Full Regular Transcription

Sanofi

Investor Relations Conference Call

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COMPANY REPRESENTATIVES

Olivier Brandicourt – *Chief Executive Officer*

Jérôme Contamine - *Executive Vice President, Chief Financial Officer*

Bill Sibold - *Executive Vice President, Sanofi Genzyme*

George Grofik – *Vice President, Head of Investor Relations*

PRESENTATION

Operator

Ladies and Gentlemen, good morning or good afternoon. Welcome to the Sanofi Investor Relations Conference Call and Live Webcast. I am Emma, the Chorus Call operator. I would like to remind you that all participants will be in a listen-only mode and the Conference is being recorded. After the presentation, there will be a Q&A session. You can register for questions at any time by pressing * and 1 on your telephone. Should you need assistance, please press * and 0 to call an operator. The Conference must not be recorded for publication or broadcast.

At this time, it's my pleasure to handover to Mr. George Grofik, Vice President, Head of Investor Relations at Sanofi. Please go ahead, Sir.

George Grofik

Good morning and good afternoon everyone. Thank you for joining us on the call to review Sanofi's acquisition of Bioverativ. As usual, you can find the slides of this call on the investors' page of our website at sanofi.com.

I would like to remind you that information presented in this Call contains forward-looking statements that involve, known and unknown risks, uncertainties and other factors that may cause actual results to differ materially. I refer you to our Form 20-F document on-file with the SEC and also our document de référence for a description of these risk factors. On this slide, I draw your attention to additional disclosures regarding the tender offer for Bioverativ.

With that, let me introduce our speakers. With me are Olivier Brandicourt, Chief Executive Officer, Bill Sibold, Executive Vice President, Sanofi Genzyme and Jérôme Contamine, Executive Vice President and Chief Financial Officer.

I'd now like to turn the call over to Olivier.

Olivier Brandicourt

I am delighted to announce the acquisition of Bioverativ. Bioverativ is a specialty care business which shares a high degree of complementarity with Sanofi Genzyme, and we believe this deal is strategically and financially attractive.

On this slide, I remind you that rare disease is one of the five categories in which we are committed to sustain leadership. The acquisition of Bioverativ is consistent with this goal, extending our leadership from genetic diseases into Hemophilia, the largest rare disease market, and providing the basis for a new platform in Hemophilia and other rare blood disorders.

So why is this deal attractive to Sanofi? First, Bioverativ is a pure player in the large and growing Hemophilia market and brings an immediate leadership position for Sanofi.

Second, it brings opportunities to leverage growth of a new platform including Bioverativ's pipeline of rare blood disorder assets and our novel Hemophilia agent fitusiran.

Third, we see opportunities to maximize the franchise through expansion in emerging markets. And lastly, we expect the deal to meet our strict financial criteria generating immediate business EPS accretion and returns exceeding our WACC within three years.

Next slide, expanding on my earlier thoughts, we see Bioverativ not just as a readymade strong Hemophilia portfolio, but also as a platform for expansion in rare blood disorders. We believe we can leverage many of our core competencies in Sanofi Genzyme to capitalize on this opportunity. So we are excited by the opportunity to build the rare blood disorder franchise based on Bioverativ's pipeline assets and the additional opportunities that Sanofi can provide.

So having briefly set out the rationale, I will handover to Bill for the detail. So Bill...

Bill Sibold

Thank you, Olivier. Here I want to say a little bit more about the Hemophilia market. As Olivier mentioned, this is the largest rare disease market worth around 10 billion Dollars and growing at 7% per year. Around 180´000 patients have been identified with Hemophilia, although the true prevalence is probably over double this.

Hemophilia A accounts for around 80% of patients and a similar proportion of the market value. Market growth is being driven by the trend away from treatment on demand towards prophylaxis.

This trend has been reinforced by the launch of extended half-life products, such as Eloctate and Alprolix, and by increasing evidence that this approach brings improved health benefits.

We are aware of the new recently approved bispecific antibody to broaden treatment options for Hemophilia A patients with inhibitors. We have of course factored this into our assessment of the prospects for Bioverativ and its valuation. We have also factored in our assessment the potential that this product could be indicated in non-inhibitor patients. Next slide.

So Bioverativ is a biotech company that develops transformative therapies for rare blood disorders, it was spun out of Biogen at the start of 2017 and, like Sanofi Genzyme, is based in Massachusetts.

In terms of financials, Bioverativ generated net sales of nearly 850 million Dollars in 2015 plus a royalty flow of around 40 million. Based on their recent disclosure, they are expected to grow more than 30% in 2017.

Bioverativ's success has been built on the launch of two blood factors, Eloctate for Hemophilia A and Alprolix for Hemophilia B. These are differentiated products which utilize Fc Fusion technology to produce extended half-life and this may in turn give rise to improved long term outcomes. Beyond its marketed products Bioverativ has a pipeline which includes assets in Hemophilia and other rare blood disorders including gene editing technologies for Sickle Cell Disease and Beta-Thalassemia. Next slide.

On slide 9, I want to say a little more about Bioverativ's marketed products. Eloctate is a recombinant protein containing factor VIII, and is approved to reduce bleed frequency in Hemophilia A. It is typically dosed in three to five day intervals and there is growing evidence that it results in better long term joint outcomes.

Alprolix uses the same recombinant technology, but incorporates factor IX, it is approved for Hemophilia B and can be dosed once every one to two weeks. Like Eloctate, study suggests that the fusion technology results in improved long term joint outcomes. Next slide.

This slide shows the strong penetration achieved by Eloctate and Alprolix in the US, Canada and Japan, the first three launched markets for Bioverativ, helped by the trend towards prevention, Eloctate has captured 16% to 21% share, while Alprolix has captured a greater share of 23% to 34% albeit in the smaller Hemophilia B category.

Moving on to the pipeline, you can see here Bioverativ diversified rare blood disorder portfolio. The pipeline includes a once weekly factor VIII and the antibody for cold agglutinin disease and from Bioverativ's collaboration with Sangamo, early projects on gene editing technologies for Sickle Cell Disease and Beta-Thalassemia. Next slide.

Of course, we also have Fitusiran which we believe could be leveraged through Bioverativ's expertise in this disease. Fitusiran is an investigational novel RNAi therapeutics which may be effective in both Hemophilia A and B and in patients with and without inhibitors. A small Phase 1/2 study showed the potential of our drug to test the annualized bleeding rate to zero in patients with inhibitors. We recently restructured our agreement with Alnylam to gain global rights to this promising agent and will be resuming the Phase 3 program this quarter. Next slide.

Now, when we think about the geographic scope of Bioverativ's activities, we are confident that we can utilize Sanofi's global infrastructure to expand sales in new markets. Bioverativ has only launched Eloctate and Alprolix in four countries and there are a number of other countries where the two products could be rolled out notably in emerging markets.

I would like to now hand the call over to Jérôme to discuss the financials.

Jérôme Contamine

Thank you, Bill. Good morning, good afternoon, I am turning to slide 18. I want to briefly discuss the financial highlights of this transaction.

So Sanofi has agreed to pay Bioverativ shareholders 105 Dollar per share in cash which results in a fully diluted equity value of 11.6 billion Dollar. This represents a 64% premium to Friday's closing price.

Based on our projections, we expect the return on invested capital of the deal exceed our cost of capital within three years. When we look at business EPS, we expect immediate accretion, although the precise level will depend on the timing of the closing and the pace of the integration.

In 2019, with a full year's ownership, we expect accretion of up to 5%. I should point out that when we provide financial guidance for 2018 on February 7th it is our intent to include the contribution from this transaction in our guidance.

In terms of financing, we expect to fund the transaction with our internal cash resources our new debt to be raised. It should lead to a blended cost of debt of funding for this acquisition around 1%.

Importantly, we do not expect this to impact our strong credit ratings. In addition, you should know that the scope of the deal size allows us to retain flexibility to pursue other value creating opportunities.

On timing, the transaction has been approved by both Board of Directors, and we expect to close within the next three months. Of course, this will be subject to regulatory approvals and other customary closing conditions.

With that, I would like to handover to George to start the Q&A.

George Grofik
Thank you, Jérôme. We will now open up the call to questions.

QUESTION & ANSWER

Operator
We will now begin the Question and Answer Session. Anyone who wishes to ask a question, may press * and 1 on their touchtone telephone. You will hear a tone to confirm that you have entered the queue. If you wish to remove yourself from the question queue, you may press * and 2. Participants are requested to use handsets while asking a question. Anyone who has a question may press * followed by 1 at this time.

First question comes from the line of Mr. Verdult with Citi. Please go ahead.

Verdult Peter
Yes. Good afternoon everyone Peter Verdult, Citi. Just three quick ones if I can. Bill, could you talk about the pipeline in a little more detail at BIVV's, particularly 009 I realized you don't want to go line-by-line through the assets. But this seems to be the most promising pipeline asset that Bioverativ's have. So just wanted to sort of... you to scope the opportunity that you are thinking for this asset longer term when the data comes out? Jérôme, question number 2, could you talk a little more about the synergies you expect to drive both cost and the revenue from the combination. And can I... can you confirm that your cost of capital is about 7.5%?

And then lastly, just I know you have mentioned, the comments around taking into account ACE910, both in inhibitors and non-inhibitors. But can I just confirm the... your base case expectation is BIVV's Hemophilia franchise continues to grow in absolute terms over the next or over the foreseeable future? Thank you very much.

Olivier Brandicourt

Thanks Peter. So we have in our room actually... we have Rand Sutherland, who is our Head of Research and Development for rare disease. So Rand, can you give clarity around the pipeline.

Rand Sutherland

Sure, so I think just a comment on the 009 the BIVV009 assets that was acquired as part of the transaction. We are in Phase 3 in cold agglutinin disease as Bill mentioned, I think we see this as a leading opportunity for the asset, significant unmet need in this disorder and we are moving rapidly to execute the pivotal trial there. I think obviously, you know, the position in the classical complement pathway opens up a host of other potential indications and we will be reviewing these strategically. We have some prioritization decisions to make there but we looked obviously fully to exploit the value of this asset. I think with regard to other aspects of the portfolio, these are earlier and we can address specific questions as they come.

Olivier Brandicourt

Bill do you want to answer the last question on Hemlibra before we give Jérôme the last one.

Bill Sibold

Great. Thanks for the question. So we have obviously done extensive work to analyse the market and its trends and looking at Bioverativ and its current and future competitive environment and our assessment is adequately reflecting potential future competitive threat including the potential approval of Hemlibra in non-inhibitor population as you mentioned. And despite such potential future approval, we are convinced that factor replacement therapy will remain the standard of care for many years due to excellent safety and its increasing superior extended half-life profile, and that Eloctate will retain the leading position in this category given its superior features.

Specifically we are confident in Bioverativ leading position because it has an excellent safety and increasingly superior profile. There is physician and patient conservatism and reluctance to switch as non-inhibitor patients are really well controlled at this point and there is uncertainty surrounding monitoring impaired dynamics.

So we see recent announcements overall as good for the Hemophilia market as a whole and as it enlarges the range of treatment options for patients and will help better address their various needs.

Also there is still a lot to know about Hemlibra's clinical and competitive profile in the non-inhibitor population and we are looking forward to learning more about Roche's release of the full details of the HAVEN 3 study. You know eventually, we feel we are well positioned on novel therapies in Hemophilia through fitusiran, which will address both Hemophilia A and B, with and without inhibitors, and which will be complimentary to Bioverativ's portfolio.

Olivier Brandicourt
Alright, thank you, thanks Bill. Jérôme

Jérôme Contamine
Yes, thank you, thank you Olivier. So...and Peter, so to your question on synergies, I would say the synergies are threefold and I think maybe we can just not go in all the details today for obvious reasons as the deal is not closed, but the first one is that the we are assuming that there will be some commercial synergies in ex-US countries where clearly Sanofi's cost structure can be potentially leveraged. Getting the size of Bioverativ's ex-US business, these commercial synergies will ramp up progressively but we feel that we have been conservative in our assessment and can thus leverage our platform to offer global footprint to support the roll up and the launches of Bioverativ products into these countries.

Secondly on the cost side, I would say, well this is a deal where the cost synergy is not a key driver obviously and this will be mainly relating to G&A, where clearly we are going to get some synergies by just you know plugging the Bioverativ organization into the global functions, some organizations that we have put in place, particularly for the last two years over the world and particularly in the US. Beyond that we think that in R&D it will be more a question of plugging this portfolio into our own portfolio and we are trying to make the best out of it and maybe Rand can say something here.

The last piece is tax. And here I'd like to confirm two things. The first thing is that we will benefit from the newly expected tax rate for Bioverativ that they disclosed a few weeks ago based on the new tax environment in the US, i.e., around 21% tax rate and on top of that we think this is going to have some tax synergies in the financing structure of this Bioverativ's acquisition. So synergies are threefold, which are the one I just described.

Verdult Peter

And just one follow-up, just on the cost of capital that you used for Sanofi, is it 7% or 7.5%

Jérôme Contamine

I think it's always difficult to disclose your cost of capital because as I said, it's competitive information. Now, it is fair to say that when you go into acquisition of this type which is a biotech, you just combine the cost of capital for already approved programs and products, and then you have a higher cost of capital for R&D. So all in all, ballpark I mean just using what you can read , maybe you are not too far from what we have been considering.

Verdult Peter

Thank you.

Olivier Brandicourt

Thank you. Next question, please.

Operator

Next question comes from the line of Ms. Walton with Credit Suisse. Please go ahead.

Jo Walton

Thank you. I wonder if you could tell us a little bit about the market ex-US where you are going to have rights. I can understand that Bioverativ is probably able to promote its products very successfully in the US today, but not ex-US. But in those ex-US regions where you will gain rights, are price much lower, would this be essentially tender pricing. I am just trying to think what sort of margin we should apply to the incremental sales that we would get in the relatively short term.

Olivier Brandicourt

Okay...go ahead Jo.

Jo Walton

No that's fine. Thank you.

Olivier Brandicourt

Alright, so until now Bioverativ has launched in 4 markets as Bill mentioned, right?

Japan, Australia and the US as well as Canada, so beyond that there was submission ongoing, approval coming in and the expansion that we can have access to immediately are China and Latin America. So that's where we see and that's the reason why we have mentioned emerging markets several times, that's where we see the potential expansion. When it comes to pricing, it's a little too early for you to give you an indication of where the net price in those markets will be related to competition. So I can't really answer that question. Bill, do you want to add anything to that?

Bill Sibold

No, I think that's all right. I think, that... I mean if you just take a look at, for example, LATAM is estimated to have 20´000 Hemophilia patients on therapy. So we know that it is a prevalent... for rare disease, a prevalent disease, and we will now in this next phase, be accessing each of the markets what the opportunity is and what the best strategy is to bring these products to patients.

Jo Walton

Thank you. And the... my second and last question. When we look... when you look at the adoption rates that you have shown us for Alprolix and Eloctate on slide 13, in some markets you have got to 20% to 30% level of penetration. Do you think that is the sort of rate that we could expect? We are trying to get a sense of your modeling for a potentially disruptive short-term products like Hemlibra coming in. And so, we are trying to think about how you might accept the... or think about the adoption there. Do you think with the same sort of rate of adoption might be realistic for that product when we are thinking about how you are scoping what will be left for you?

Olivier Brandicourt

Well, Jo you have seen the penetration and the expansion and the market share gains that Bioverativ has been able to do in the last 11 to 12 months. I think that's really very, very impressive, and that comes from the fact that, there is a very large pool of patients under on-demand therapy with short-acting who are currently switching and seeing frankly the advantage of being under longer half-life therapy such as Eloctate and Alprolix. So that pool is, in fact, is a growth engine if you want for the long acting, and that's the reason why we see Eloctate and Alprolix continuing to be very successful in the future and becoming standard of care in this area despite the emergence of new products and new assets.

Again, you know, Bill said it, we have done an extensive assessment of these markets before making that move as you can imagine. We have done a lot of market research ourselves with KOL and Hemophilia centers.

And so, we have done a thorough work which allows us, you know, to offer what we offer for that acquisition. So yes, we could... the short answer to your question is, yes, we believe Eloctate and Alprolix are going to continue to grow at a very significant level. Of course, I cannot give you the exact CAGR for the next 10 years, we put in our model, but we have accounted for the... I like to make sure that everybody understand, we accounted for the competition which is emerging with those new products. So, I will stop there.
Alright, can we have the next question operator, please?

Operator
The next question comes from the line of Keyur Parekh with Goldman Sachs. Please go ahead.

Keyur Parekh
Hi, good afternoon and thank you for taking my questions. I have three, please. The first one, would it make strategic sense for you to own these two molecules on a global basis. If so, have you tried attempting to speak to SOBI about it, that's question number 1? Question number 2 is, in the context of the growth outlook that you are talking about, how much of that is dependent on the ITI studies being positive and showing a differentiation versus the existing products or is that not a large part of the revenue outcome that you are looking at?

And thirdly, in sense of the actual process that you have just gone through; can you help us contextualize it, was it a competitive bidding process, where you in exclusive negotiations with them and to the extent there is any? Can you help us think about what the break fee on this transaction is? Thank you.

Olivier Brandicourt
Okay, thank you very much. So starting with the SOBI because you had four questions I think. So the SOBI questions, we are not going to make any comments on... related to SOBI you know, how you know, the territories are shared between Bioverativ and SOBI. I think it's a good collaboration so far and there is no comment to be made there.

On the ITI question, I can venture to tell you that, it is certainly something important medically and we are working on it and we have two Phase 4... they have, Bioverativ have, two Phase 4 looking into that specific mechanism which would be a very nice addition. However, it's not accounted as a major part of the future revenue and performance of the compound, and I'll ask Jérôme to answer your last question. Jerome, can you answer the last question.

Jérôme Contamine

Thanks for the question. So actually we... I mean this would described in the public offering, the documents in the coming days, so we entered into a bilateral discussion with Bioverativ over the last weeks let's say. And second to your question, so yes, there is a breakup fee and the breakup fee is 2.8%. And this again will be public in the coming days.

Keyur Parekh

Thank you.

George Grofik

Thank you very much. So we can take one additional question. Operator.

Operator

Next question comes from the line of Seamus Fernandez with Leerink Partners. Please go ahead, Sir.

Seamus Fernandez

Thanks for the question. So just a couple, in terms of just a Factor IX market and how you guys are thinking about that area, it seems like gene therapy is quite competitive in that space. I'm trying to get a better sense of how you are thinking about the longer term potential disruption of this market and how you see your participation in that space. And then, I think to Jo's question, can you just give us a better sense of the pace at which and which key market you are most focused on bringing Eloctate into sooner under the Sanofi umbrella so that we can get a sense of some of the value-add that this acquisition brings to Sanofi and Bioverativ, the Bioverativ opportunity at the same time? Thanks.

Olivier Brandicourt

Alright. Thank you for your question. So Rand is here. But we believe those innovative therapies including gene therapy will gain market share on the long-term, but slowly and certainly again, they are very welcome. But at the end, we are absolutely convinced that for the foreseeable future Factor VIII and Factor IX will remain the basic standard of care.

So Rand, do you want to mention anything regarding gene therapy and where we are with our zinc finger nuclease and what Bioverativ has done so far with Sangamo?

Rand Sutherland

Yes, I think we see Bioverativ's portfolio quite innovative particularly in regard to these technologies both genome editing and gene therapy. The projects are at their very early stages and I think that we will continue to progress as we can and I think from the standpoint of the market as you said, tremendous innovations will be beneficial to patient and something we look forward to participating.

Bill Sibold

And let's not forget fitusiran. So we... so if we take a look where the current market dynamics are, the market is growing well, it is growing into higher prophylaxis use, and it's moving towards the extended half-life products. So those are all variables, which are favorable towards the current portfolio. And if we look with fitusiran we consider that an innovative next generation product as well. So we are... we clearly believe that we are on the right area of the market today and with fitusiran that takes us into the next generation as well.

Olivier Brandicourt

Alright. Thanks Bill. And to your last question on emerging market, as you can imagine right now we are focused on closing the transaction, which I think as we said is expected within three months. So of course, we would have after that point to work on the details regarding expansion and geographic expansion.

Now again, where is that expansion possible, it includes in Asia, I mentioned China, but also Korea and Taiwan and in LatAm, Colombia, Brazil and Argentina. So those are the priority markets. As soon as again, we can start planning after closing, but that's what it is. Okay, so thank you very much everyone for your questions. I think, we are closing the call now. Thanks a lot.

Operator

Ladies and Gentlemen, the Conference is now over. Thank you for choosing Chorus Call and thank you for participating in the Conference. You may now disconnect your lines. Goodbye.

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