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INCY - Q3 2014 Incyte Corp Earnings Call

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PRESENTATION

Operator

Greetings and welcome to the Incyte Corporation Third Quarter Financial Results Conference Call.

(Operator Instructions)

It is now my pleasure to introduce your host, Pamela Murphy, VP, Investor Relations and Corporate Communications. Thank you. You may begin.

Pamela Murphy - *Incyte Corporation - VP of IR and Corporate Communications*

Good morning and welcome to Incyte's Third Quarter 2014 Conference Call. Herve Hoppenot, our President and CEO, will begin with a few words summarizing the quarter and Jim Daly, who leads our commercial organization, will provide details on Jakafi's strong momentum. Rich Levy, who is in charge of Incyte's drug development activities, will update you on our clinical portfolio and Dave Hastings, our CFO, will describe our third quarter financial results.

Then we'll open up the call for Q&A, for which we'll joined by Reid Huber, who leads discovery. Before beginning, we'd like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for the commercialization of Jakafi and our development plans for Jakafi and other indications and for other compounds in our pipeline, as well as our expectations for our net product revenue, R&D expense, and SG&A expense.

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 June 30, 2014 and from time to time in our other SEC documents. Herve?

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thank you, Pam, and good morning, everyone. Let me begin by speaking about our CFO transition that was just announced a few days ago. It is a transition that has been planned and organized over the past several months and I want to start by thanking Dave Hastings, who will be leaving Incyte at the end of November, for all of his contributions to our successes over the years.

I'm sure I speak for all within the Company, and many outside of it, when I say that he has played an integral role driving Incyte from an early-stage drug discovery company to one that has successfully commercialized its first product. We wish Dave all the best and also thank him for agreeing to remain at Incyte until the end of [next month] (corrected by company after the call) to ensure a seamless transition with David Gryska, who will be joining us tomorrow.

The overlap between the two of them should prevent any issues associated with the transition. Moving now to the results of the third quarter, the performance of Jakafi in Q3 surpassed our expectation and leads us to raise our full-year guidance for Jakafi net product revenues. We are making significant investments in the long-term success of both of our development pipeline and our drug discovery engine.

We are also ready, pending the anticipated approval from the FDA, to launch ruxolitinib in the US for the treatment of patients with polycythemia vera who have had an inadequate response or are intolerant to hydroxyurea. We believe that our pipeline of potential cancer therapies is unparalleled in a company of our size and we continue to move forward on many fronts.

We are recruiting patients into a series of studies investigating the potential of both ruxolitinib and our JAK1 inhibitor, '39110, as well as initiating a combination study of our IDO1 inhibitor with other immuno-oncology agents. We are also looking forward to the results from Lilly of four Phase III trials of baricitinib in rheumatoid arthritis. I will now pass to Jim, who will provide some additional details around our commercial accomplishments with Jakafi.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Thank you, Herve, and good morning, everyone. Our third quarter net product revenues of $98 million for Jakafi reflect continued strong growth in underlying demand in intermediate or high risk myelofibrosis. Year-over-year net sales grew 63% and quarter-over-quarter sales grew 16% with the following components of change relative to the prior quarter.

Underlying demand, as measured by bottles dispensed to patients, grew by 11%. The net price impact for the quarter was 1%, driven by a slight improvement in gross to net. 4 points came from inventory, or an increase of approximately $4 million. We believe this was driven by speculative buying from a few wholesalers at the end of the quarter, in anticipation of our October 1 price increase.

Inventory in the channel ended the quarter in the middle of the normal range of 3 to 3.5 weeks.

As a result of current performance trends, we've increased our 2014 full-year net product revenue guidance from the previous range of $330 million to $340 million to an updated range of $350 million to $360 million. Our guidance assumes no meaningful contribution to revenues in 2014 from a potential FDA approval of Jakafi in PV.

We believe the strong increase in underlying demand in third quarter reflects the continued effective execution of our strategy to grow Jakafi in MF, bolstered by the expansion of our sales force early in the year and the FDA approval of the label update in late July. The sales force expansion has resulted in a significant increase in promotional activity and educational programs, as compared to the same period last year.

According to our market research, the label update, which contains updated safety and dosing information, as well as the Kaplan-Meier curves from COMFORT-I and COMFORT-II, has already resulted in an increase in awareness and impact of the survival data on physician behavior. Overall, we remain convinced that MF is a source of sustainable long-term growth for Jakafi.

Turning to our next potential new indication, we are fully prepared to launch Jakafi in polycythemia vera, pending expected FDA approval. Based upon claims data, there are at least 100,000 patients in the US diagnosed and treated for PV. Our addressable population will be those who are intolerant of or have had an inadequate response to hydroxyurea.

Our market research, corroborated by independent publications, indicates that there are at least 25,000 PV patients who meet these criteria, or one in four. Based upon the results of the RESPONSE trial, we're confident in the ability of Jakafi to deliver consistent and durable hematocrit control that is superior to best available therapy. We look forward to a busy and productive ASH Conference in early December, which occurs immediately after the December 5 PDUFA date for our PV submission. With that, I'll turn it over to Rich.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Thanks, Jim. We have multiple trials ongoing across our portfolio in multiple indications and I'll now give you a short progress report on our key pipeline drivers. Our near-term focus remains on the FDA review of the ruxolitinib sNDA in advanced polycythemia vera. The FDA accepted our submission for priority review in August and assigned a PDUFA date of September 5.

Turning to Jakafi in solid tumors, the two global phase 3 JANUS studies evaluating the use of ruxolitinib, in combination with capecitabine, for the second line treatment of pancreatic cancer, continue to enroll patients and we expect top line results from these trials during 2016. Similarly, the randomized Phase II trials of ruxolitinib in non-small cell lung cancer, breast cancer, and colorectal cancer are all enrolling patients as planned.

We're also moving forward with Incyte '39110, our selective JAK1 inhibitor, on several fronts. We're enrolling the proof of concept Phase II trial of '39110 in patients with EGFR wild-type non-small cell lung cancer, in combination with docetaxel. In the next two or three months, we expect to open a second Phase II trial of '39110, in combination with erlotinib, in patients with EGFR-mutated non-small cell lung cancer.

We're also making good progress with '110 in combination with gemzar and abraxane. We've selected a dose of '110 that can be combined with gem/abraxane and are in the planning stages to potentially begin, in 2015, a fully-powered, randomized blinded controlled study in first line pancreatic cancer. We'll provide further information on this study when our plans are finalized and are ready to begin enrollment.

Lastly, we are also studying '110 with Incyte '40093, our PI3K delta inhibitor, in patients with B-lymphoid malignancies. JAK1 and PI3K delta inhibition are distinct mechanisms of action and they exhibit synergy in preclinical models of lymphoma. The combination study is ongoing and we'll look to present at a medical conference when the data are more mature.

Moving now to our IDO inhibitor '24360, recruitment into the trial of 24360 and Merck's anti-PD-1, pembrolizumab, in patients with non-small cell lung cancer is progressing. This is the KEYNOTE-037 trial and we expect to initiate dosing in three other studies of IDO plus either PD-1 inhibitors or PD-L1 inhibitors from Bristol-Myers, AstraZeneca, and Genentech within the next month.

And lastly, on baricitinib, the rheumatoid arthritis Phase III program being run by Lilly is ongoing and the core of the registration package is made up of four different Phase III studies. We understand the first trial to complete will be reported by Lilly via top line results press release in late 2014 or very early 2015. With that, I'll now turn the call over to Dave to give us the financial highlights for the quarter. Dave?

Dave Hastings - *Incyte Corporation - CFO*

Thanks, Rich. Good morning, everybody. Let's begin with Jakafi, for which we recorded $97.8 million of third quarter net product revenues and $12.1 million in product royalties from Novartis for sales of Jakavi outside the United States. Additionally, we recorded $88.2 million in contract revenue, including two milestones from Novartis: $25 million for the approval of Jakavi in Japan, and $60 million related to the reimbursement of Jakavi in Europe.

Our gross and net adjustment for product revenue recognized was approximately $10.6 million or 9.8% for the third quarter. We still expect that our full-year growth to net adjustment will range from 9% to 10%. Our cost of goods sold for the third quarter was immaterial as we continue to benefit from the fact that our starting finished goods inventory was previously expensed as R&D, prior to FDA approval.

In terms of operating expenses for the year, we expect that our R&D expense will be on the low end of our guidance of $350 million to $370 million and in terms of our SG&A expense, we expect to be on the high end of our guidance of $145 million to $155 million.

From a cash perspective, we ended the quarter with $532 million, which does not include the $60 million milestone payment that we expect to receive in Q4. Our cash position continues to benefit from increasing product, royalty, and milestone revenue which allows us to appropriately invest in our growing development pipeline.

Now on a personal note, as you know, this will be my last call as CFO of Incyte and I want to thank everyone who has supported me throughout the years; particularly, my team here, as well as you, of course, our analysts and investors. Personally, I've never been more confident about the future of Incyte to become one of the leading global oncology-focused companies in our industry. So with that operator, that concludes our formal remarks. Please open the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator instructions)

Thomas Wei of Jefferies.

Thomas Wei - *Jefferies & Company - Analyst*

Thanks. I had a Jakafi question and a '360 question. On Jakafi, I just wanted to understand a little bit more about the growth and underlying demand that you had talked about. Is that about -- do you think that's a new patient-driven phenomenon and is that just more within the current label? Is it earlier staged disease, off-label use in PV or is it an attrition/compliance thing?

On '360, just a reminder on any detail that you've shared on the size of each one of these dosing cohorts in the pembrolizumab study, and how long? Just a reminder of how long you think it might take to do each dosing cohort before we get into the dose expansion study?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Hi, Thomas, this is Jim. In terms of the underlying strength of the business, first, from a physician perspective, I think we're seeing both breadth and depth of prescribing. We're seeing physicians come on board prescribing Jakafi for the first time and we're also seeing greater depth of prescribing with existing prescribers. At a patient level, we're seeing strength in new patient starts and we're also seeing continued consistent improvement in persistency over time.

In terms of the primary driver, I really think the expanded sales force is hitting full stride right now. I think our sales force and our commercial team overall is executing at a very high level. I don't think we felt the full impact of the label update in third quarter. If you remember, the label was updated at the end of July. We had to train the sales force on how to properly communicate the new label information in August.

So I think we're just starting to feel the impact of the label update. I think the strength in third quarter was primarily due to the expansion in our sales force. It takes time once to realigned territories to manage disruption, to get new people trained, but I think they really hit full stride in third quarter.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Hi, Thomas, it's Rich. So on the IDO plus pembrolizumab question, we're using three plus three standard designs for dose escalation, starting at the 25 milligram bid dose and working up from there. The observation period for DLTs is six weeks and then if there is one DLT within that group, then after that finishes out, then we would need to add another one. So we're estimating nine weeks per cohort.

That could either be -- nine weeks per cohort that doesn't need to get expanded and potentially another nine weeks if it does. We are not planning to try to get up to doses of 300 milligrams, for example. We think that 25 milligram bid is a dose that is likely going to be effective and we're just trying to see whether we can get a little bit more.

But until we really have a better sense of how many dose escalations there are and whether there needs to be expansion of cohorts, it's really hard to know exactly when we would then go into the randomized phase of that study, comparing our IDO inhibitor plus the PD1 inhibitor versus the PD1 alone in patients with non-small cell lung cancer. And while there are minor differences between the studies in terms of the first part, they're quite similar.

Operator

Liisa Bayko, JMP Securities.

Liisa Bayko - *JMP Securities - Analyst*

Hi, thanks for taking my question. Can you first talk about Japan market size and economics? I know you've just recently gotten approval there.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Herve speaking here. Ruxolitinib (inaudible) for Japan with Novartis. We know the approval and reimbursement is now achieved and frankly, I don't want to comment on the size and the potential size of that market for Novartis. In a big picture view of what's happening with ruxolitinib outside of the US is that there are a number of countries where recently, like Japan, reimbursement has been obtained.

And we are anticipating that the growth of the ruxolitinib/Jakavi business outside of the US will continue to be very dynamic over the next years. But I would not comment specifically about the size of the market in Japan.

Liisa Bayko - *JMP Securities - Analyst*

Even patient numbers?

Herve Hoppenot - *Incyte Corporation - President and CEO*

No, no.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Just turning to PV, can you just update us on what you're thinking about timing in terms of commercial launch? I know it's getting towards the end of the year when your PDUFA date is and market preparedness. Can you just elaborate on that a little bit?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Sure, Liisa. Our PDUFA is December 5. The timing could not be better as that is the kickoff to our ASH meeting. We are fully prepared, from a commercial perspective, to launch upon receipt of the approval.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Great. Can you maybe talk about any potential trials in your oncology portfolio that could report out data next year?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Yes. I would not set an expectation of any major disclosures in our oncology portfolio next year, but I won't close the door to the possibility that something could have better than expected results or that the results become clear to us earlier than we might have otherwise thought. So, I just would not guide either for a JAK program in solid tumors or for the IDO program also in solid tumors for any significant disclosures in 2015. I think 2016, on the other hand, will end up having a lot of information come out into the public domain.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Great. Maybe one question for Rich, when you think about 110 and the PI3 kinase combo, where do you see that fitting in the world where you have ibrutinib and idelalisib? Where could you have an advantage from a physician perspective? Thanks.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Yes, I'll ask Reid to get more into the science, if that is important here, but there clearly are resistance patterns with both PI3K Delta's as well as BTK inhibitors like ibrutinib that suggest that JAK inhibition could reverse, in some of those patients, the innovation, which also leaves the possibility that you may develop resistance less quickly if you are using both drugs on board at the same time and that's kind of the hypothesis that we're working on. Reid, I don't know if you want to add anything to that.

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

Yes, I would just say that there are some B-lymphoid malignancies where ibrutinib and idelalisib have not been as important or as transformational as they have, for instance, in CLL. I'll give you one example of this is diffuse large B-cell lymphoma where we've spent quite a bit of time studying the interaction between the PI3K-delta and JAK STAT pathways. So it's biology like that and clinical opportunities such as that one that really underpin the basis for the combination study. We'll be studying those patients as part of the expansion cohort once we get there.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Great. Thank you very much for taking my questions.

Operator

Matt Roden, UBS.

Matt Roden - *UBS - Analyst*

I just want to say Dave, you'll be missed. You're awesome and good luck with everything in the future. Really impressive Jakafi performance, I just wanted to get a little bit more into the number there. Can you talk about whether or not the data at ASCO in PV and pancreatic may have driven any sort of prescriber-initiated spontaneous adoption in those settings and to what extent you're seeing that there?

On the inventory side, you mentioned you are still in the normal range of inventory. Jim, should we expect that as the product is growing that inventory is going to continue to contribute to sales growth, just in a sort of keeping up with the increasing level of demand? Is that the way we should be thinking about that? Thanks.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Thanks Matt. First non-MF use has been relatively consistent throughout the year, so we did not see any significant increases in non-MF use as a result of the PV data presented at ASCO. Second on the inventory, we finished the quarter at about 3.3 weeks of inventory, which is a little higher than our typical inventory level. If you look at the quarter, net sales increased by $14 million, going from $84 million in the second quarter to $98 million in the third quarter.

Of that increase, about $4 million was inventory and that was driven, we believe, by some speculation on the part of some wholesalers. Now to your point, Matt, our inventory calculation is based upon most current sales, so as sales grow, you would expect each week of inventory to increase. So we do expect to be carrying slightly more inventory over time as our sales increases.

Matt Roden - *UBS - Analyst*

Okay. Great. Rich, I wanted to ask on baricitinib, can you confirm whether or not the Phase III for baricitinib that has Humira as a competitor, whether or not there is actually a test for superiority as a secondary end point there? Related or maybe unrelated is what level of Phase III activity in this first study that we're going to get would get you guys excited about the potential for this to be a more like a mainstream competitor in RA as opposed to a product that would be used after biologics? Thanks.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Sure. So the way the study that has Humira as one of the control arms works is that the primary endpoint is based on comparison to continued methotrexate alone and then there's a series of tests that get done before you actually do get to test for superiority versus Humira, including first testing for non-inferiority to Humira. So there is a pathway, which I have high expectations that will get to be tested without failing on something else first, but it's not certain to be tested, depending upon how that goes.

With respect to the first study, this is in a TNF inadequate responders, a population that we and Lilly did not specifically study in the JADA study that was reported out a couple of years ago, which is all inpatients who were TNF naive. We had a few patients in our first Phase IIa study which were TNF inadequate responders and they seemed to do as well. Additionally, with tofacitinib, they have clear data showing that they are superior to methotrexate alone in TNF IRs.

I don't want to put a number on it. I do think that one of the things we tend to look at in addition to things like ACR 20 results are this becoming more and more emphasis on the percentage of patients who go into a remission, which is typically defined by a DAS28 score less than 2.6 or 2.7. Those data have been something that, within the Phase II studies, baricitinib showed more impressive results than a number of other drugs, including tofacitinib.

So that's one of the things that I would tend to look at. But I do think that, to look at the ultimate success of baricitinib, it will include not just this first study, but the results across the board in early RA inpatients who are TNF naive and TNF experienced, as well as the comparative safety databases of the two programs.

Matt Roden - *UBS - Analyst*

Great. Thanks very much. Congrats on a great quarter.

Operator

Eric Schmidt, Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks. Just want to pass on my congratulations to Dave. Thanks for all the work over the years. For Jim, maybe on MF trends, it looks like you're at around a $400 million annualized run rate. You just posted 63% year-on-year growth. You noted that you still have a overall survival benefit, mostly on the comp. So is it time to start thinking that this market is quite a bit bigger than we've been thinking and if so, how big?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Well, Eric, I'll chunk your questions down into two parts. So Part A, is it time to be thinking that maybe there's greater upside in MF than we originally thought? I think the answer to that probably is yes. When we first looked at MF representing $0.5 billion, plus or minus, opportunity, that was two years ago. At the time, that seemed like an aspirational assessment. Based on the facts that you quoted, it now looks to be somewhat conservative.

What we'd like to do is get a couple of quarters of PV under our belt and then maybe come back to you with a more updated and informed view of the overall longer-term MPN commercial potential.

Eric Schmidt - *Cowen and Company - Analyst*

Okay, fair enough. Maybe a quick one for Rich on the approaching PDUFA date for PV. Is there anything surprising or remarkable that you'd want to tell us about your FDA discussions at this point?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

No, and I consider that to be good news. So it's going very smoothly. You never know until it is over, but we're pretty optimistic that things are going smoothly.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks a lot.

Operator

Brian Abrahams, Wells Fargo.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

Congrats on the quarter and my congrats and best of luck to Dave, as well. Just want to understand a little bit more about potential PV dynamics once you have label expansion. Jim have you had any initial interactions with payers around PV at this point? How should we be thinking about the pricing reimbursement process relative to MF? Also on the commercial side, I'm just wondering how well aware educated physicians are now, ahead of the PV launch?

Is the reason that you're seeing limited off-label use today really a reimbursement issue or is it the fact that you don't yet have the ability to really detail the data and inform the physicians?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

We have had extensive interactions with payers over this past year. Our account team has been engaging payers, educating them on the disease burden of PV. There was a payer meeting up in Boston a couple of weeks ago, the AMCP, and I had a chance to personally engage with a large number of payers. The feedback we're receiving is that they will most likely, what they call, PA it to the label, which means they will prior authorize PV to the language in the approved label and we're fine with that.

As we've stated numerous times, we see a large unmet need in the one out of four patients who are uncontrolled right now with hydroxyurea. In terms of the absence of off-label use, our sense is that is largely driven by reimbursement. There is a growing awareness by physicians of the sub-population of PV patients under their care, but until you have an approved product and more importantly, you have reimbursement, I think more and more these days, we're seeing a reluctance to prescribe.

So we anticipate that with approval and with relatively hassle-free reimbursement that we should see good uptake with the indication.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

Okay and then just one quick follow-up for Rich. I'm curious if there's other combinations of targeted therapies in solid tumors that you might be thinking about looking at with Jakafi or 110 in the future?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Yes, there are. We just need to decide whether we want to keep making additional investments before we get readouts on the number of trials. So I described to you, in addition to the two Phase III studies with Jakafi, we talked about a potential additional study with ['39110] in first-line pancreatic cancer for 2015. We have the three Phase IIs going. For 39110, we just described two non-small lung cancer studies, plus the study in combination with the delta inhibitor.

So clearly, there are other opportunities out there. We just need to make a decision as a company as to what is the trigger for starting some of these things. But, as a whole, I don't see the reason why targeted therapies wouldn't be just as good combinations where they exist as for other more classical chemotherapies. It just depends upon the opportunity.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

Thanks very much.

Operator

Part common sense.

Navdeep Singh - *Goldman Sachs - Analyst*

Congrats on the strong quarter. A quick question for Jim. Jim, what you think was the larger driver of Jakafi growth in Q3? Was it an increased penetration or was longer duration of use?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Nav, I think it's difficult to quantify. I hate to say that it was multifactorial, but I think we saw both contributing to the underlying demand. I think we had a very, very robust increase in new patients combined with a continued increase in persistency over time. I think both factors contributed meaningfully to the quarter.

Navdeep Singh - *Goldman Sachs - Analyst*

Jim just to follow-up to that, do you still think you're in the early innings of the MF launch or are we mid-innings or do you know where we are?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

We're seeing no indications of a slowdown, Nav. If you take a look at new patient starts month over month, we're not seeing any indications of slowdown. Now that the World Series is over, we may have to find a different analogy. Underlying growth continues to look very robust.

Navdeep Singh - *Goldman Sachs - Analyst*

Okay, that's helpful. Given the strong quarter and the strong go-forward commentary, your guidance for a Jakafi seems pretty conservative and requires only single-digit growth or low single-digit growth quarter-over-quarter to hit the bottom end of your guidance of $350 million to $360 million. Are you expecting any headwinds in Q4?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

No. We have very strong third quarter, but I think we make need to remain sober. We did have $4 million in inventory build that we have to burn. If you re-base the third quarter for that $4 million, the low end of guidance, $350 million, requires a 9% quarter-over-quarter growth. The high-end requires a 16% quarter-over-quarter growth. So we think that range, $350 million to $360 million is both ambitious and achievable.

Operator

Josh Schimmer, Piper Jaffray.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

My sentiments as well to Dave. It's been a pleasure working with you over the past many years.

Dave Hastings - *Incyte Corporation - CFO*

Thanks.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

One question for you, Dave, before we let you go, on the last call, you mentioned that on a fully diluted basis, we should expect a share count in the range of 205 million to 210 million. It looks like you've come in well below that. I'm wondering if you could help clarify what that represents and why the difference. Maybe just one more question to get them all in, as we think about the strategy with the PV launch, the revenue should probably reflect considerably next year.

How is the group thinking about managing the P&L? Is it going to be towards profitability and earnings growth or is it going to be more towards reinvestment in the R&D? When do you think should be making that transition to sustainable earnings positive trajectory? Thank you.

Dave Hastings - *Incyte Corporation - CFO*

On the EPS count, so the difference there, really, is the 2018 and 2020 notes, which, in this calculation, are anti-dilutive, Josh, because the add back to interest does not impact like the 2015 notes. So that's the difference between fully diluted that we're reporting and the fully diluted shares for the Company.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

Thank you.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Herve here. On the second question, I think you have to look at it, we agree with you. There is chance for a number of years of growing top line and the question becomes how do we allocate what we're spending. The way we think about it is based on two dimensions. One is to be prudent with our spending, so that we don't spend the money before we make it.

That's one aspect of the decision, but the certain one is to maximize the potential of our pipeline and to look at opportunities to obviously maximize the long-term of the organization. So you know from our development program, on the early stage, we are really maximizing the funding of the programs that are going to go into the clinic over the next few months and on the clinical stage, as Rich was describing, we have very important information on ruxolitinib in solid tumors in 2016 with the three Phase II studies and the two Phase III studies in pancreatic cancer.

We have the '39110 program that has been increased in size over the past few weeks and months and now has a number of important questions that are being asked. Obviously, depending on the results of this question, it will lead us to a fairly large program in Phase III or not. We have the IDO questions that have been also asked at this point that would lead us to potentially what could be a very significant Phase III program.

Frankly, that's the way that we look at it. The result on profitability will be coming out of these clinical results. If these clinical results are promising enough, we will invest in our own pipeline and maximize value over the long-term.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

Got it. Thank you.

Operator

Michael Schmidt, Leerink.

Michael Schmidt - *Leerink Swann - Analyst*

How does the Genentech acquisition of the new link IDO inhibitor affect your relationship with them for your program?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Sure. This is Rich. We're still going ahead with our planned study in combination of Genentech's PD-1 inhibitor and our IDO as planned and while I can't talk about the specifics of the collaboration agreement with them, we remain confident that the proposal protects our interest in doing the study.

Michael Schmidt - *Leerink Swann - Analyst*

Great. You mentioned in order to maximize the value for the IDO inhibitor, you're looking at immuno-oncology combinations more broadly. I was wondering, outside PD-1, PD-L1, whether you are looking at other potential combination partners at this point and what are your plans in that regard?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Yes. So we're not ready to talk specifically about any combinations, whether it be with our own internal products or with further collaborations. We do think that the PD-1 and PD-L1 are going to be and continue to be an important component of combinations here. We think that our focus this year on demonstrating the safety and activity in combination with PD-1s or PD-L1s is central to our strategy. Reid, did you want to add anything to that?

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

Yes, I would just say that we have a fairly robust internal effort to understand places where IDO inhibition can add value even beyond the PD-1, PD-L1. As Rich said, that's clearly the most important task at hand is to demonstrate that benefit first. Even beyond that, there are efforts to evaluate the drug in combination with internal assets in our pipeline. Of course, the immuno-oncology landscape's changing pretty dynamically quarter-over-quarter.

We now have immuno-agonists entering into the clinic, we have other antagonists. We have vaccines that are starting to emerge and have a place in the treatment landscape and even other therapies like bispecifics and CAR-T-cells. All of these things are on our radar screen and we'll be as thoughtful and opportunistic as we can going forward, but always based on what we think the science tells us to do.

Michael Schmidt - *Leerink Swann - Analyst*

Great, thanks. One more, can you remind me of the overlap in the PV and MF prescriber base?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Yes, it's a very high overlap. Today, we have a target audience of about 6,500 physicians for MF. We see that expanding to about 8,000 physicians for PV, so the overlap is very high.

Michael Schmidt - *Leerink Swann - Analyst*

Okay great. Thank you.

Operator

Salveen Richter, SunTrust.

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

Dave, firstly think congratulations on a great job at Incyte. It really has been a pleasure working with you.

Dave Hastings - *Incyte Corporation - CFO*

Thank you, Salveen.

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

With regards to the IDO, just wondering, any decisions on tumor choice that's going to be driven by upcoming data readouts like the liquid tumor data at ASH? When would we see data from the 75 milligram dose group in the study with Yervoy?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Yes. So, we are, with our partners, even though we have certain indications that are picked for different studies, we are actively in discussion with some of the collaborators about potentially adding in additional tumor types at some point. So we're constantly looking at the data and updating our plans. In terms of the additional data from the ipilimumab study, we do anticipate presenting this at an upcoming scientific meeting, but we're not at 100% sure at this point in time exactly which one that will be.

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

Great. Just in terms of the outlook for strategy for pipeline growth here, you've been focused on in-house R&D and from pipeline growth and just wondering what your strategy here going forward might be as you look at M&A and end licensing?

Herve Hoppenot - *Incyte Corporation - President and CEO*

You have to look at potential external growth as what it is adding to what we have. The reality of our current flow of products in the pipeline is that its very rich, both on the clinical side and the preclinical side. So the Plan A is to maximize our internal pipeline and that's really what we are working on. At the same time, and it's not OR, it's really AND, we are also looking at what would be complementary to what we have.

It's really a diligence obligation that we have and it could happen that something would be complementary and good enough to justify doing external growth. But I want to say, the internal pipeline as it is, when you develop it over the next five or 10 years it's really providing already a very good base plan for the corporation. So that's really the thinking. We want to maximize internally and we are looking -- because also looking around is giving us a lot of information on what's happening in the world of oncology and immuno-oncology.

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

Thanks, Herve.

Operator

Steve Byrne, Bank of America.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Does a reduction of tumor-induced inflammation with your anti-JAK strategy have any impact on expression levels of checkpoint inhibitors?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Reid, do you want to take that?

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

I don't think we have any data that really speaks to that. What we do know is that PD-L1 expression is governed by a host of cytokines, most importantly interferon gamma. So its expression level clearly is, at least in part, dictated by what that local immune environment is.

How JAK1, JAK2, which selective JAK1 inhibition may alter that is still an open question, I think, at this point, but it's probably a very complex question and much more complex than just interferon gamma and PD-L1 as the ultimate governors of inter-tumoral immunity or multi-factoral and JAK inhibition itself is a very pliotropic mechanism. This requires some pretty careful work and probably also will require some clinical translational studies to know for sure what governs these dynamics in man.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Reid, do you see other drugs in development that essentially affirm or potentially compete with this strategy of yours to address tumor-induced inflammation?

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

There have been efforts over the years, as you know, to study anti-inflammatory agents in cancer, probably most notably the anti-TNFs and even some work early on with anti-L6. Those studies were generally unremarkable in terms of the data they produced. They also were relatively unfocused in terms of the kinds of patients they enrolled, certainly categorizing patients in terms of inflammatory status, and focusing on specific histologies where perhaps this biology is most operative.

We know that Gilead is in the area. Of course, we follow their work very closely. We study their compound very closely. I don't think that's going to be the end of the entrants into the space if the data we have with RECAP are confirmed in the JANUS studies. If we see activity with ruxolitinib or

'110 in other solid tumors scenarios, I think that it's very likely to open up an entire new area of thinking about how to treat patients with oncology, with cancers in treating the host, as much as you're treating the tumor.

So we're kind of on a leading edge here. There is some competition, but if we're successful, we can be sure there's going to be other competition. We're committed to staying at the front edge of that space as long as we can.

Steve Byrne - *BofA Merrill Lynch - Analyst*

I have one quick one for Jim. With respect to ex-US market opportunity for Jakavi, it seems as if your revenue trends in Jakafi have really accelerated more so than the ex-US market. Do you see the ex-US opportunity to be meaningfully different than the US or do you just think it's going to be chunkier?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

I think chunkier or lumpier is what we're seeing right now, Steve. Given the rollout in various European markets, given some of the issues with, for instance, price accruals, inventory, I think they're simply more susceptible to one-offs, so I think you have to take a step back and look at the overall trend for rest of world and it remains very robust. Our Novartis colleagues, I think, are very sanguine on the long-term commercial upside in rest of world.

Herve Hoppenot - *Incyte Corporation - President and CEO*

It's a very traditional way of building the rest of the world business versus the US where it to go a little slower at the beginning, because reimbursement issues are sort of slowing down the ramp up and you see it in Europe. Then you have the rest of the world catching up like Japan recently. Overall, the way we see it is that it is potential that is at least as large as what we have in the US.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Thank you.

Operator

Ian Somaiya, Nomura.

Ian Somaiya - *Nomura Asset Management - Analyst*

I want to echo the sentiment on the call, David, you're going to be missed. We all hope to have an opportunity to work with you again.

Dave Hastings - *Incyte Corporation - CFO*

Thanks, Ian.

Ian Somaiya - *Nomura Asset Management - Analyst*

In terms of the questions I guess just maybe starting off with Bristol's data this morning, there's a study that they were guiding with nivolumab and every pre-treated events of squamous cell non-small cell lung patients that results were disappointing. I was wondering if you had any plans to evaluate that population in combo with IDO?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

I'm sorry, I had trouble hearing the question. I'm not certain what came out this morning. Are you saying that they had disappointing data where?

Ian Somaiya - *Nomura Asset Management - Analyst*

In heavily pretreated advanced squamous cell non-small cell lung cancer patients?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

We're certainly looking at non-small cell with a number of other companies, including BMS. With respect to the specific subpopulation of heavily treated squamous, I have no real comment. You know, I don't think we've had that level of specific discussion. But in general, where we tend to look at things is where there are imperfect data from monotherapy with the PD-1.

So you don't necessarily want to focus all of your efforts on someplace that's going to be hard to beat the results that they're seeing and we are continuing to do studies in melanoma, but that's an example of something where the response rates are quite high and the durability of either stable disease or responses are quite good. On the other hand we don't tend to focus on things where they show no activity at all, so we'd have to look at the specifics of this data set to determine whether that is an area that's kind of in the middle where the bump could help.

Ian Somaiya - *Nomura Asset Management - Analyst*

On the c-MET, I guess I was one of the other surprise data sets at the ASCO. Could you just remind us of your agreement with Novartis, some of the financial terms? And then whether the deal precludes you from, at some point in the future, pursuing your own product in the space?

Dave Hastings - *Incyte Corporation - CFO*

Yes we licensed globally the rights to Novartis, but we do have very healthy royalties, a tiered double-digit. So we're very pleased with our progress and pleased with the economics we have. Obviously, there's a separate milestone slate for c-MET as well.

Ian Somaiya - *Nomura Asset Management - Analyst*

Okay. Just a last question, maybe just following up on several questions that have been asked related to your strategy with IDO. At this point, are you able to say that the next potential combination will be with another checkpoint inhibitor versus potentially a cancer vaccine? Maybe as a follow-up, have you, from a business development standpoint, maybe evaluated a lot of the cancer vaccines that have been put to the wayside over the years, which potentially could benefit in combination with an IDO?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

We have nothing specific to announce at this point. I will say that there are some investigator-sponsored trials where we reached agreements in the past to look at a small number of vaccines. But vaccine technology and some of the approaches to vaccines have changed since some of those things were created. So there may be new opportunities there, but in terms of specifics, we don't have anything to share this time.

Ian Somaiya - *Nomura Asset Management - Analyst*

When will we see data from those efforts?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

The data on the combinations of the PD-1s and PD-L1s, as we said, our base case expectation would be sometime in 2016, not ruling out the possibility of seeing something in 2015. In terms of plans to do other combinations, we would probably not talk about them until we had a firm, specific announcement, either an agreement or a trial that was about to start.

Ian Somaiya - *Nomura Asset Management - Analyst*

I guess I was specifically asking about the investigator-sponsored studies you mentioned and whether they might be large or small in combination with the vaccines? When could we see data from those?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

I am not one to tends to make predictions about how fast the academic investigators will move with ISTs. A lot of times the most difficult step is actually going from the agreement to do a study to initiating them and those can take quite a bit of time. I think some, but not all of them, have actually started. Both because I don't really trust external numbers as well as my own and also, because I just haven't had those discussions lately, I just don't know.

Ian Somaiya - *Nomura Asset Management - Analyst*

Okay. That's fair enough. Thank you so much for your help.

Operator

Cory Kasimov, JPMorgan.

Cory Kasimov - *JPMorgan - Analyst*

Let me just add on top of all the other prior comments and say best of luck to you, Dave. It really has been great working with and you will be most definitely be missed.

Dave Hastings - *Incyte Corporation - CFO*

Thanks, Cory.

Cory Kasimov - *JPMorgan - Analyst*

Jim, I'm also interested in the really impressive Jakafi growth. I know there have already been a lot of questions on this call around demand and persistence and inventory and such, but I'm wondering if you are still also confident in the initial epidemiology around MF or are there also potentially more patients than you previously anticipated?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Cory, I think there could very well be more patients than we anticipated. All along, we viewed the addressable patient population as 15,000. That was based on our best epi work. When you don't have an effective treatment, there is a phenomenon where physicians will code patients as having something else, in this case, possibly MDS.

When you do have an effective treatment, you will see the diagnosis of myelofibrosis go up. So that phenomenon could very well be taking place, where when physicians are confident in a new tool, they actually look for opportunities to use it.

Cory Kasimov - *JPMorgan - Analyst*

Okay.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

We could be seeing that happen right now.

Cory Kasimov - *JPMorgan - Analyst*

Okay. For other Rich or Reid, I'm wondering how much visibility you have into the emerging competitive landscape for IDO inhibitors? How much do know about other molecules that are out there?

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

Cory, this is Reid. We take a pretty careful look at the patent landscape, as well as the scientific presentation landscape to stay on top of the competition for all of the programs. IDO is no different. We've certainly spent a lot of time carefully studying what's come up.

The NewLink program, for example, it's not appropriate for me, I don't think, to comment on any of the specifics around those data, but I will say that, based on everything that we know, we remain very confident in the emerging profile of '24360 and continue to feel that we have an opportunity here with this drug to not only have a first, but also a potentially best in class IDO1 inhibitor. We've learned nothing over the subsequent or the previous few months to change that view.

Cory Kasimov - *JPMorgan - Analyst*

Okay, great. Lastly, for Rich, on baricitinib, can you just lay out your expectations or views regarding the relative importance of the different Phase III studies in terms of their potential clinical impact.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Yes. So, what Lilly and we have done is devised a program that looks at all the different phases of rheumatoid arthritis treatment from early RA, where patients are being randomized to get either baricitinib alone, baricitinib plus methotrexate, or just methotrexate alone to two studies in the TNF naive but methotrexate or DMARD inadequate responders and then one in the TNF IR.

I think they're all important to the overall picture, but if I had to pick one, I would say that it is the study that goes head-to-head with Humira for a couple of reasons. One, that's also the structure study and we think that Lilly has learned from some of the mistakes that in retrospect that were made with the tofacitinib in terms of how to design that study, pick the appropriate population, et cetera.

That study, in itself, has the potential to both get a structure claim for them, as well as show possibly superiority to Humira, but I would be very surprised if it didn't show at least non-inferiority. It's also a study of over 1,200 patients, followed for the longest period of time and so whereas there's going to be over 3,000 patients in the safety database, this study will contribute more than 1/3 of those.

That one is the one that because it's a 52 week end point on structure will be one of the last ones to report out, but I think each one will add to the growing picture and the growing safety picture, as each one comes out over the course of late this year and in through next year.

Cory Kasimov - *JPMorgan - Analyst*

Okay, that's helpful, that's it for me. Appreciate you taking the questions.

Operator

And Chris Marai from Oppenheimer.

Chris Marai - *Oppenheimer & Co. - Analyst*

Congrats on a great quarter. Just regarding the PI3 kinase and JAK combination, I was wondering if you could comment on how you're looking at the potential toxicities, particularly liver tox. Also, if you're looking at any of the BTK inhibitors, any combination there. Maybe remind us when we'll see data from some of those combinations. Thanks.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

First of all, we recognize that the existing PI3K-deltas do have some degree of reversible liver toxicity, but the JAK inhibitors generally do not. At least, our Jack inhibitors generally do not. So in terms of combination of risk, I don't see that as enhanced of liver toxicity because you're using two drugs in combination.

In terms of other combinations, we have nothing to announce at this time, but we're always looking for opportunities to use our drugs not only in combination with things that we own, but we're, as you've seen, very amenable to doing collaborative studies with other companies. But again have nothing to add at this time. Reid, I don't know if you wanted to say anything.

Chris Marai - *Oppenheimer & Co. - Analyst*

Okay. Thanks for taking the questions.

Operator

Matt Roden, UBS.

Matt Roden - *UBS - Analyst*

I've gotten a number of incoming emails on this, just to clarify, if we could. Jim, to better understand your comments on squaring the inventory in the guidance and a couple of these moving parts. So if I look at the results here, you did $98 million. The normal range of inventory should be about, according to my calculations here, $22.5 million to $26.5 million.

You say you're at about 3.3 weeks inventory now and then you said that you might have to burn off as much as $4 million of inventory in the fourth quarter. I'm just trying to square that because it looks to me like you might be at about $24.5 million or so. I only see really $2 million down to the bottom end of the normal range. As you think about guiding, is there a reason to think that you're going to go down to the lower end of normal for inventory into fourth quarter?

Because I see that you took price at the end of the third quarter. So that's behind us. Maybe there was buying ahead of the price increase?

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Yes, Matt, your estimate of what our baseline inventory is, is a little low. Probably a good estimate of our baseline inventory is about $28 million. I think you really need to look at the $4 million as being a real incremental inventory build that we will have to burn off over the course of the quarter. Now you raise a fair point which is should we anticipate an inventory build at the end of the fourth quarter?

Matt, that is a reasonable assumption. I think a reasonable assumption would be an absolute inventory build comparable to the one we saw at the end of last year, which was about $4 million. Now that is something that is highly variable. You never know what your distributors of going to do on the last day of the year.

Matt Roden - *UBS - Analyst*

Okay, great.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

So we cannot give you specific guidance as to what will happen with inventory at the end of the year.

Matt Roden - *UBS - Analyst*

But you would think that it would probably stay within the range, which is a relatively tight range.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Yes, we would expect it to stay within the range of 3 to 3.5 weeks.

Matt Roden - *UBS - Analyst*

Okay, great. Thanks for clarifying.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Sure.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Really, it's important to keep in mind that the success of Q3 is really driven by demand and volume growth, which is sort of building the stage for the future of the brand in the myelofibrosis. That's really what the --

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

I would underscore that. If you negate inventory, underlying demand grew at 12%. Generally, the third quarter, as you all know, tends to be a soft quarter. So we're very pleased with 12% underlying demand growth and that's quarter-over-quarter in the third quarter and we think it bodes very well for the fourth quarter.

Pamela Murphy - *Incyte Corporation - VP of IR and Corporate Communications*

Okay. So I think we'll turn the call now over to Herve.

Herve Hoppenot - *Incyte Corporation - President and CEO*

With that, we'll thank you again for your time on the call today and we look forward to talking to you again at our fourth quarter conference call in February. Thank you to all who are attending today.

Operator

Thank you. Ladies and gentlemen, this concludes today's program. You may disconnect your lines this time. Thank you all for your participation.