Poulton who will review the specifics of the transaction. Jeff!

Jeff Poulton:

Thank you, Flemming. Good morning, good afternoon, everyone.

Let's please now turn to slide 16.

Shire has agreed to acquire Dyax for $37.30 per Dyax share, for a closing cash consideration of $5.9 billion and a non-tradable contingent value right (CVR) that will pay an additional $4.00 per Dyax share upon FDA approval of DX-2930 for the prevention of type 1 and type 2 HAE prior to December 31, 2019, representing a potential additional $646 million in consideration.

The proposed transaction is expected to enhance Shire’s long term top and bottom line growth profile, and is expected to be slightly dilutive to earnings in 2016 and 2017, and accretive in 2018 and beyond assuming US approval of DX-2930 in 2018. The accretion is

expected to grow significantly, assuming the 2018 launch of DX-2930, reaching an expected double-digits by 2020.

We will fund the transaction with a new $5.6 billion fully underwritten term loan bank facility, along with amounts undrawn under Shire's existing $2.1billion revolving credit facility. We anticipate the funding structure will support an investment grade credit profile and continue to provide long term financing flexibility.

The proposed transaction, which has been unanimously approved by the respective Boards of Directors of Shire and Dyax, is subject to the satisfaction of closing conditions, including customary regulatory and Dyax's shareholder approvals and is expected to close in the first half of 2016.

We expect to achieve operating synergies of $50 million starting in 2017 and growing to at least $100 million in 2019 and thereafter when comparing to the Street's standalone Dyax analyst consensus forecast.

Shire's significant M&A and rare diseases development and commercial expertise are expected to enable rapid and effective integration and deliver operating synergies. Assuming approval and subsequent launch in 2018, DX-2930 could generate annual global sales of up to $2.0 billion, delivering substantial value for Shire's shareholders. The $2.0 billion in revenue is projected to drive significant topline growth for Shire and is expected to be derived from the following sources:

- ~1/3 of the $2B will come from market expansion driven by increasing diagnosis and treatment rates.
- ~1/3 of the $2B will come from patients switching away from first-generation prophylaxis products, including Cinryze, and androgens. As we have mentioned today, we believe many current prophylaxis patients will likely find the convenience and efficacy of DX-2930, if approved, very appealing. Shire would benefit financially from switches from Cinryze or androgens to DX-2930 as gross margins for DX-2930 are expected to be substantially higher than for Cinryze because of lower anticipated costs of goods sold for DX-2930.
- And the last 1/3 of the $2B will come from patients who currently are solely on acute therapy who will be enticed by the potential enhanced convenience and efficacy of DX-2930. Any reduced use of Firazyr because of fewer attacks will be outweighed by the anticipated addition annual revenue from DX-2930. Additionally, Firazyr's IP expires in 2020, while DX-2930's patent and anticipated regulatory exclusivity extends beyond 2030.

And with that Flemming, I will turn the call back to you

Flemming Ornskov:

Thank you, very much. And please to turn to slide 17. If we did not already know that this is the fast moving program between talking earlier and now I've learned that EU has no longer just recommended we've actually received I think, according to Gustav, we have now received, orphan drug designation as Dyax has. So, it is a fast moving program, very exciting. But with that, I'm equally excited to hand over to Dyax's President and CEO, Gustav Christensen for a few remarks. Gustav!

Gustav A. Christensen:

Thank you Flemming, good morning and good afternoon everyone.

I would like to echo Fleming's excitement about this transaction. After thoughtful deliberation, our Board unanimously approved the merger agreement with Shire, which we believe will deliver substantial value to our shareholders. Dyax has accomplished what few companies of any size actually have been able to do since we shifted our focus exclusively onto biotherapeutics more than a decade ago. Through our proprietary platform, we have discovered, developed and are commercializing our first product and we have, also discovered and developed a promising portfolio of next generation and additional pipeline programs as Flemming just outlined for you.

Through that journey, we were driven by one goal: to improve the lives of patients. And I am pleased that Shire shares that vision, particularly for patients with HAE, who I am confident, will continue to be served for many years to come.

While a benefit for patients and their families, today's announcement also represents a substantial return for shareholders upon completion of the deal.

I would like to take this opportunity to thank all the Dyax employees for their incredible drive, sacrifice and service along with the commitment they have shown both to the company and to the patients we serve. I would also like to thank the Board of Directors for their support and guidance through this journey.

We Dyax look forward to the prospect of extending this commitment to the Shire family, combining our shared interests, and contributing to the future success of these programs.

And I'll now turn the call back over to Flemming.

Flemming Ornskov:

Thanks very much. Gustav, thanks a lot. So, if I could ask you all to just go to slide 18 to provide a summary.

So, I, too, would like to pass on my appreciation to your team Gustav, as we are thrilled to be involved with such a talented and focused organization.

So in summary, this proposed transaction offers a significant opportunity for value creation from:

- A continued focus on rare diseases and HAE category leadership with a next-generation, long-acting injectable agent that has the potential to drive market growth.
- From additional upside potential from follow-on indications for DX-2930;
- From further upside potential from Dyax earlier-stage pipeline;
- And from licensing and royalties from a proprietary discovery platform

Before taking questions, I would like to make a very brief comment on Baxalta. Today's proposed transaction with Dyax reflects our core strategy of supplementing internal development capabilities with highly strategic M&A focused on our core therapeutic areas. Even with this transaction, we will continue to have the financial firepower to proceed and pursue other value-added strategic acquisitions, including Baxalta.

And with that, we can open up the call to questions.

Q&A

Operator: Thank you very much, sir. [Operator Instructions]

And our first question comes from the line of Ken Cacciatore from Cowen and Company. Please go ahead.

<Q - Ken Cacciatore>: Great. Good morning, guys. Congratulations. Flemming, just a real quick question on the FTC. Can you just talk about what type of review you all did to make sure that this has both achieve FTC clearance? And then the second question on DX-2930, efficacy is clearly, unquestionably strong. Just maybe talk to us, if there was anything in the safety, we should be looking at or thinking about or anything in your diligence that you had access to that maybe we don't, just to ensure that the safety profile matches that efficacy profile? Thank you.

<A - Flemming Ornskov>: Thanks a lot, Ken. We're equally excited. I think, Mark, would you like to say a few things about the FTC concerns on how we look at that, would that be okay?

<A - Mark Enyedy>: Sure. Thanks, Ken. Nice to hear from you. So, we do operate in the same therapeutic area here. And so, the transaction will receive comments for its competitive review. That said, we did comprehensive diligence on Dyax. And I think at this point, it would be premature to comment further with respect to the specifics of the antitrust review, we plan to work closely with the regulatory authorities to support their approval of the transaction, I think that's all there is to say at this point.

<A - Flemming Ornskov>: That was Mark Enyedy, who is now our Head of Corporate Development and led the team that managed this deal from the Shire side. Phil, do you want to say something about, well efficacy was again touted has been great. What about safety, any insights there?

<A - Phil Vickers>: Yeah, of course, Ken, it's a good question, and of course we do a thorough analysis to make sure that, not only we're developing efficacious drugs but safe drugs as well. And there was nothing of concern to us, the drug was well tolerated, there was no dose limiting toxicity and no significant serious adverse events that we saw. So, we're very confident moving forward on the safety, based on the safety profile.

<A - Flemming Ornskov>: Ken did that answer your questions, was that sufficient?

<Q - Ken Cacciatore>: It does. Thank you very much

<A - Flemming Ornskov>: Thanks very much. Thanks very much for your questions.

Operator: Thank you. And our next question comes from the line of David Amsellem from Piper Jaffray. Please go ahead.

<Q - David Amsellem>: Thanks. So, in terms of how you are thinking about the competitive dynamics regarding CINRYZE, and I guess, what gives you confidence that you're not going to see a dramatic decline in the product over the years, maybe talk to us about the - about that franchise. And then, the second part of the question is, do you think that, is this sort of a concession that you are unlikely to see a compelling ROI from the ViroPharma transaction. In other words, by doing this, you're essentially saying that CINRYZE has an endangered future. And just in terms of that, I mean how are you thinking about, what you're paying here and just ROI in general, given that you're essentially acquiring the product that's going to compete with another product you already has? Thank you.

<A - Flemming Ornskov>: Well, thanks very much, David. Well, maybe first a few introductory remarks in general, then I'll ask Jeff to supplement.
So, I think Shire's strategy is clearly, we want to be the company that in our portfolio in the segments where we compete that we have the best-in-class products. That's basically a clear strategy of Shire, I think we have that in many categories and we have several candidates to bring to market that we think have that profile like you recently saw a new data in ophthalmology.
And we think that DX-2930 has the opportunity if it mirrors in Phase 3 what we've seen in the clinical data so far to be a best-in-class product. As we have outlined on many of our earnings calls, this is a rapidly growing, rapidly evolving segmenting market and you've seen significant growth of 30% plus for both CINRYZE and FIRAZYR in the last quarter on a constant-exchange rate basis. So, we see that this is the market that continuous grow, so will CINRYZE, so will FIRAZYR and CINRYZE also will continue to grow from having new indications we announced at the last earnings call that we got Fast Track designation for the indication of antibody mediated rejection in kidney transplant patients and we also have a program in NMO, potentially coming up. So, we have a number of additional opportunities for CINRYZE and we think it's a segmented market, DX-2930 has an opportunity to deliver outstanding efficacy and also convenience, but also to grow the overall market. But in terms of how we see the impact on the franchise overall, Jeff, do you want to comment a little bit where we see the sources of revenue and how we see the impact on our franchise?

<A - Jeff Poulton>: Yeah. I think it's a good question and our - what I said earlier in terms of where we think sources of revenue are going to come from for the product longer term. We think there are three specific sources, first would be from market expansions driven by increasing diagnosis and treatment rates. We had a slide in the deck that showed where we are globally from a diagnosis and treatment rate perspective today. So, we think over time those rates will increase offering opportunities for growth for DX-2930.
I think your question about prophylaxis therapy and impact on CINRYZE is a good one. So, the prophylaxis market today in the U.S. has more than a couple of thousand patients on therapy between CINRYZE and androgens we believe with CINRYZE having more than 50% share of those patients on therapy. So, we do think there will be cannibalization of CINRYZE and also opportunity to move patients from - more patients from androgens on to DX-2930. As it relates specifically to CINRYZE, however, what I pointed out in my prepared remarks is that the expected gross margin for patients that were beyond DX-2930, we think we'll be higher than that for those patients that are on CINRYZE today, because we do anticipate DX-2930 to have significantly lower cost of goods sold.
And then the last area that we think there will be opportunity for revenue for DX-2930 is from the patients that are currently on acute therapies only today. And there is four different acute therapies in the market in the U.S. today, one of which is FIRAZYR. We do think that this product DX-2930 with it's very promising efficacy and convenience profile based on the 1B data will be attractive to some of the patients that are using acute on-demand therapies today.
If there is cannibalization of FIRAZYR, as a result, one of the benefits is that the intellectual property that we have for FIRAZYR expires in 2020, I think we've noted a couple of times on the call that the IP and exclusivity on DX-2930 will take us beyond 2030 in the U.S. So, long term, that would be a positive switch for us if that occurs with FIRAZYR. I hope that answers your question.

<A - Flemming Ornskov>: Probably also worth noting that, in most categories, I think, if you have a product that is eventually brought to market that is highly convenient and highly efficacious, you typically see significant expansion of the market, particularly with the mild to moderate patients, and I think you probably will see the same here. But I think with that, David, did we answer your question?

<Q - David Amsellem>: No. That's helpful. Maybe just comment just how you're thinking about ROI in general on transactions, just given that you're acquiring a competitor or future competitor to CINRYZE, just philosophically. I mean, if do you see hurdles?

<A - Flemming Ornskov>: Yeah. Okay. Good question. Jeff, do you want to put a comment on that?

<A - Jeff Poulton>: Yeah. I mean, I think, David, when we look at acquisitions, ROIC is certainly one of the foremost metrics that we look at. And on this transaction, we think it's quite attractive. We think we've been north of our cost to capital by the 2019-2020 timeframe assuming an approval of the DX-2930 in 2018. So again, I think that's pretty compelling for investors in Shire.

<Q - David Amsellem>: Thank you.

<A>: Okay. Thanks, David. Thanks for your questions.

Operator: Thank you. Our next question comes from the line of Jason Gerberry from Leerink Partners. Please go ahead.

<Q - Jason Gerberry>: Hi, good morning. Thanks for taking my question. First question, could you just talk a little bit about how competitive the process was for this deal? And just wondering, how in the context of doing this deal we should be thinking about Shire's appetite for doing larger deals where there is an element of clinical risk versus prior deals, which were largely for commercial stage deals which were less - which were more de-risk, I guess, from the clinical perspective?

<A - Flemming Ornskov>: Thanks, Jason, I will start and then probably I'll ask Mark to make any comments. I think we have to go back again to Shire strategy. So Shire has an aspiration to become a leading global biotech company focused on rare diseases and highly specialized condition. We've clearly stated that, in order to fulfill our aspiration, we see M&A and business development as a key part of that. We also clearly want to be a product that bring -- a company that brings significant and differentiated and value enhancing products to the marketplace, DX-2930 fits squarely into that. So, when we look at opportunities, I think of course, in many deals where you don't have approval, you have to take a certain amount of risk, but if you look at Sire's track record, when we take such risk, we typically do it in categories where we have outstanding in-house expertise. When we licensed in lifitegrast for dry eye disease. Phil Vickers and his team had already built out significant research and clinical development expertise within the company. So I think we took a calculated risk in a category that had seen many people fail, and I think obviously so, that we could show a path even under these challenging circumstances. if you look at our assessment of NPS with Natpara, which I think the deal was concluded a few weeks before the expanded PDUFA date. Again here, we had a strong regulatory and clinical team that look at that and asses that I think rightly so. So, hereditary angioedema is a category we know really well, and where we have significant expertise, we love that Dyax brings a lot of additional expertise there, but I think it's a calculated risk, worth taking when you have such a unique product, but Phil, do you want to say something about how diligent we are, and how we asses candidates, that are not yet approved?

<A - Phil Vickers>: You're - I think you've captured it well, Flemming, and in fact in this deal, we found the Dyax team very impressive. The data is very impressive, the Dyax team was very impressive. They gave us access to all of the key documentation that we needed to see in order to assess this, including the regulatory correspondence that they had and we see a very clear path. We think it's compelling that it's an end of phase 2 meeting that they've had. It was an agreement that a single pivotal study can be significant - can be sufficient for registration. Pivotal design has been agreed. The data is compelling. And then, when you

look at how the FDA is responding to the data and giving break through therapy designation, it speaks for itself that they think that this drug has a potential to make it a profound difference in patients lives.
So, I think with the data, the access to the information that we saw and the way that the FDA has responded to the data, we saw this is being very compelling. Of course, it's not yet approved and there's always risk associated with that, but we're not going to build a great company, if we don't take a few calculated risks.

<Q - Jason Gerberry>: And Flemming, can you just comment, was this is a competitive M&A process?

<A - Flemming Ornskov>: Mark, do you want to say something about the process? I don't think we're going to comment on...

<A - Mark Enyedy>: Right.

<A - Flemming Ornskov>: Because we were aware of there were other people or not, but Mark, do you want to say a few words about the process.

<A - Mark Enyedy>: This is an attractive rare disease asset and we think that these kinds of companies are very attractive to a number of people. That's say, we can't comment on the BD activities of other companies. And I would refer to you the proxy statements that will be filled in conjecture with the transaction, and you can see there, what their internal process was relative to the sale?

<A - Flemming Ornskov>: I think the other thing important is also, I think we've given some insight into the Shire process. Shire, at any given time has a portfolio project that are more or less active. We monitor companies, we look at when is the best time so to speak, to approach a company, this was exactly the case here. And one of the advantages we have seen also both with our acquisitions in Phase 2 and things that our Phase 3-ready is that it provides significant advantage to a company like Shire is that, we also get in at the time of the Phase 3 design because we also have to think about it, not just as a U.S. product, but as a global product. And we also need to fulfill certain criteria for proving the value, in terms of cost effectiveness or cost benefit analysis. So, it fits squarely into how we think about things, and I know people have asked many questions, particularly in context of Baxalta, can Shire only do one thing at a time. I think we've shown here that not only financially, but also from a team perspective, we can multitask.

<Q - Jason Gerberry>: Okay. Thanks, and congrats on the deal.

<A – Jeff Poulton>: Operator, we've been added for about 45 minutes now. So, I think, just one more question, and then we'll wrap it up.

Operator: Thank you very much. So, our final question comes from the line of James Quigley from JPMorgan. Please go ahead.

<Q - James Quigley>: Hello, just a couple of quick questions. First of all, what does this deal mean for the subcutaneous version of CINRYZE. Is there any risk that you may not take it forward into Phase 3? And in terms of the Phase 3 for DX-2390, DX-2930 even, and how long do you think Phase 3 would take? And what are the key risks relating to any delays in the trials? Thank you.

<A - Flemming Ornskov>: Well, thanks very much. Thanks for - James for the question. So, I'll provide some introductory comments and I'll ask Phil to add to it. So, we are acquiring a company with significant expertise with this deal closes which we are confident in. We are having a platform that will be added Shire's platform, which we find very attractive. We have

DX-2930 in hereditary angioedema. And potentially in another indication, we have other compounds that are at clinical stage that we find very attractive and we will take a serious look at. And we have, I'm sure, a great number of fantastic and very smart colleagues that will be added to our organization. So, that's what Dyax brings and much more.
The subcutaneous program and CINRYZE, we feel we'll continue to pursue that program, we're very excited about the program. I'll get Phil to say some specifics. And I think it may be too early to give all the details on a Phase 3 program that - of course, the deal has not yet closed, but we can maybe give some additional thoughts about it still.
Phil, do you want to comment on subcutaneous and kind of the length of a potential Phase 3 program for DX-2930?

<A - Phil Vickers>: Sure. We currently are planning to move forward to Phase 3 with the subcutaneous program, those plans are unchanged. And I think that, as we've talked about this morning that, we have a commitment to HAE patients and so a number of short-term goal of different types of molecule is what we've done in the past and what we're doing in moving forward the subcutaneous program.
But of course, we regularly review all of those commitments on which patient segments would be appropriate for what approaches. With respect to DX-2930 program, there is a pivotal design that's been defined by Dyax and has been agreed by the FDA. I don't think all of the details of that design are yet in the public domain, so I want to respect our hopefully future Dyax colleagues and not share all of that information. But I think Jeff said on an assumption of a 2018 approval, so you'll need to back away from that to recognize that you would be filing in 2017. And so, that gives you some - the Phase 3 study will - we've anticipated to start fourth quarter of this year and then 2018 would be approval for 2017 submission.

Flemming Ornskov:
So, thanks very much. And with that, I think we've come to the close of the meeting that marks another major milestone in the journey that Shire is on, which is to become a leading biotech company globally that is focused on rare diseases and highly specialized conditions. Hereditary angioedema is one of those segments, one of those markets that we are highly interested in, it's a journey that we started in 2008 with the acquisition of Jerini that brought us the acute therapy treatment called FIRAZYR for hereditary angioedema. 2014 we supplemented that with the acquisition of ViroPharma that brought us many additional products, several of them now going into Phase 3, but also an in-market product CINRYZE for the prophylaxis of hereditary angioedema and potentially other indications that we're working on.
Today, we made another potential large leap forward with the proposed acquisition of Dyax which would bring to us a potential best-in-class breakthrough therapy in the form of DX-2930. So, we are delivering on the strategy, this is another potential significant milestone today. I want to thank my team for all the hard work in bringing this to this stage, but I certainly also want to thank Gustav and his team of talented, hopefully future colleagues of Shire at Dyax and I really look forward to this deal closing and to us integrating two great companies bringing lots of potential innovation to the marketplace and true value to shareholders, but most importantly to patients. So, thank you so much for your attention today, an exciting day for Shire.

Operator:
Ladies and gentlemen, those conclude our webcast for today. Thank you very much for your participation. Participants may now disconnect your lines.