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INCY - Q4 2016 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 2016 total revenue of $1.1b and net income of $104m. 4Q16 total revenue was $326m and net income of $9m.

CORPORATE PARTICIPANTS

Mike Booth *Incyte Corporation - VP of IR*

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Barry Flannelly *Incyte Corporation - EVP and General Manager*

Steven Stein *Incyte Corporation - SVP and Chief Medical Officer*

David Gryska *Incyte Corporation - EVP and CFO*

Reid Huber *Incyte Corporation - EVP and Chief Scientific Officer*

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PRESENTATION

Operator

Greetings and welcome to the Incyte Corporation's fourth-quarter and year-end financial results. (Operator Instructions) As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host Mr. Mike Booth, Vice President of Investor Relations. Please go ahead, sir.

Mike Booth - *Incyte Corporation - VP of IR*

Thank you. Good morning and welcome to Incyte's fourth-quarter and year-end 2016 earnings conference call and webcast. The slides used today are available for download on the Investors section of incyte.com.

Speaking on today's call will be Herve Hoppenot, our CEO, who will begin with some comments on both our long-term strategy and our recent business development activities. Herve will then pass to Barry Flannelly who leads our US organization and who will provide an update on Jakafi sales and provide some detail on US demand growth in MF and PV.

Steven Stein, Incyte's Chief Medical Officer, will highlight the depth of our late-stage programs and detail our key expected value drivers for the year. David Gryska, our CFO, will summarize fourth-quarter and full-year results for 2016, as well as provide 2017 guidance before opening up the call for Q&A for which we will be joined by Reid Huber, our Chief Scientific Officer.

We would like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for 2017 guidance, the commercialization of our products, and the development plans for the compounds in our pipeline. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended September 30, 2016, and from time to time in our other SEC documents.

I would now like to pass the call to Herve for his introductory remarks.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thank you, Mike, and good morning, everyone. So we had a very productive year at Incyte in 2016. We showed our revenue growing at 47% year on year and during which we expanded our geographic footprint to include Europe and further advance our clinical portfolio. We also added to our early-stage program in a meaningful way.

To start, I would like to begin our discussion today by talking about the DNA of Incyte, which is innovation. We believe that innovation and the discovery of new products is where value is created in our industry, and Jakafi's growth enables Incyte to make significant investments in our R&D portfolio. In fact, more than 60% of 2016 Jakafi product revenue was reinvested into R&D during last year. We are in a strong position to drive our broad portfolios through the clinic and beyond, and just yesterday we announced with Lilly that baricitinib has been approved in Europe for the treatment of rheumatoid arthritis.

Baricitinib would be marketed as Olumiant, and royalties from Olumiant has the potential to be a significant future revenue driver for Incyte.

This next slide shows the evolution of our full-year annual revenues since 2012. As you can see, we have had impressive growth since the launch of Jakafi both in the US and ex-US with Novartis, and we are pleased to announce today that for the first time ever, total annual revenue recorded by Incyte has surpassed $1 billion.

Next, I will talk about how we are reinvesting these resources in an effort to sustain and accelerate our future growth. As you can see on slide 7, we now have seven late-stage programs. Baricitinib and capmatinib are partnered globally with Lilly and Novartis respectively, and we intend to maintain our current rights for the other five candidates in major markets. Steven will provide updates on the details of our late-stage plans showing that having this depth of late-stage candidates places us in a very good position for future growth.

Within the early-stage portfolio, we have added our new clinical candidate, 62079, which is a selective FGFR4 inhibitor. Last month we added the first-in-class arginase inhibitor, 1158, to our portfolio through an alliance agreement with Calithera, and in December we further enhanced our discovery effort through a long-term collaboration with Maersk.

I will discuss this collaboration further in the next slide.

I would begin with our Calithera collaboration. We believe that arginase is an important target within the tumor microenvironment and could have a role in combination with other immuno-oncology targets including epacadostat. We are excited to have secured global rights to a first-in-class molecule which is already in the clinic. '1158 has shown an attractive preclinical profile, including potency, selectivity, oral bioavailability, and in vivo efficacy and safety. It is currently being studied in a monotherapy dose escalation trial, and combination trials are planned.

Concerning Merus, our strategic collaboration with Merus is expected to provide us long-term access to their Biclonics technology for up to 11 programs. We believe Biclonics is the leading bi-specific technology for four main reasons: it uses fully human antibodies, it uses a native IgG format, it allows for the functional screening of potential candidates, and manufacturing of biclonics is expected to be relatively simple. We had just had the initial scientific kick-off meetings, and we very much look forward to working with the Merus team in the coming years.

I will now pass the call to Barry for the updates on Jakafi.

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Thank you, Herve, and good morning, everyone. Sales of Jakafi continue to perform well. On the left side of this slide, you see that Jakafi's revenue for the full-year 2016 was $853 million, a 42% increase over the full-year 2015. In the fourth quarter, net product revenue from Jakafi was $238 million, a 6% increase over Q3, and a 30% increase over the fourth-quarter revenue of 2015. In the next slide, we will provide more detail on the 30% growth we saw from Q4 2015 to Q4 2016.

On slide 11, you can see that growth in Jakafi is substantially driven by patient demand. The bar graph on the left shows that the number of patients on Jakafi at the end of Q4 2016 grew 28% over Q4 2015. In comparison, revenue growth in the same period was 30%.

The bar graph on the right shows how the 28% growth in total patients is split by total and new patients in each indication. Both indications are contributing to the growth of the brand, and PV growth is greater than MF growth. This is due to the significantly larger established patient base in myelofibrosis, and we expect polycythemia vera to be a major long-term driver of Jakafi growth due to the larger potential patient population and the potential for longer duration of treatment.

Next, I would like to talk to you about Jakafi guidance for 2017 and the longer term. As we announced about a month ago, we expect long-term peak sales of Jakafi to reach $2 billion. This guidance includes revenue from myelofibrosis and polycythemia vera indications and the potential GHVD indication, but does not yet reflect estimates for the potential approval of Jakafi in essential thrombocythemia.

Today, we announced that our 2017 Jakafi net product revenue guidance is a range of $1.02 billion to $1.07 billion. This reflects what we believe will be continued patient demand growth in both approved indications.

With that, I will pass the call to Steven for a clinical update.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Thank you, Barry, and good morning, everyone. We have a broad and deep portfolio here at Incyte. We have multiple late-stage assets that are in or expected to begin pivotal trials this year. I will provide more details on the next slide.

The pivotal program of ruxolitinib in steroid-refractory graft versus host disease is underway, and the pivotal programs that we expect to begin this year include those of ruxolitinib in essential thrombocythemia and itacitinib in treatment-naive graft versus host disease.

In addition to the ongoing Phase 3 trial of epacadostat plus pembrolizumab in melanoma, we expect to begin pivotal trials of epacadostat plus pembrolizumab in non-small cell lung cancer, bladder cancer, renal cancer, and head and neck cancer during 2017.

We are also currently running three Phase 2 trials that, if successful, may be registration enabling. These are our FGFR1/2/3 inhibitor, '54828, in patients with bladder cancer, cholangiocarcinoma, and an 8p11 MPN. A fourth Phase 2 trial that may also be registration enabling is with our PI3 kinase delta inhibitor, '50465, in patients with diffuse large B-cell lymphoma. This trial is expected to begin in the first half of 2017.

In addition, we have two late-stage assets, the JAK1/JAK2 inhibitor baricitinib, and the cMET inhibitor, capmatinib, which are partnered with Eli Lilly and Novartis respectively. Baricitinib is now approved in Europe, and other global regulatory reviews for rheumatoid arthritis are ongoing.

Lilly announced that it plans to begin a Phase 3 trial of baricitinib for patients with psoriatic arthritis during 2017. We have opted into co-development for this indication, as well as for codevelopment of axial spondyloarthritis and atopic dermatitis, should Lilly also progress these indications into clinical development.

Novartis expects data from the trial of capmatinib in combination with EGFR inhibition in patients with non-small cell lung cancer to read out later in 2017 and also expects to submit an NDA to the FDA for capmatinib in non-small cell lung cancer in 2018.

Next, I would like to move to our epacadostat program.

As we announced with Merck last month, we have decided to expand the combination of epacadostat plus pembrolizumab into four additional tumor types, and we expect to begin these pivotal programs during 2017. Of the nine total tumor type studies in ECHO-202, five are now in or being moved into pivotal development. We continue to collect data for the diffuse large B-cell lymphoma and micro-satellite instability high colorectal cancer cohorts and have no current plans to move ahead with either ovarian cancer or triple-negative breast cancer.

Slide 17 shows our current portfolio. Over the course of 2016, our portfolio has evolved significantly and is now nicely balanced between early-stage versus late-stage assets. Since our call this time last year, we have added five new clinical candidates and have moved more than half of that existing portfolio into the next stage of development. We believe that our portfolio is unique and unparalleled for a company of our size and contains both first-in-class and best-in-class candidates. We intend to pursue development of our product candidates in both mono and combinatorial settings, further enhancing the optionality of our opportunities.

The agreements with Merus and Calithera are both additive to and potentially synergistic with our in-house discovery and development efforts, and the agreement we have reached with Agenus to restructure our collaboration gives Incyte control of the global development and commercialization of our two lead large molecule therapeutics. I will now finish my section on our expected news flow.

On slide 18, you can see the progress we expect to make in our portfolio over the next year. Much of this has already been communicated with our previous slides, so I would like to highlight just a few things. First, we are preparing to present first-in-man data for '54828 our FGFR1/2/3 inhibitor during the first half of 2017 with the data from the BRD and PIM programs potentially later in the year. We plan to begin the new pivotal programs of epacadostat in non-small cell lung cancer, renal cancer, bladder cancer, and head and neck cancer during 2017, and we also expect to initiate a proof of concept trial of topical ruxolitinib in patients with vitiligo. We expect 2017 to be a busy year at Incyte, and we look for to keeping you updated on our progress.

With that, I will pass the call today for the financials.

David Gryska - *Incyte Corporation - EVP and CFO*

Thanks, Steven, and good morning, everyone. I would like to start by discussing our fourth quarter and 2016 performance, and then provide guidance for 2017 which will include the accounting for Agenus, Merus and Calithera agreements.

In the fourth quarter, we recorded $326 million in total revenue. This was comprised of $238 million in Jakafi net product revenue, $13 million in Iclusig net product revenue, $33 million in Jakavi royalties from Novartis, and $43 million in contract revenue, including a milestone paid to us by Novartis related to pricing approval of Jakavi for PV.

For 2016, we recorded $1.1 billion of total revenue. This was comprised of $853 million in Jakafi net product revenue, $30 million in Iclusig net product revenue, $111 million in Jakavi royalties for Novartis, and $113 million in contract revenue.

Our gross to net adjustment for Jakafi for 2016 was approximately 12%. Our cost of product revenue for the quarter and full year was $20 million and $58 million respectively. This includes the cost of goods sold for Jakafi and Iclusig, the payment of royalties to Novartis for US Jakafi net sales, and the amortization of acquired product rights related to the Iclusig product acquisition. Our R&D expense for the quarter was $162 million, including $17 million in non-cash stock compensation. For the full year, our R&D expense was $582 million, including $60 million in non-cash stock compensation. Our SG&A expense for the quarter was $96 million, including $10 million in non-cash stock compensation. For the full year, our SG&A expense was $303 million, including $36 million in non-cash stock compensation.

We recorded $7 million in expense related to the change in the fair market value of the contingent consideration for the Iclusig royalty liability in the fourth quarter and $17 million for the full year. As for net income for the quarter and full year, we reported $9 million and $104 million respectively. Looking at our balance sheet, we ended the fourth quarter with $809 million in cash and marketable securities.

To summarize, we are extremely pleased with our performance in 2016. Jakafi delivered strong revenue growth, we grew our cash position by over $100 million for the year, and continue to make significant advancements in our clinical development programs.

Turning to slide 21, I would like to highlight some key drivers of our 2017 guidance. We anticipate that milestone payments may add significantly to Incyte's total revenue during 2017. The events which may trigger these milestones are laid out on the left-hand side of slide 21. The announcement yesterday of the European approval of baricitinib, which will be marketed as Olumiant, is the first of what we expect will be several global approvals of baricitinib.

In addition, Lilly moving baricitinib into Phase 3 in new indications would also trigger milestone payments to Incyte. We also anticipate that development and commercialization milestones on Jakavi may be triggered by Novartis.

On the expense side, we anticipate epacadostat and baricitinib to be drivers of ongoing R&D expense, and the recently signed agreements with Agenus, Merus, and Calithera will add one-time items to our R&D expense in 2017. In terms of SG&A expense, 2017 will be the first full year that we include our European operations.

Moving on, I will now summarize the key components of our 2017 guidance. Please note that the guidance we provide today does not include any additional potential future strategic transactions beyond the Merus and Calithera collaborations already announced.

For 2017, we expect net product revenue from Jakafi to be in the range of $1.02 billion to $1.07 billion. For Iclusig, we expect net product revenue to be in the range of $60 million to $65 million, and as I detailed on the previous slide, we expect to receive up to $300 million in milestone payments from our collaboration partners. The most significant portion of the $300 million milestone payments will be $165 million in milestone payments from Lilly for baricitinib approvals in the US and Europe. We anticipate receiving royalties from Lilly after the approval of Olumiant and will continue to receive royalty payments from Novartis on Jakavi in 2017. We are not providing guidance on these royalties.

We expect our gross to net adjustment for 2017 to be approximately 13% for Jakafi. Jakafi is the main driver of our gross net adjustment, and as with similar oncology drugs, our gross to net adjustment is higher in the first quarter than the rest of the year, primarily because of our share of a donut hole for Medicare Part D patients.

We expect total cost of goods sold to be in the range of $75 million to $80 million. This includes the cost of goods sold for Jakafi and Iclusig, the payment of royalties to Novartis on US Jakafi net sales, and the amortization of acquired product rights related to the Iclusig product acquisition.

2017 R&D expense guidance is made up of two parts: one-time expenses associated with Agenus, Merus and Calithera collaborations, and ongoing expense associated with the development of our extensive product pipeline. The Merus collaboration consisted of $120 million upfront cash payment and an $80 million stock investment. We will recognize the $120 million payment, along with approximately a $2 million premium on the stock purchase as R&D expense in the first quarter.

The Calithera collaboration agreement consisted of a $45 million upfront cash payment and an $8 million stock investment. We will recognize the $45 million payment, along with an approximate $4 million discount on the stock purchase as R&D expense in the first quarter. This will result in $41 million of R&D expense in the first quarter for this particular collaboration. The amendment on the Agenus agreement consisted of $20 million in accelerated milestone payments and a $60 million stock investment. We will recognize the $20 million payment, along with approximately $20 million premium on the stock purchase as R&D expense in the first quarter.

We, therefore, expect these one-time expense items to be approximately $205 million, and we expect ongoing R&D expense to be in the range of $785 million to $835 million, including non-cash expense related to employee equity awards. The increase in our ongoing R&D expense year over

year is mainly driven by the advancement of our products in the pipeline, including the previously announced plans to move into multiple Phase 3 studies of epacadostat and an opt-in to co-fund additional indications for baricitinib with Lilly.

We expect SG&A expense to be in the range of $340 million to $360 million, including non-cash expense related to employee equity awards. As I mentioned earlier, the increase to our SG&A expense year over year includes a full year of expense for our recently acquired European operations versus seven months in 2016. We expect total non-cash expense related to employee equity awards to be in the range of $130 million to $140 million.

In addition, we expect the change in the fair market value of the contingent consideration for the Iclusig royalty liability to be in the range of $30 million to $35 million. And finally, we expect net income to be in the range of $50 million to $70 million. I would note, however, that the inherent uncertainty with respect to achievement and timing of milestones I detailed earlier may create variability in our net income on a quarterly basis.

I will finish on slide 23, which provides a summary of our clinical and strategic goals. Incyte is very well positioned from a cash and operating income perspective to execute on our strategies for growth which we are confident will deliver significant long-term shareholder value in 2017 and beyond. Incyte has a broad portfolio of late-stage assets which have the potential to drive significant momentum and value over the next several years.

We also have plans for further geographic expansion into the Asia-Pacific region to enable us to maximize the potential of our product portfolio.

Operator, that concludes our prepared remarks. Please give your instructions and open up the call for Q&A. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Brian Abrahams, Jefferies.

Brian Abrahams - *Jefferies LLC - Analyst*

Thanks very much for taking my question, and congrats on all the progress.

I guess on epacadostat, I was wondering if you could maybe talk through some of the considerations and designing of Phase 3 for epacadostat plus pembro in non-small cell lung? Any learnings from the biomarker data and evolving clinical results that might shape the trial design or patient selection for lung or other indications?

And then I'm curious if you have yet established economic terms around the future Phase 3 trial conduct with Merck. Is there any consideration to an exclusivity arrangement akin to melanoma? Thanks.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Brian, hi. It's Steven Stein. Thank you for your question. I will do the first part, and Herve will address the second part of your question.

I can't give you any granular details. They're still being worked out. The data that enabled a decision has been submitted to a major meeting, and the abstracts for that meeting will be released in the middle of May. And until then, we are bound by the rules -- embargo rules related to that.

But we do take into consideration in any histology all of the above that you mentioned: response, duration of response, and the biomarker piece.

Just to end on the lung one, because that is the one you highlighted, obviously that's an area that is moving quickly both in the first-line, second-line setting, PD-L1 positive, PD-L1 negative, and has numerous report-outs this year as well. So it's an area we will be obviously paying very, very careful attention to in terms of the study design, and that will be shared with you on clinicaltrials.gov when it goes live.

In terms of the terms, I will let Herve speak to it.

Herve Hoppenot - *Incyte Corporation - President and CEO*

As Steven said, the work today -- most of the work today that is ongoing is related to the design of the study and the way we are going to organize the teams to manage the studies. At the same time in parallel, we are discussing with Merck on the term and the economics.

The basic assumption is that we have drug that will be provided by each of the companies to contribute to the study. Then one of the companies will be leading the execution of the study. There would be cost sharing for all of them. We don't know yet exactly how that will be done for the pembro program. And we had no further information of discussion related to exclusivity. So that is really where we are and it's ongoing. We expect that to be running in parallel with the clinical work and coming to conclusion over the next few weeks as a target.

Brian Abrahams - *Jefferies LLC - Analyst*

Thank you.

Operator

Kennen MacKay, Credit Suisse.

Kennen MacKay - *Credit Suisse - Analyst*

Maybe one for Barry just on the guidance. I was just wondering if the Jakafi guidance included any pricing increase assumptions and maybe just in line with what we've seen in terms of the timing of historical price increases, or if this was purely based on volume growth? Thank you.

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Well, most of it is based on volume growth. We don't really talk about price increases at all. Going forward we might assume modest price increases. But, as you can see from the slides for 2016, we have nice uptake in total patients and new patients, both for MF and PV.

Kennen MacKay - *Credit Suisse - Analyst*

And then again maybe just a follow-up for Barry. Is there anything you can -- any sort of color you can provide on the duration of treatment we are seeing in polycythemia vera versus in myelofibrosis?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

What we have said is that it is longer. Getting an accurate reading on persistency for an oral drug over time is not that easy, but PV has been longer than MF. But even our MF patients, we have many of them that have been on for five years or more. But when you look at a 12-month cohort of patients -- PV patients are longer than MF patients.

Kennen MacKay - *Credit Suisse - Analyst*

Thanks so much for taking my questions.

Operator

Ying Huang, Bank of America Merrill Lynch.

Ying Huang - *Bank of America Merrill Lynch - Analyst*

My first question is for Mike. My team loves your music selection. How do you choose those?

Mike Booth - *Incyte Corporation - VP of IR*

I'm pleased you like it. Next question, please.

Ying Huang - *Bank of America Merrill Lynch - Analyst*

Okay. I have a serious question here. So for Steve, on slide 18, it seems like you put the timing for initiation of additional pivotal trials for epacadostat in combination with pembrolizumab towards the end of this year. I was wondering what is the gating factor here since you already have the data from Phase 2 in-house?

And then secondly also, you guys are starting to recruit for the Phase 3 for ET. Can you tell us about the addressable size for ET?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Yes, hi. It's Steven Stein. Thanks for your questions, Ying. We said 2017 because it's hard to give precision in terms of exactly when a first patient will be enrolled. The things that go into it are obviously the standard stuff in terms of writing a protocol, but the real critical part is getting the regulatory meetings done and the regulatory feedback and get an agreement on the design and the endpoints. And I would say -- to answer your question at a high level, that is the critical piece. The plan, though, is very much to get hopefully every one of the Phase 3s started in 2017, but a lot will depend on the regulatory feedback.

Your second question related to ruxolitinib in essential thrombocythemia. It's an indication we've been interested in obviously for a while given that it is one of the myeloproliferative neoplasms. There is a Phase 2 data set that was presented and published by Incyte in 2014 in 39 patients looking at various aspects, but including endpoints in terms of control of platelet count, white blood cell count, and then the few patients that had splenomegalies, in fact four of them, three of them got resolution of that splenomegaly.

So we know we have activity in terms of the endpoints of interest. The only thing we have guided to is to start the study in 2017 and nothing further at this moment.

Ying Huang - *Bank of America Merrill Lynch - Analyst*

Thank you.

Operator

Cory Kasimov, JPMorgan

Cory Kasimov - *JPMorgan - Analyst*

Two of them for you as well. First of all, was the Agenus amendment driven by any new or additional data you've seen on the GITR or OX40 programs?

Reid Huber - *Incyte Corporation - EVP and Chief Scientific Officer*

Hi, Cory. This is Reid. Thanks for the question. No, really the Agenus amendment is one that is really designed to, as Steven said, give Incyte the control of the global development and commercialization of those two programs which had previously been structured as a 50-50. We think that's going to significantly simplify the decision-making process and really increase the flexibility around the conduct of the current trials, as well as help speed the initiation of any new clinical trials. That's nothing to do with any emerging data with respect to those two programs.

Cory Kasimov - *JPMorgan - Analyst*

Okay. And then the second question I have is I'm curious about the difference between ruxolitinib and 110 or, I guess, itacitinib I think it's called now in treating GVHD. Curious why one is specifically geared towards steroid refractory patients and the other targeting treatment-naive patients. Is there something particular about the two molecules that leads you in this direction? Thanks.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

So, Cory, I will start off, and Reid may want to add something about the biology. But '39110 which is now called itacitinib is -- if you take rux as your reference for JAK1/2 and use a 1-1 ratio there, then '39110, itacitinib now, is about 20-fold more selective for JAK1. So there was always a feeling, at least theoretically, that because of its potential to be more sparing in terms of cell counts, that it may have a different utility in certain settings.

If you look at our data set from our proof of concept study that we presented at the American Society of Hematology at the end of 2016, you'll see that, in fact, in the steroid-naive acute setting, itacitinib, had an 83% response rate. In the latter steroid refractory chronic setting, it was 63%. And so we feel that data is supportive of doing steroid-naive acute development, which is where we are heading with the compound, which is an area, by the way, where you may want to be more sparing given that people have just received transplants and may have more trouble in terms of cytopenias. So that's all I will say about why we are headed that way.

Cory Kasimov - *JPMorgan - Analyst*

All right. Thank you.

Operator

Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs - Analyst*

So, firstly, with regard to the 2016 results, we see 28% growth in patients on drug, but only 30% revenue growth. So does this mean that you are netting 2% of price increases?

And then on the SG&A expense side, your 4Q run rate is about $24 million above the top end of your 2017 guidance. So were there any one-time items in 4Q that should not recur in 2017, or what do those trends suggest?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Salveen, it's Barry. Just to clarify, I will take the first part of your question, and I guess Dave will take the next part of your question is, first of all, it is 42% net sales growth full-year 2016 over 2015.

And then what you are referring to as 28% is just new patient growth on Jakafi, and it doesn't necessarily correlate directly with net product revenue because patients get fewer or greater number of bottles in a given quarter as they come on. And then you have the effect of inventory and burning off of inventory from one quarter to the next quarter.

David Gryska - *Incyte Corporation - EVP and CFO*

Salveen, it's Dave. I will take your second question on the SG&A expense. The reason it is slightly higher in Q4 is just an artifact of timing between Q3 and Q4. So that was just a timing issue, and on a go forward basis, if we look into 2017, we wouldn't expect to see that kind of a difference between Q3 and Q4.

Salveen Richter - *Goldman Sachs - Analyst*

And then just on the pipeline, you have previously suggested that your Phase 3 go forward decisions with Merck were in part due to the Phase 2 starting first. So when should we expect data from the other three partnerships to be sufficient? Decide on next steps?

And then essential thrombocytopenia, I think in the past you opted not to move forward with this program. So what has changed on this front?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Salveen, hi. It's Steven. In terms of the collaboration, you are absolutely right. It's an effective timing. So the Merck collaboration with IDO, the ECHO-202 program, was first to begin, and that's why that data set matured first.

The other data sets across the other collaborations are, as we have always said, maturing as we speak. So, over the next weeks and months, those will come in. We will be looking at them and making further decisions there.

So you are right. It's just an operational timing issue, but those are coming in.

Essential thrombocythemia, it was around what to do in terms of the endpoint. So the first-line treatment is commonly hydroxyurea. There is an FDA approved drug for second-line treatment, anagrelide, which can lower platelet counts. The data set that I quoted earlier with ruxolitinib in essential thrombocythemia patients shows that we can both lower platelets, lower white blood cell counts, and resolve splenomegaly when it is present.

So the ability to use those as a regulatory endpoint in a setting that is post hydroxyurea is where we are interested now. And it was just an evolution in terms of the understanding of our own data set and the opportunity with regulators to design the correct study.

Salveen Richter - *Goldman Sachs - Analyst*

Thanks, guys.

Operator

Ian Somaiya, BMO Capital.

Ian Somaiya - *BMO Capital Markets - Analyst*

Thanks. Maybe just wanted to get a couple of clarifications. So, on the decision to move forward with the IDO/pembro combo in the four different tumor types, just wanted to clarify that doesn't limit it to four Phase 3 studies? That you could run multiple studies -- multiple Phase 3 trials in a given tumor type?

And separately, just wanted to ask if the decision a evaluate pembro/IDO/chemo combo, would that need to be preceded by Phase 1/2 data, or do you feel like you have learned enough to maybe sort of -- maybe a little bit of leap faith, but move that into pivotal trials as well?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Ian, hi. It's Steven. Thank you. So you are absolutely correct. In terms of the histologies, they stand on their own, but there are opportunities to do different settings. So, for example, a first-line setting, a second-line setting, and then as you alluded to in the second part of your question, with or without chemotherapy combinations.

And then the nuances. For example, in some cancers, people can't receive chemotherapy first line for various reasons, either age or tolerability. So you are absolutely correct. This is not limited to a finite number of Phase 3 studies in any histology.

In terms of chemotherapy combinations, it is safety that needs to enable it as you alluded to. We do have and are about to open studies looking at combinations of the triplets, PD-1 and IDO1 inhibitor plus chemotherapy. But there is also the opportunity to potentially do safety run-ins within either Phase 2 or Phase 3 studies and will satisfy either regulatory requirements or IRB requirements to get the safety data you need to enable a chemotherapy combination. And we will explore both in terms of the most efficient way to get the data we need and then obviously safety first in making sure these combinations are safe.

Ian Somaiya - *BMO Capital Markets - Analyst*

Should we assume then that the potential chemo combos would start a little bit later so they potentially might not be in 2017? And then just a separate question, if I just can ask. On baricitinib, I thought the opt-in decisions were contingent on Phase 2 data? Have you seen the atopic dermatitis Phase 2 data for baricitinib already?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

So just, again, your first question -- it's Steven again -- I don't think it's gated particularly to time because you can start the Phase 3 with a safety run-in, and the required number of patients may not be large. So you could end up doing 10 to 20 patients worth of data and not incur a tremendous time hit. So I don't feel that the case would mean any substantial delay.

The opt-in decisions are something we work carefully with obviously with Eli Lilly. The one that is absolutely going forward currently is the psoriatic arthritis one. We have communicated that we are opting in to atopic dermatitis and in axial spondyloarthritis, but we have yet to go through in detail those data packages with Lilly.

Ian Somaiya - *BMO Capital Markets - Analyst*

Okay. Thank you.

Operator

Geoff Meacham, Barclays.

Geoff Meacham - *Barclays - Analyst*

I had a few quick ones for Reid and then a follow-up. Just want to get some perspective on epacadostat in breast or ovarian cancer. Should we interpret your Phase 3 as evidence that IDO value is more correlated to the PD-L1, PD-1 access, and what does the science tell you about whether other mechanisms like arginase synthesis can turn cold tumors hot?

Reid Huber - *Incyte Corporation - EVP and Chief Scientific Officer*

Yes, Geoff. This is Reid. Thanks for the question. I think we're obviously learning in real time with epacadostat as the data from the ECHO program comes in. But, as you alluded to, the fact that we have go forward decisions now and data to support those in melanoma, renal cell, head and neck, lung and bladder, those would all be classified as the inflamed tumor types, those with a resident T-cell population, and ones which are generally responsive even to single agent PD-1. The lack of activity thus far in triple-negative breast and ovarian cancer would be consistent again with IDO being active there.

Love to see how the data comes in for the other tumor types, but that is certainly where we are leaning and what the data supports.

In terms of arginase, it is a completely different mechanism targeting the myeloid cell population. Could be subject to very different rules in terms of which patients are more likely to respond, and that is something that will be studied very carefully in the Phase 1/2 development program for '1158.

Geoff Meacham - *Barclays - Analyst*

Okay. That's helpful. And then bigger picture question for Herve or Dave. So when I look at you guys' pipeline, obviously a lot going on in oncology with partnered and wholly-owned programs. I guess the question is, how do you think about capacity constraints, either, say, capital or personnel as more and more programs move from proof of concept to Phase 3? Thanks.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Herve here. I can start. And maybe in terms of capital, we are really managing the P&L in a way where we are careful that we are allocating resources to the programs that we believe are the most promising. So that is the first discipline, and it is really applied to every program that we have. You can see from the numbers that we are cash flow positive. We have a cash position at the end of Q4 that was around $800 million. So we are in a position where we can do in parallel epacadostat Phase 3, and as we discussed, some of this Phase 3 will be -- could be cofounded by some of the partners we are working with. And at the same time, the baricitinib opt-in, which is financially relatively significant, but we believe it is an excellent investment for the Corporation.

The rest of the portfolio, assuming some of these products are going to move forward into later stage and Phase 3 studies, we believe at this stage that from the capital standpoint, we can afford that.

From the personnel standpoint, obviously the baricitinib programs are -- we are not dedicating any headcount to these programs. They are all conducted by Lilly. As we discussed with epacadostat, some of these programs hopefully will be done with a partner involved, which could also help from that standpoint.

And for the rest, we have become over the past few years, a company that is attracting some of the top talent in the industry. We are increasing our capabilities in clinical research across Europe thanks to the acquisition of the ARIAD Europe team. We have a medical team in place on top of

the existing medical team we were building in Geneva over the past few years. And in the US, we have a team now that is fully flexed and is really operating at capacity. There is no overwhelming situation yet, as we are growing in parallel with the portfolio.

Obviously in Japan, we have not yet established our own team there. It is something that I would like to do over the next few months in a progressive way. Nothing crazy, but where we would have the opportunity to do our own clinical development -- regulatory pharmaco activities in Japan, and that, from the financial standpoint will be, in fact, cost saving versus using CROs. So it's something that we would be replacing internal capabilities versus external CROs.

So, overall, we are managing the cash flow. That's really important. And we are looking at how to grow the teams as we need through the portfolio evolving. And, frankly, the past two years have shown that it can be done in parallel in a way that is pretty effective. So that's where we are.

It was a long answer, but it is a very important subject for me.

Geoff Meacham - *Barclays - Analyst*

Okay. Thank you.

Operator

Tony Butler, Guggenheim Securities.

Tony Butler - *Guggenheim Securities - Analyst*

A couple of questions. One for Reid. You made a comment about the Agenus agreement and it not changing based on OX40 or GITR. But I noticed an abstract at the AACR, which seems to be quite interesting utilizing epacadostat plus OX40 and GITR, suggesting that OX40 GITR potentiate epacadostat. So I'm curious if you might want to -- or if you can -- spend a minute just discussing that? Does it require both and, therefore, not either to potentiate epacadostat?

And then a question around the paired biopsies. Do you actually have data and a biopsy post-dose that illustrates a clonal T cell to the tumor? Can you actually comment around that?

Then finally, can you give us the average dose of MF and PV currently? Thanks very much.

Reid Huber - *Incyte Corporation - EVP and Chief Scientific Officer*

Hi, Tony. This is Reid. I will take your first two questions, and then I will turn it over to Barry.

In terms of the AACR abstract, obviously we will have to wait until those data are presented to discuss them in more detail. But suffice it to say, that as two costimulatory receptors that can have activity at the level of a T cell, it is an interesting scientific concept to be able to use OX40 and GITR agonism in concert with checkpoint blockade such as PD-1 or PD-L1 inhibition or with IDO1 inhibition. And so there has been an area of active research that we have had over the past year, and we're excited to be able to share those data.

In terms of the other question, on paired biopsies, this is an active effort of research in our translational sciences and Steven's clinical group. We now have trials ongoing that we call platform trials where the PD-1 antagonist is dosed either with JAK1 or PI3 kinase delta inhibition, and similarly all oral doublets on the backbone of JAK1 inhibition to study exactly what you alluded to, which were paired biopsies where the on-treatment biopsy is really designed to tell us how we may be affecting the quality and the quantity of the immune cell infiltrate. So these are clinical studies and translational studies that are ongoing as we speak.

Barry?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

So, Tony, I think you asked the average dose in MF and PV. So, for the entire brand, the average dose is 10 mg. The average bottles that we ship is 10 milligrams. It's about 60% of the bottles shipped. That is mostly because of PV. MF patients on average, it is more than 10 milligrams BIP. But that's -- for the brand, it is 10 milligrams BIP.

Tony Butler - *Guggenheim Securities - Analyst*

Thank you.

Operator

Eric Schmidt, Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Couple of big picture questions maybe for Herve. Could you characterize Bristol, AstraZeneca, and Roche's current interest in moving forward with epacadostat? I think in the past you said that Roche might be a little less interested than the others.

And then I have noticed you've got a lot more going on in dermatology, both topical and systemic than you have in the past. Is Incyte ready to commit to dermatology as a new focused indication of interest? Thanks.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Okay. No, I think as we've said, the sequence of available data is different for each of the partners. So, if you assume that the viability of data is raising their excitement about the potential of the combination, it is also coming with time and depending on when the data is available. So I would not characterize any their interest as being different.

It's true that with Genentech Roche, we started a little bit later with a narrower program. So that's the only thing I would say related to that. But there is certainly a lot of interest, as you know, in the target and in -- certainly also in working with us for some of these programs.

Regarding dermatology, I must say, there is no strategic great vision about moving Incyte into dermatology. As we've said multiple times, we are -- the products are leading us in different therapeutic areas. It is not really us trying to drive them into one place or another. It just happens that obviously with JAK inhibition, we have a number of indications in dermatology. The Lilly programs would be done independently by Lilly, and we are not involved more than the cofunding that we discussed and the ability to receive royalties or milestones.

On the topical side, we have decided now it was a little bit more than a year ago to go through the programs. If there's two programs, we established the right dose and find where it works, where it doesn't work. There are a number of indications now where we are doing some level of Phase 2 studies, and obviously we will see after that where we go with that. There is no decision that has been made yet.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

Liisa Bayko, JMP Securities.

Liisa Bayko - *JMP Securities - Analyst*

Hi. I was wondering if you could just expand a little bit more on the opportunity for Jakafi in ET? So you would be looking at -- it sounds like post hydroxyurea. Could you maybe quantify that patient population a little bit better and where you -- just trying to understand the opportunity?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

It is Steven Stein. So you are correct that the study is most likely to be in a post hydroxyurea setting and with the endpoints I discussed. What we do know at a very high level is that it is smaller than MF and PV in terms of the opportunity. Beyond that, it's hard to say anything more at this stage to you in terms of its size.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Fair enough. And then for capmatinib, can you please remind us of the economics that surround that for yourselves? I noticed that that will be reporting out Phase 3 data this year.

Herve Hoppenot - *Incyte Corporation - President and CEO*

So capmatinib is licensed to -- Herve here -- it is licensed to Novartis. It is basically -- the very traditional kind of deal where there are milestones which I don't think we have disclosed precisely and the royalties. And the royalties have been disclosed, and they are 12% to 14% depending on the cumulative sales barrier.

Liisa Bayko - *JMP Securities - Analyst*

Thank you.

Operator

Peter Lawson, SunTrust.

Peter Lawson - *SunTrust Robinson Humphrey - Analyst*

Question for David or Barry. Just around any timing issues or inventory burn or stocking we should think about for Jakafi for 1Q and anything around -- any color around the milestones for 2017 around the timing? If that was kind of back-half loaded?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Hi, Peter. It's Barry. Just trying to understand your question. So inventory in Q1, our inventory has been relatively consistent between 2.8 and 3 weeks of inventory on hand. I don't see any change in Q1 for inventory, but, of course, we do know that the gross to net is impacted by our ability for all-oral oncology drugs because of closing the doughnut hole. But inventory is not going to affect that.

David Gryska - *Incyte Corporation - EVP and CFO*

Hi, it's Dave. I will try to attempt to answer the question on the milestones. We announced today that, obviously with the approval of baricitinib in Europe, we will get a $65 million milestone. That will come through in Q1, and Lilly has stated on US approval once you look to that in terms of the Q2 timeframe. So it's safe to say that there will be at least a good amount of milestones in Q2. But Q1, there is just one so far in that, as a result of that, plus with the additional programs we talked about, collaborations between Agenus, Merus and Calithera, there will be a loss in Q1 because the milestones -- there won't be enough milestones to offset those one-time R&D costs. And after that in Q2, there will be substantial -- another substantial milestone and some smaller ones that carry in Q3 and Q4.

Operator

Ren Benjamin, Raymond James.

Ren Benjamin - *Raymond James & Associates, Inc. - Analyst*

Hi. Good morning, guys. Thanks for taking the questions and congratulations on the quarter.

Maybe the first question, can you give us any color or an update to the PD-1 inhibitor program and how you are thinking about that going forward and what the profile is that you have assessed so far?

And then the second question is just pertaining around baricitinib. Do you have any color regarding what the additional data that might have been submitted by Lilly to the FDA? And in a bigger picture sort of question, not focusing in on royalties per se, but thinking about your internal expectations for the growth ramp and how you are viewing sales coming in for baricitinib?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Hi, Ren. It is Steven Stein. I will address your first question and a little bit of your second, but Herve will take the backend piece.

In terms of our PD-1 program and the '1210 compound, we are this quarter looking through the data we gathered through dose escalation last year and completed and trying to understand the product's profile in terms of its PK, etc. We will point you towards the meeting we submit an abstract to and when we present it for any further detail on that. But we're in the midst of doing that exercise right now.

In terms of the baricitinib negotiations of the Food and Drug Administration and what is going on, I will just have to refer you to Lilly on that. But Lilly did say in their public remarks that they expect to get to a good point with the FDA sometime soon, and I will leave it at that.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Regarding the economics of baricitinib, obviously for us it's very important because -- so there's the milestone which we expect -- in fact, in what we described today, we expect that to reach us this year. And then there are royalties in the 20% to 29% range that will be coming over the next 10 plus years. So it's going to 2030 for the first patent expiration. So we look at it as a product that can become very significant for us over the years. We are very happy to see Lilly moving into a number of new indications where obviously -- and that's why we are also opting in for these programs because it will obviously grow the top-line potential and, therefore, the royalty potential for this product over the years.

In terms of calibration in each of these indications, frankly, we need to see the guidance from Lilly, and I would not comment more than what they have said about the fact that it is a very promising and very important product for patients with rheumatoid arthritis.

Ren Benjamin - *Raymond James & Associates, Inc. - Analyst*

Maybe just, Herve, if you don't mind a quick follow-up. How do you guys think about the Pfizer drug already being out there or a run rate established of about $1 billion and a quick second-to-market JAK inhibitor coming in? How are you guys thinking about that potentially?

Herve Hoppenot - *Incyte Corporation - President and CEO*

So the way we look at it is that we look at the US and that is what you are describing, and then we look at the rest of the world and they are fairly different situations there. In fact, the markets if you think of it that way for these type of products are not very homogenous worldwide. So you have to take that into account.

If you look at the profile of the product, what we think is that in the JAK1, JAK2 category, baricitinib is fairly unique. Xeljanz has a different profile, including the JAK3.

We also see in the US that there is an anti-TNF situation that is totally unique in the world, and it has a huge impact on the way these patients are treated. So all of that can lead to the right position for baricitinib. There will be fairly significant changes in this market over the next years with availability of different types of products on top of the existing ones.

So I really think there is a huge opportunity. The clinical profile that came out of the Phase 3 studies is really -- was really better than expected from a lot of standpoints, and we are -- I am personally very confident that there is a lot of room to make it a big success.

But don't think that the US picture is the same everywhere in the world. In fact, you see very different types of who is the market leader by country, and the potential to outsell the US on top of the US potential is certainly important also for baricitinib.

Ren Benjamin - *Raymond James & Associates, Inc. - Analyst*

Got it. Thank you.

Operator

Michael Schmidt, Leerink.

Michael Schmidt - *Leerink Partners - Analyst*

I guess one bigger picture question. You've been obviously very active in terms of augmenting your pipeline and discovery capabilities in the first quarter here with some BDand licensing agreements. What role do you expect BD to play going forward, in particular if you think about building out operations in Asia? Thank you.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Okay. Herve here, so. I think our priorities are our own internal discovery programs. So that is something that is the core of what we do at Incyte. So we are not in a mode of changing that in a way that would be dilutive in any way. We have protected that team very much in a way where the partnerships we did -- were in technologies that were different. So that was Agenus and Merus antibodies where we didn't have the internal capabilities. And what we plan is to continue to rely on our internal discovery capabilities and just complement them in the technologies where we are not pregnant.

Concerning Asia, frankly, when I look back at 2016, we can see a number of things that were very successful, including the approval of baricitinib just yesterday, which is the second product from Incyte being approved after ruxolitinib. So it tells you something about our discovery capabilities. But when I look back, there's one thing that has been also very successful is the expansion in Europe through the acquisition of the ARIAD team, and it was done in a very economically reasonable way for us. So we are -- we would love to have a similar situation in Asia. We have not found it yet.

So what we're doing now is starting the planning again in a careful way where we would be establishing a team in Japan to start with to take care of the pipeline -- the late-stage pipeline and make sure that we are putting that on a ramp to approval in Japan. If there were an opportunity to do it through a small transaction, I wouldn't be against it, but we have not found that yet.

Michael Schmidt - *Leerink Partners - Analyst*

Hey. Great. Thanks and congrats on all the progress.

Operator

Ladies and gentlemen, that was our final question. I will now turn the conference back over to Mr. Herve Hoppenot for closing remarks. Thank you.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thank you for the time today and for your questions. And as I said, I look back at 2016 in a way -- with a lot of pride because we spoke about the geography. I think baricitinib moving forward is an important milestone. We are a company that has discovered two new products that have been approved by health authorities, and obviously the fact that we, for the first time, crossed the revenue line of $1 billion is also symbolically an important milestone.

So we look forward to seeing some of you at the coming investor and medical conferences. And for now, I will thank you again for your participation in the call today. Thank you, bye-bye, and happy Valentine's Day.

Operator

Thank you. This concludes today's call. All parties may disconnect. Have a good day.
