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# EDITED TRANSCRIPT

IPN.PA - Ipsen SA to Acquire Oncology Assets from Merrimack Pharmaceuticals Inc Corporate Call

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**Peter Welford** *Jefferies - Analyst*

**Jean-Jacques Le Fur** *Natixis - Analyst*

## PRESENTATION

**Operator**

Ladies and gentlemen, thank you for standing by and welcome to Ipsen's acquisition of oncology assets from Merrimack Pharmaceuticals. (Operator Instructions). I must advise you all that the conference is being recorded today, on Monday January 9, 2017.

I will now hand over to your speaker for today, David Meek, Chief Executive Officer of Ipsen. Please go ahead, sir.

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**David Meek** - *Ipsen SA - CEO*

Good morning and good afternoon. Thank you for joining the Ipsen teleconference. I'm excited to share with you our acquisition of oncology assets from Merrimack and we'll go over the background. Aymeric Le Chatelier, our CFO from Ipsen, and I will go through the background slides and, at the end, there will be a question and answer period.

Please go to slide 2. As usual, here are the customary disclaimer and safe harbor comments.

We can now go to slide 3, the acquisition of oncology assets from Merrimack Pharmaceuticals. First of all, the primary purpose of the acquisition is for ONIVYDE. The key product is ONIVYDE, which is currently approved the treatment of patients with metastatic pancreatic cancer, following gemcitabine-based therapy. It is prescribed in combination with 5-FU and leucovorin.

Generic doxorubicin, or DOXIL, is also part of the transaction.

What do we get from this? We get a wholly owned product of ONIVYDE. We have rights for current and potential ONIVYDE indications in the United States. The ex-US rights will be held by Shire through a licensing agreement and PharmaEngine maintains licensing in Taiwan.

From an infrastructure perspective, we secure the manufacturing and commercial structure from Merrimack.

The transaction financials are $575 million cash at closing; and, up to $450 million upon FDA approval of additional indications for the USA.

Next slide. This is a unique transaction with compelling rationale for us. We'll cover three areas: strategic, financial and integration.

From a strategic perspective, ONIVYDE is a clinically differentiated FDA-approved product for patients with high unmet medical needs. This is a unique opportunity to secure a marketed and wholly owned asset with current US revenues, based on solid clinical data and potential approvals in additional indications already in clinical development.

And three, we have a partnership with Shire for ex-US rights and co-development of future indications.

Financially speaking, this is an attractive transaction, the value [has] given future forecasted product performance in approved indications; significant growth and profitability enhancements; and long-term upside to financial performance from potential additional indications.

From an integration and synergy perspective, there is a high level of commercial synergies with existing US Ipsen oncology infrastructure. We have an experienced US oncology commercial team, with a proven track record with Somatuline.

Next slide. This transaction accelerates the transformation of Ipsen. There's three pillars: strengthening oncology focus, growing US presence and increase in growth and profitability.

For strengthening our oncology focus, we are emerging as a recognized market leader in several specialized markets. Our global oncology business currently represents over 50% of our sales. New oncology products are important growth contributors to the Ipsen portfolio.

Growing US presence. Our US -- we're establishing a meaningful presence in the oncology market. The oncology commercial team has strong expertise and a proven track record. We're leveraging our current infrastructure to optimize resources.

Increase in growth and profitability. There are substantial synergies to further leverage profitability with limited short-term dilution. The transaction will be accretive from 2018 for Ipsen's growth, profitability and earnings. We have supporting confidence to achieve longer-term goals and a sustained profitability.

The transactions over the last 12 months have accelerated Ipsen's transformation to a leading global specialty care company, with a growing oncology franchise.

Next slide. ONIVYDE is a new product in a tumor with high unmet medical needs, with overall survival data and established safety profile. ONIVYDE is a differentiated product for metastatic pancreatic cancer. It is the first and only FDA-approved therapy in a post-gemcitabine setting for pancreatic cancer. There's a novel encapsulation of irinotecan. There's a superior pharmacokinetic profile with selective accumulation of a tumor site.

From an IP's perspective, we have market exclusivity until 2028.

The strong clinical profile of the NAPOLI-1 study, which was the Phase 3 trial for registration, was published in the Lancet. ONIVYDE plus 5-FU leucovorin significant approved overall survival among patients previously treated with gemcitabine-based therapy. There is superior PFS, ORR and [time] progression in patients receiving ONIVYDE plus 5-FU leucovorin.

This level of evidence is category one evidence in the NCCN guidelines for second-line treatment of metastatic pancreatic cancer.

Slide 7. ONIVYDE is highly differentiated and contains a novel formulation of irinotecan. The liposome is designed to keep irinotecan in circulation and in the tumors for a prolonged period. The longer half-life keeps drugs circulating in the system longer. There is an increase and prolongation of inter-tumor levels of the drug. You can see the details there of how ONIVYDE works on a tumor.

The next slide. There is significant commercial opportunity in metastatic pancreatic cancer in the US. Beginning, there are about 50,000 patients a year that have pancreatic cancer in the United States.

How the patient journey begins, it's the physician will determine is -- can there be surgery or not; can the tumor be resected? If there is a resection, that goes to surgery. If there is no resection, that goes to drug therapy.

You've got adjuvant/neoadjuvant therapy; front-line metastatic therapy; second-line metastatic therapy; and third-line metastatic therapy.

One can see that ONIVYDE eligible patients are for all metastatic patients with pancreatic cancer, with disease progression following gemcitabine therapy. So, there's a significant patient potential for ONIVYDE in the US market.

Next, slide 9. We all know there have been very few improvements to the treatment paradigm for metastatic pancreatic cancer in the last 20 years. In fact, there's only been a couple of products approved in the last few years. Going back to 1996, one can see there's very few approvals, and the pancreatic landscape has experienced a large number of Phase 3 trials reporting disappointing results.

The most recent approvals are gemcitabine plus Abraxane, one can see that in 2013. In 2015, was the ONIVYDE approval for post-Gemcitabine patients compared to 5-FU leucovorin. So, there remains high unmet medical need for these patients.

Next slide. We're also very excited about the future potential of ONIVYDE. There are development programs currently underway for ONIVYDE for new indications.

The first indication is previously untreated metastatic pancreatic cancer, also referred to as first-line metastatic pancreatic cancer. That is a Phase 2/3 trial that is underway already, and currently enrolling patients.

There is also a trail underway for relapsed small-cell lung cancer, and there is a Phase 1 trial for breast cancer.

So, we can see there are three ongoing programs, and we share the partner -- the partnership and co-development we share with Shire. There are 19 ongoing investigator-initiated studies in various tumor types, and a variety of combination targeted agents.

We're very excited not just about the current indication for ONIVYDE in the post-Gem setting, we're also very excited about the future potential indications that ONIVYDE may provide to patients.

On slide 11, we have a thriving and very successful US oncology commercial organization. They are experts and they're ready to accelerate the growth trajectory and maximize the product potential with ONIVYDE.

There is a current team already in place with extensive experience in oncology, and with the physicians that are treating pancreatic cancer patients.

Ipsen has a track record of successfully launching to key stakeholders in the pancreatic cancer market, making ONIVYDE a natural fit with our Somatuline oncology organization.

We have a team of over 130 dedicated sales; marketing; reimbursement; medical affairs; patient services; GPOs; payer services; health economics and outcomes research colleagues with deep oncology experience, and they're well positioned to take on the new opportunity with ONIVYDE.

Let me now turn it over to Aymeric, our CFO.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

Thank you, David. On slide 12, the total size of the transaction is close $1 billion. We structured the transaction in a way where the cash consideration of $575 million will be for the current indication, and we have structured a deal where we are eligible to pay up to $450 million additional upon approval of additional indications in the US.

To provide more detail, as Merrimack provided in its press release, we [are] to pay $225 million in case of approval in first-line -- in metastatic pancreatic cancer.

We are eligible to pay $150 million in case of indication and approval in the US for small-cell lung cancer, an additional $75 million for a potential third indication for ONIVYDE in the US.

The transaction will be fully financed by existing cash, and a long-term line of credit of Ipsen's, especially as we raised $300 million of bond transactions earlier in 2016.

On top of that, as David was mentioning, we are taking over the licensing agreement with Shire, which will provide us with a tiered royalty and milestones, and which also we'll share some of the development costs.

We are not anticipating a lot of value from that agreement as we have also back-to-back agreement with PharmaEngine, a company from Taiwan, where we have to give back a large portion of the royalties and milestones.

Turn to slide 13, financial impact for Ipsen of the transaction. Just to remind that ONIVYDE today has been launched a little more than a year ago, in October 2015. Today, based on the latest filing from Merrimack, run rate sales are about $60 million.

We expect the transaction to have significant synergies with existing US commercial organization. As I mentioned before, clearly, we'll benefit from the contribution in terms of development of Shire for the today-identified, future potential indication, mainly on first-line and small-cell lung cancer.

Financially we expect the transaction to be slightly dilutive in 2017, mainly due to the amortization of the intangibles that will come from the transaction; and, to be significantly accretive from 2018 and beyond to both our operating margin and, also, earnings per share.

Then on top of that, the way we structure the transaction, we believe that if we were to pay the additional contingent payment of $450 million, there is a significant upside for Ipsen with ONIVYDE.

Clearly, this transaction, financially, will accelerate our growth trajectory; will increase the share of our US sales, and the profitability of our US business; and, clearly, will support our mid-term financial outlook.

David?

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**David Meek** - *Ipsen SA - CEO*

Thank you, Aymeric. Our next slide, slide 14, the next steps to closing.

We expect the deal to close by the end of Q1 2017. This is subject, of course, to customary closing conditions, including Hart Scott Rodino. This deal will also be subject to Merrimack shareholder approval.

For integration, we will work on transferring the manufacturing's facility and supply chain from Merrimack to Ipsen. We will also be transferring over 100 employees from Merrimack to Ipsen. And, we're currently preparing for US commercial synergies for ONIVYDE.

The next slide. Strategically for Ipsen, this establishes global leadership in specialty oncology markets. Ipsen has been in the oncology market for decades, going back to Decapeptyl, which is still a thriving product for us in Europe and the rest of the world. We're clearly a leader in the neuroendocrine market with Somatuline globally, including the US.

In first half of 2016, we signed a partnership agreement with Exelixis for CABOMETYX. CABOMETYX is now registered and approved in Europe and we're currently in launch mode with CABOMETYX in renal cell carcinoma.

Now, we add ONIVYDE, which is a differentiated product for high unmet medical need in pancreatic cancer. We have a significant oncology presence, and we have a growing US oncology presence.

Thank you very much for listening to us. We will now open the call up to a Q&A period. Operator?

## QUESTIONS AND ANSWERS

**Operator**

(Operator Instructions). Nicolas Guyon-Gellin, Morgan Stanley.

**Nicolas Guyon-Gellin** - *Morgan Stanley - Analyst*

I have three questions actually. So, the first one is about the financial impact. Aymeric, you have guided for dilutive deal in 2017. I'm not asking for any precise guidance about margins for next year, but could you please comment at least directionally about margins in 2017 versus 2016?

In other words, you reiterate the comments that you've made right after the Cabo deal that 2017 margins will not be lower than 2016.

Question number two around the accounting of the transaction. My understanding is that the bulk of the dilution comes from the goodwill amortization costs that, unlike your peers, you don't restate in your core earnings. But, also, to a lesser extent from the Merrimack's commercial and manufacturing infrastructure that you will initially keep.

Could you please elaborate on potential synergies and how committed you are to this infrastructure?

And the third question is about the ex-US rights of ONIVYDE. Would you be interested in acquiring the European rights of ONIVYDE from Shire, if they would agree to sell them? Thank you very much.

**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

Okay, thank you. I will answer to the first two questions. Then, I will leave to David to comment more on the commercial and mainly the third question.

Clearly, we are not going to provide any guidance for 2017. That will be done in February. But, clearly, as you know, we are on track to deliver for 2016, so we shouldn't expect any bad surprise.

Regarding the dilution, and to be more precise, we are talking about both a dilution on the core operating income and on the EPS.

As you mentioned in your second question, where we're talking about the core operating income, the way we are accounting for does include the amortization of the intangible, which for this transaction is very material. Clearly, the impact will be -- but not that significant at the core operating income. There will be further dilution at the earnings per share, the net income level.

You are right, there will be some one-off knowing that we are not taking over the full infrastructure coming from Merrimack. But that we are going to ensure there is a smooth transition operationally to take over the business, and be able to grow and achieve our target for ONIVYDE.

**David Meek** - *Ipsen SA - CEO*

Great. And then the question regarding European rights or ex-US rights for ONIVYDE. As with any transaction or opportunity, we would look at the strategic and financial opportunities ahead for us, and consider those.

Thank you. Next question?

**Operator**

Luisa Hector, Exane.

**Luisa Hector** - *Exane BNP Paribas - Analyst*

Just to follow up further on the amortization, can you give us any more color what percentage of the upfront should we assume as an intangible? And what the schedule of amortization is like, is it the same amount each year? Or is there a heavier weighting into 2017?

And then just in terms of what you're actually acquiring, the manufacturing facilities and, I think, 100 employees. Is all of that within the US? And how are you seeing the overlap in terms of your existing infrastructure, and some of that additional infrastructure coming from Merrimack, both within selling and R&D? Thank you.

**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

Okay, thank you for the question, so I'll take the first question. Clearly, to provide you with the bulk figures, we expect something on EUR40 million to be the amortization of the intangible, as most of the value will be within intangible outside of the -- some of the manufacturing and commercial assets that we are buying in the $575 million.

Amortization will be straightforward. So, you should not anticipate any rise, unless we are to pay, but which won't be before after 2020, any of the contingent payments for additional indications.

Specifically, for 2017, it will really depend when we do the closing. We should expect potentially if we were to close by the end of Q1 to only have nine months of this EUR40 million. This is going to be amortized over the patent of the ONIVYDE products.

**Luisa Hector** - *Exane BNP Paribas - Analyst*

And that was EUR40 million amortization, yes?

**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

EUR40 million.

**Luisa Hector** - *Exane BNP Paribas - Analyst*

Thanks.

**David Meek** - *Ipsen SA - CEO*

Regarding integration with Merrimack colleagues, there will be over 100 employees from Merrimack that will transition to Ipsen. The majority of those colleagues will be in manufacturing, because we are assuming the manufacturing of ONIVYDE globally.

We will also add some of the R&D organization that is responsible for ONIVYDE, as well as some commercial colleagues that are responsible for ONIVYDE. These colleagues will be added to the 130 dedicated oncology colleagues we have already in the Ipsen organization.

So, that explains the integration of the Merrimack colleagues. But for the most part it rounds out what we don't have. But we have a very solid oncology organization already in place.

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**Luisa Hector** - *Exane BNP Paribas - Analyst*

Thank you.

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**Operator**

Richard Vosser, JPMorgan.

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**Richard Vosser** - *JPMorgan - Analyst*

Firstly, just in terms of Merrimack's R&D spend, what sort of proportion is related to ONIVYDE? If you could give us some help there.

Also, the SG&A cost I think is about [$]60 million or so. Again, what sort of proportion of that is related to ONIVYDE, and you think you'll need funds, in terms of the spend behind ONIVYDE to continue the ramp?

Also, I note that the -- as you've noted, the launch has been -- well, the launch has been a little bit disappointing in the US, relative to the expectation in the financial market.

So, if you could give us a little bit more detail of why you think that is? What you think you need to change in terms of to drive more acceleration, that would be useful.

Also, it would be useful if you could give us some idea of the peak sales you think you can achieve for ONIVYDE in the US.

And then finally just on tax, if you could give us an idea of how many tax losses, or the length of time you've got left on tax losses, in the US to offset what could be significant profits from ONIVYDE coming through, that would also be very useful. Thanks very much.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

Okay, thank you. I will take the financial questions and I will leave to David on the launch to (inaudible).

Clearly, we're not taking over most of the R&D from Merrimack. As you've seen from the press release, they are now refocusing the company to be really an R&D company, early-stage biotech company and have been restructuring also quite heavily. So, when David was talking about some of the development people we are taking -- we are talking about very limited people.

Having said that, we're going to support all the cost of the trials for first-line and small-cell lung cancer. So, this will represent a significant investment in R&D that will be, for sure, fully financed by the commercial sales of ONIVYDE.

In terms of SG&A, we are not taking at all very, very, limited as it will be very synergetic to our existing infrastructure in the US.

Second question on the peak sales, I will leave to David to really talk about the launch. We're not providing detailed peak sales, but just to give an idea, as you know, Merrimack was followed by analysts, so I'm sure that you have some information on that one.

We expect to do better. To just give a bulk figure, we expect to be in excess of $300 million peak sales for the current indication of ONIVYDE.

Last on the tax losses, I'm not going to comment on the structuring of the transaction, especially at a time when the tax in the US are moving. There is a lot of pieces, and maybe the value of our tax losses could be different if the tax rate was to change. But, you're right, we may have an opportunity to accelerate the recognition of our tax losses that we -- today, we are using -- through Somatuline, with this acquisition, we may have a benefit to do so.

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**David Meek** - *Ipsen SA - CEO*

Great. Thank you, Aymeric. And regarding the [market] potential and why we think we can ramp up quickly the sales of ONIVYDE, let me begin with the pancreatic cancer market in the US.

It is now, pancreatic cancer is now the third leading cause of cancer death in men and women in the US. This has been growing. About 42,000 people die from the disease in the US.

And survival for all stages combined, the one and five-year relative survival rates are 29% and 7% respectively. Half of these patients are already diagnosed with metastatic disease. The one-year survival rate is 15% and the five-year survival rate is 2%. So, there's significant unmet medical need with pancreatic cancer.

ONIVYDE with the overall survival data, the progression-free survival data, and the time to treatment failure data, the clinical profile, is excellent. It's the first and only approved product in a post-gem setting.

Now, we are also when we put ONIVYDE into the Ipsen engine, on day one there will be triple, so 3 times the share of voice, that Merrimack had in the marketplace. When ONIVYDE goes into the commercial engine, which is sales, marketing, medical affairs, account management, patient advocacy, and so on, there will be a significant inflection of share of voice with a team that is already calling on the pancreatic cancer treaters today.

So, we're out there today. Already, we've been successful with Somatuline in a very competitive marketplace, with Sandostatin and Novartis Oncology. So, we're very confident we can increase the trajectory of ONIVYDE in the current indication, as well as potential indications to come.

As Aymeric mentioned, we see peak sales above $300 million just for the current indication.

Thank you. Next question?

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**Richard Vosser** - *JPMorgan - Analyst*

That's very helpful. Thanks very much.

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**Operator**

Del Le Louet, SocGen.

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**Delphine Le Louet** - *Societe Generale - Analyst*

I have three questions, if I may. Can you clarify a bit about the manufacturing, and tell us a bit where you are and where it's going to be produced right now? How the transfer is going to be made and where, also in term of capacity and quantity that you have in inventory, possibly, regarding the launch that you're expecting.

Second question deals with, of course, the dilution. With the comment, you just been doing regarding especially the peak sales potential, am I right in thinking about the fact that you might be dilutive at the level of the specialty care operating margin as soon as 2018?

Secondly, can we -- yes. No, it's okay. Thank you.

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**David Meek** - *Ipsen SA - CEO*

Sure. I'll cover the first question relative to the manufacturing. The manufacturing for ONIVYDE as well as the colleagues that are currently with Merrimack and those transferring to Ipsen, this is a good news story for us, because they're currently in the same neighborhood as our Ipsen R&D site in Cambridge, in Boston, just a few hundred meters away everybody is.

We'll assume the manufacturing, which is where Merrimack manufacturing is, and some of those R&D and commercial colleagues will join our team in our facility that we already have in Cambridge.

We expect to have adequate supply for the next one to two years for ONIVYDE upon on immediate close of the transaction.

I'll turn over to Aymeric.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

On the dilution, I'm not sure to -- fully understood the question. If the question is will the transaction be accretive in 2018 at the income level, the question (sic) is yes.

If beside the question, the question is the deal in 2017 accretive, excluding the amortization of the intangible, which I assume was the question, the answer is yes.

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**Delphine Le Louet** - *Societe Generale - Analyst*

Okay. Well, that was partly the question, but the question was the accretion in 2018. You were talking about the operating margin at a Group level, but I was talking about the operating margin at the specialty care level.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

Yes, the answers will be the same. The specialty care and especially oncology in the US will benefit from high level of margin. So clearly, it will be accretive to the specialty care business.

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**Delphine Le Louet** - *Societe Generale - Analyst*

Thanks.

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**Operator**

(Operator Instructions). Peter Welford, Jefferies.

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**Peter Welford** - *Jefferies - Analyst*

Thanks for taking my questions; I've got two left, please, I think.

Firstly, can you just outline the deal with PharmaEngine, with regards to how many of the sales milestones still owe the value to PharmaEngine; and what proportion of US sales you owe back to them under the terms of the deal done with Merrimack?

Then secondly, just on the first line pancreatic, I think, at the moment, if I look at clinicaltrials.gov, there could be some data relatively soon in first line. Can you give us an update perhaps on where actually recruitment stands and when you envisage we could potentially get first line, because it sounds from your 2020 statement as though first-line data are unlikely to be for at least a few years, best case. Thank you.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

The first question, clearly there is no royalty to be paid on the US sales to PharmaEngine. It's only royalty on ex-US sales. That's why it's like a natural hedge between the royalty that we're going to receive from Shire, based on the sales ex-US that we're going to offset with mainly with royalty to PharmaEngine. But there is no royalty to be paid for US sales.

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**Peter Welford** - *Jefferies - Analyst*

Sorry, are there any sales' milestones outstanding?

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

The same on the milestones. The milestones are also -- have been structured by Merrimack when they did a deal with Shire (inaudible) [at that] time. In a way, there is also a back to back on most of the milestones. So, there is no milestones payment to be expected and neither there is no significant milestone to be expected from Shire on the commercial side. This is really more the sharing of development that we will benefit from, and having a partner to potentially look after other indications.

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**David Meek** - *Ipsen SA - CEO*

Peter, I'll answer your question regarding the first-line metastatic pancreatic cancer trial that is up and running already and is enrolling patients. We'll be able to provide a little more color in the next couple of months regarding this trial. There could be a data -- there could be some data signal as early as 2018, but I would say that would be towards the end of 2018 for this first-line setting.

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**Peter Welford** - *Jefferies - Analyst*

Okay, that's great. Just to confirm that it's still in the relatively early stage, therefore, enrolling patients.

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**David Meek** - *Ipsen SA - CEO*

Well, yes, it's there and then we have to wait for the data mature to get the PFS signal. Then if the data's positive, we roll this Phase 2 right into a Phase 3 trial. So, we're pretty confident it can go quick if there's an efficacy signal.

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**Peter Welford** - *Jefferies - Analyst*

That's great. Thank you.

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**Operator**

Jean-Jacques Le Fur.

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**Jean-Jacques Le Fur** - *Natixis - Analyst*

Natixis; two quick question, if I may. The first one is sales in the US for ONIVYDE are expected to be $60 million this year -- last year, sorry. Could you tell us to which penetration rate or market share does it correspond in second and third line, just to have an idea where the product is now?

The second one for [Merrick], what will be the additional financial expenses we may expect due to this acquisition? Thank you.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

Okay, we'll not provide any detail on the $60 million sales today but they are under the current level, and you know the current level is mainly second line. But we won't provide any detail by line of treatment of the current sales.

On the financial expenses, as you know, we've secured most of the financing at a pretty cheap and interesting, and attractive condition, which are around 2% for the bond. The bank financing is even cheaper than that.

But we will probably hedge a significant proportion of our debt in US dollar, so we may have to carry some extra costs due to the interest rate in US dollars. We are potentially talking about something around $5 million to $10 million, depending on the maturity and the interest rate between euro and US dollar.

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**Jean-Jacques Le Fur** - *Natixis - Analyst*

Okay.

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**David Meek** - *Ipsen SA - CEO*

Regarding the run rate for -- let me add one more point to that is that was third-quarter run rate from Merrimack. So, Merrimack will give a fourth-quarter update at their 2016 full-year results. We'll gain a little bit more clarity on full-year 2016 results.

Then as the transaction closes, we'll be able to provide even more regarding full-year sales and projections. But, as we did state today, we see peak sales for the current indication at well over $300 million.

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**Jean-Jacques Le Fur** - *Natixis - Analyst*

Okay. Thank you.

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**Operator**

(Operator Instructions). Luisa Hector, Exane.

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**Luisa Hector** - *Exane BNP Paribas - Analyst*

I just wanted to clarify on the first-line pancreatic, it sounds like you're expecting to have to move into a Phase 3 study, so that data, and linking that then to the milestone, is still some way out. But I wonder about the small cell lung cancer, could we actually see that milestone potentially being payable sooner than the first-line pancreatic? That's first question.

I wonder if you could just make any comments on the ONIVYDE pricing in the US and just the pricing environment in general. I assume you're comfortable, given the higher price point of this new formulation.

Then finally on ONIVYDE US, you talked about exclusivity to 2028. I just wondered how confident you are in this. Does that include a patent extension? Thank you.

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**David Meek** - *Ipsen SA - CEO*

Let me answer the first question. Just for clarity regarding the milestones, we only pay milestones if there is an FDA approval for first-line metastatic pancreatic cancer, or small-cell lung cancer, or a third indication to be chosen later. That is the only time we pay milestones.

So, it's upon FDA approval. Just so we're clear on that for the trials.

The first-line trial, it is in the Phase 2 setting now. That Phase 2 can run into Phase 3, and we should see some top-line data near the end of the second half of 2018, for the first-line setting.

The small-cell lung cancer, that's also in a Phase 2 trial; it's up and running. We should be able to add more color to all of these trials as the transaction closes in the coming months.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

Just to make sure, we clarify there is no way any of this Phase 2 trial will be adjustable and that we'll be paying any of the contingent payments before the completion of the Phase 3 and, as David was reminding, on the approval by FDA of the product.

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**David Meek** - *Ipsen SA - CEO*

Then regarding the price, the wholesale acquisition cost price today is currently over $10,000 per month, $10,200 per month.

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**Aymeric Le Chatelier** - *Ipsen SA - EVP, Finance*

IP. The last question was on IP.

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**David Meek** - *Ipsen SA - CEO*

IP, I'm sorry. The IP is 2028 for the US. That is just our base IP and we'll certainly do what we can to extend that IP, but minimum 2028.

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**Luisa Hector** - *Exane BNP Paribas - Analyst*

Okay. Thank you.

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**David Meek** - *Ipsen SA - CEO*

Any more questions, operator?

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**Operator**

There are no further questions waiting, sir.

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**David Meek** - *Ipsen SA - CEO*

Well, again, everybody, thank you very much for joining us on this call.

As you can tell, Aymeric and I are really excited about this opportunity for Ipsen. We think it's a great strategic fit for Ipsen. It's a great financial opportunity for Ipsen. Now, we can get busy integrating the portfolio as soon as the deal closes in the next couple of months.

Thank you very much and have a great day.

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**Operator**

Thank you very much, sir. Ladies and gentlemen, that does conclude the call for today. Thank you all for participating. You may now disconnect your lines.

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