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INCY - Q2 2013 Incyte Corporation Earnings Conference Call

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INCY reported 2Q13 results.

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PRESENTATION

Operator

Greetings, ladies and gentlemen, and welcome to the Incyte Corporation's second-quarter 2013 earnings call. A brief question-and-answer session will follow the formal presentation.

(Operator Instructions)

As a reminder this conference is being recorded. It is now my pleasure to introduce your host Ms. Pamela Murphy, Vice President Investor Relations, Communications. Thank you, Ms. Murphy may begin.

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

Good morning and welcome to Incyte's second-quarter 2013 conference call. On the call today are Paul Friedman, Incyte's President and Chief Executive Officer; Jim Daly, Executive Vice President and Chief Commercial Officer; Dave Hastings, Executive Vice President and Chief Financial Officer; and Rich Levy, Executive Vice President, Chief Drug Development and Medical Officer. Paul will begin with an overview of the quarter and highlight progress made in our lead clinical programs, Jim will follow with an update of our ongoing commercialization of Jakafi and Dave will describe our second-quarter financial results. Paul will then open up the call for Q&A.

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Before beginning we'd like to remind you that some of the statements made during the call today are forward-looking standards, including statements regarding our expectations for the commercialization of Jakafi, our development programs for Jakafi and other indications as well as other compounds in our pipeline and our revised 2013 financial guidance. 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 March 31, 2013 and from time to time in our SEC documents. Paul?

Paul Friedman - *Incyte Corporation - President and CEO*

Good morning, everyone. It's been a productive quarter on a number of fronts, commercially, clinically and financially. Commercially Jakafi continued to experience solid growth, and in fact as Jim is going to describe in his remarks, we've increased our 2013 guidance for net product revenues. Clinically, important new data presented in the second quarter showed that Jakafi improved overall survival in myelofibrosis patients. And the data also advanced our scientific understanding of how JAK inhibition may impact a basic aspect of the disease. And we're in a strong financial position, which Dave will address in his remarks.

I'm going to start with the overall survival data presented at the European Hematology Association Meeting. Three-year data from the COMFORT-II trial showed the treatment with Jakafi not only led to sustained reduction in spleen volume, but also provided a 52% reduction in the risk of death relative to patients treated with best available therapy. This survival benefit for patients randomized to Jakafi is particularly noteworthy given that all patients randomized to best available therapy had crossed over to receive Jakafi by week 48. The benefit observed underscores the importance of treating earlier with Jakafi and we expect this information to further encourage physicians to prescribe Jakafi for their intermediate or high-risk MF patients and to do so earlier in the course of this progressive disease.

Regarding COMFORT-I, last year at ASH we showed that with two years of follow-up, Jakafi continued to be associated with the survival advantage over placebo. At that time there were 27 deaths in the group treated with Jakafi and 41 in the placebo group. This translates to a hazard ratio of 0.58. We look forward to sharing the three-year data in December at ASH. At EHA and ASCO results from an exploratory analysis of long-term exposure to Jakafi were presented which showed that in the majority of patients with MF, bone marrow fibrosis stabilized or reversed after 24 and 48 months of Jakafi treatment. This was not observed in separate database analysis of patients treated with hydroxyurea or with other therapies. Bone marrow fibrosis is a hallmark of underlying disease in MF, and these data suggest that Jakafi may have the additional effect of slowing or reversing bone marrow fibrosis.

In June, we announced that the FDA added new safety information to the Jakafi product label which put the reported case of progressive multifocal leukoencephalopathy in the appropriate context by placing it in the warnings and precautions in patient counseling information sections. Within this label update and as a result of the FDA's review of our sNDA for expanding dosing guidance, we now have specific recommendations on the starting dose and dose titration for patients with low platelet counts. We believe this guidance will help physicians titrate to appropriate doses so that these patients are more likely to maintain therapy and obtain the long-term clinical benefits of treatment with Jakafi.

Beyond myelofibrosis, we're evaluating Jakafi in other indications and our most advanced program is in patients with polycythemia vera, or PV. Later stage PV patients manifest splenomegaly and/or the same symptom complex seen in patients with MF. This group of PV patients represents a significant unmet medical need for which there are currently no FDA approved medications. We expect results from the pivotal Phase III PV trial called RESPONSE early next year which would keep us on track to submit a supplemental NDA in the first half of '14. And as you'll hear from Jim, we're already actively preparing for this next launch which is a meaningful growth opportunity for Jakafi.

We also have development programs evaluating Jakafi in cancers outside of the myeloproliferative neoplasms including pancreatic cancer, a particularly difficult tumor characterized both by hyperactive JAK-STAT signaling within the tumor as well as by catabolic wasting or cachexia, two aspects of pancreatic cancer biology where Jakafi has the potential to intervene. The proof of concept trial RECAP is evaluating Jakafi in combination with capecitabine versus capecitabine alone in second line pancreatic cancer patients. Overall survival is the primary endpoint and the pre-specified number of events in the trial has been reached. We expect to have top line results available later this quarter.

An additional study exploring Jakafi in combination with chemotherapy has been initiated in patients with solid tumors and there are also investigator sponsored trials underway evaluating Jakafi in several other hematologic and oncologic indications. Our second JAK1, JAK2 inhibitor baricitinib

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continues to show impressive clinical results. Lilly recently presented one-year data from the Phase IIb rheumatoid arthritis study at EULAR which showed that the clinically significant improvements in the signs and symptoms of RA at 24 weeks were sustained through 52 weeks of treatment with no new safety issues observed. Based on the strong positive Phase II results and the robust Phase III clinical program currently ongoing, we believe baricitinib could offer advantages over existing RA therapies.

With the clear effects of Jakafi in myelofibrosis and baricitinib in rheumatoid arthritis, we've elected to also explore the effects of compounds that selectively inhibit JAK1. We have a broad portfolio of selective JAK1 inhibitors, and as we did with the JAK1, JAK2 program, we've moved two distinct JAK1 inhibitors into clinical development in order to pursue both oncology and inflammation indications.

We're currently studying our lead JAK1 inhibitor, INCB39110, in proof of concept trials in myelofibrosis, rheumatoid arthritis and in psoriasis, three diseases for which there is much information about the effects of dual JAK1, JAK2 inhibition. These studies provide us with the opportunity to characterize the clinical activity of JAK1 inhibition, understand potential points of differentiation versus JAK1, JAK2 inhibition and select the appropriate pathways for further development. We expect results from these studies in the second half of the year. The psoriasis data has already been accepted as an oral presentation at the European Academy of Dermatology and Venereology in October. And we've submitted an abstract of the RA data to ACR and plan to do the same with the MF data for ASH.

We've also initiated a study with 39110 in combination with chemotherapy to better understand how JAK inhibitors could be used in this setting and will then be able to compare the results with what we've seen with Jakafi in a similar patient group. Our second JAK1 inhibitor, INCB47986 is in Phase I clinical development and we look forward to describing our plans for that compound later this year.

Beyond our JAK programs, we have other compounds in development including our indoleamine dioxygenase, or IDO inhibitor, INCB24360. The results for this novel oral immunotherapy including Phase I data presented at ASCO have been encouraging. The compound has an immune enhancing mechanism distinct from those of other immunotherapies and has shown excellent tolerability as a single agent at doses that effectively inhibit IDO activity. The compound is currently in Phase II clinical development as monotherapy for ovarian cancer and in combination with ipilimumab for metastatic melanoma. Additionally, the Moffitt Cancer Center is initiating a Phase II trial in myelodysplastic syndrome.

The immunotherapy field is evolving rapidly with increased emphasis on combination therapy to further improve overall survival. Interesting potential combinations include the use of IDO inhibitors with antibodies that target PD-1 and PD-L1. These antibodies have shown positive results in combination with other immunotherapies, not only in melanoma but also in solid tumors. In addition to the pipeline compounds I've highlighted today, we have several early-stage compounds in inflammation and oncology that I look forward to describing in the future. And now I'll turn the call over to Jim Daly.

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

Thank you, Paul, and good morning, everyone. The successful advancement of the clinical programs highlighted by Paul represent the building blocks of a well diversified high-growth global immuno-oncology business. Now from a commercial perspective, the immediate job at hand is to build a bedrock foundation with Jakafi in MF. And our second-quarter results reflect continued solid progress in executing our strategy.

In terms of quarter-over-quarter growth, net sales grew 12% with the following components of growth. Underlying demand, as measured by bottles dispensed to patients, grew by 15%. Net price accounted for 1% of growth reflecting an improvement in our gross to net line relative to the first quarter. Inventory depletion reduced growth by 4%, and while lower, inventories at the end of the second quarter remained within the normal range of 3 to 3.5 weeks. Our second-quarter performance is consistent with our expectations for steady and consistent growth in dispensed bottles.

Based on what we're seeing in new prescriptions and persistency, we expect to see continued solid growth in the second half. As a result, we've increased our 2013 net product revenue guidance to the range of $220 million to $230 million, a change from the previous range of $210 million to $225 million. Through the second quarter, our breath and depth of prescribing continues to expand as evidenced by the fact that nearly half of our target prescribers have prescribed Jakafi at least once and about a third of those have written for two or more patients.

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Turning to persistency, we believe that the message that dosing should be individualized for each patient is changing physician behavior. We continue to see the increased use of lower dose strengths, both as a starting dose and in titrating as medically necessary. In the second quarter, 5 and 10 milligram strengths represented 46% of dispensed bottles versus 37% in the first half of last year and 41% in the second half of last year. Late in the second quarter, we received FDA approval of expanded dosing guidance for the treatment of patients with low platelet counts. We believe this new information will enable our sales representatives to reinforce the importance of individualizing the starting dose in these patients and appropriately modifying the dose, especially during the first 8 to 12 weeks of therapy.

Regarding Jakavi sales in Europe, the launch continues to do well and is exceeding Novartis' expectations. Because of some one-time events, the revenues were $33 million in the second quarter and $35 million in the first quarter. However, when you normalize for these one-time events in the second quarter, Jakavi continues to grow quarter over quarter. Novartis is also continuing to make steady progress with reimbursement approvals in Europe on a country-by-country basis. Our $60 million milestone payment is triggered by reimbursement approval in three out of the top five major European countries.

As previously reported, Jakavi reimbursement is approved in France and we expect Novartis to receive reimbursement in a second major country later this year. Therefore, we expect the milestone will be achieved in the first half of 2014, a change from our previous expectation of 2013. While national health authorities are considering reimbursement, access to Jakavi is available in most EU countries through various cancer funds or on an individual patient basis. As Novartis achieves additional national reimbursement over time, we expect steady growth in Jakavi revenue in Europe.

The product profile for Jakafi in MF has continued to evolve and expand since launch. The data on overall survival and bone marrow fibrosis that Paul just discussed, have expanded the potential patient benefits well beyond spleen reduction and symptom improvement. These potential benefits strengthen the medical imperative to manage patients more proactively and more intensively to optimize their health. As a result, not only do we now believe that ultimately more MF patients will be treated with Jakafi, but we also believe that they will be treated earlier in the course of their disease and for a longer period of time. While these shifts may be subtle in the short term, they have the potential to represent a source of sustainable long-term growth for Jakafi in MF around the world.

The unmet need in polycythemia vera is real, and a successful launch represents an important growth opportunity for Jakafi. Based upon the nature of the disease and what we have learned from the Phase II study, the use of Jakafi in PV should be relatively straightforward. More than 90% of PV patients have the JAK2 V16F mutation simplifying both the diagnosis and the rationale for using a JAK inhibitor. And a primary treatment goal is to reduce hematocrit and platelet counts, which Jakafi will do in addition to its other benefits demonstrated in our Phase II studies.

Finally, based on hydroxyurea usage and Phase II long-term follow-up data, we'd expect a meaningfully greater duration of treatment in patients diagnosed with PV as compared to patients with MF. We'll be able to provide more information and keep you up to date as our launch planning continues.

With an improved product in MF and an expected indication in PV, we're committed to increasing awareness of MPNs and the unmet needs of many patients. With that in mind, we're collaborating with a variety of healthcare and patient advocacy groups within the MPN community to increase awareness and support patients through education and empowerment. We look forward to sharing more details about various upcoming activities in September which coincides with Blood Cancer Awareness Month. I'll now turn the call over to Dave.

Dave Hastings - *Incyte Corporation - EVP and CFO*

Thanks, Jim, and good morning, everybody. We'll start with revenue this morning, we recorded $54.1 million of Jakafi net product revenue in the second quarter. And as Jim noted, we are increasing our 2013 Jakafi net product revenue guidance to a range of $220 million to $230 million from the previous range of $210 million to $225 million. Our gross and net adjustment for product revenue recognized was approximately $5 million, or 8.5% for the second quarter. We still expect that our full-year gross and net adjustment will range from 8% to 9%. In addition, we recorded $5.8 million in product royalties from Novartis for sales of Jakavi outside the United States.

Now moving to our operating expenses. Our cost of goods sold for the second quarter was immaterial as our starting finished goods inventory was previously expensed as R&D prior to FDA approval. SG&A was within expectations while R&D expense came in slightly below our expectations.

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As we have mentioned in the past, R&D expenses tend to fluctuate from quarter to quarter based on the timing of certain clinical trials, and we expect an increase in R&D expense in the second half of the year.

Now moving to the balance sheet in terms of cash, we ended the second quarter in a strong position with $277 million of cash and equivalents. In addition, during the second quarter the Company entered into separately negotiated agreements with certain holders of our 4.75% convertible senior notes in which such holders agreed to exchange approximately $144 million in aggregate principal amount of the notes for the 16.4 million shares of the Company's stock into which the notes were convertible. The holders also received $9.8 million which was recorded as debt exchange expense in the second quarter. Now importantly, this amount is significantly less than what we owed in future interest expense on the exchange bonds had the notes remained outstanding.

As a result of the reduction in the outstanding principal balance of the notes, the Company now expects interest expense to be approximately $38 million in 2013, including non-cash charges of $23 million to amortize the discount on the notes. This is a decrease from previous guidance of $47 million, which included $28 million of non-cash charges to amortize the discount on the notes. So we are in a strong financial position, we have sufficient cash to fund our growth and we have multiple sources of cash flow. In addition with our successful exchange of $144 million of our notes, we have improved our capital structure. And so with that, I'll turn the call back over to Paul.

Paul Friedman - *Incyte Corporation - President and CEO*

Thanks, Dave. Operator, could you please now open the call for Q&A?

QUESTIONS AND ANSWERS

Operator

Thank you. We will now be conducting a question-and-answer session.

(Operator Instructions)

Rachel McMinn, Bank of America Merrill Lynch.

Rachel McMinn - *BofA Merrill Lynch - Analyst*

I had two pipeline questions actually. How has your thinking involved Paul for your lead JAK1 inhibitor? It sounds like there's positive data in psoriasis and you've said in the past that you need to have a differentiated profile versus baricitinib, are you seeing that? Do you plan to develop those into unique indications versus baricitinib and Jakafi? And then separately on IDO, it sounds like you're gaining some traction there. Are there any plans to combine with your own internal pipeline? Thank you.

Paul Friedman - *Incyte Corporation - President and CEO*

So I'm going to have Rich address those questions because I think you should start then I'll add on something if there are things that I have.

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

So it's a little bit hard to answer the question directly before we're actually presenting the data, which will be presented as was said, the psoriasis data at EADV. We expect the RA data at ACR and myelofibrosis as ASH. But I think it's fair to say that the data is positive and interesting and that we do see potential there. We're not in a position to compare the data to other unreleased information to say how it compares to other JAK1, 2

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inhibitors that have not presented their data yet. But we do have interest in moving 39110 forward in inflammation. And the other JAK1 inhibitor that is already in the clinic 47986, we are targeting towards oncology. Now there are still some studies that are ongoing with 39110 in oncology. Simply because that was further head in development and we felt that we can answer some questions about the role of JAK1 inhibitors in oncology with that lead compound.

With respect to IDO inhibitors, we are interested in combining it, as was indicated in the prepared remarks, with drugs that are active in tumor immunology such as the PD-1s and PD-L1s. And in terms of our own pipeline, there is potential there for other compounds which are not so much geared towards the immune treatment, immunologic treatment of cancer but that may have utility in the cancers. But we don't have anything specific to present in terms of that at this time.

Rachel McMinn - *BofA Merrill Lynch - Analyst*

Thank you very much.

Operator

Jonathan Aschoff, Brean Capital.

Jonathan Aschoff - *Brean Murray, Carret & Co. - Analyst*

I was looking at this impact in market scan claims databases and they put the MF prevalence in the US at about 12,800, 17,700 versus your 16,000 to 18,000. And the PV was at like 148,000 to 178,000 versus your roughly 95,000 figure. And I was wondering if you could help explain those differences?

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

Hi, Jonathan, this is Jim. Jonathan I think it's very important to look at when the claims data is gathered. Ours is more current and it's not unusual when you have an orphan indication without an effective treatment to actually see some undercoding and physicians will actually code for what they can treat. And as a result, we think the more current data is more reliable. And we have a lot of confidence in our epidemiology of 16,000 to 18,000 MF patients. And quite frankly as we look at our new patient starts quarter over quarter, we're increasingly confident in those numbers.

Jonathan Aschoff - *Brean Murray, Carret & Co. - Analyst*

And then how about the PV overestimation on these from these databases?

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

Yes, Jonathan, that's -- again we'll stick with our methodology and there is one where we hope we're wrong. We hope there's 150,000 PV patients out there. But we -- right now our best estimates indicate that there's at least 100,000 diagnosed PV patients being treated in the office today.

Jonathan Aschoff - *Brean Murray, Carret & Co. - Analyst*

Okay thanks a lot.

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Operator

Cory Kasimov, JPMorgan.

Cory Kasimov - *JPMorgan Chase & Co. - Analyst*

Two of them for you. First of all, do you have any additional thoughts or strategies on potentially getting the Jakafi survival data into the label given how strong it looks? and I'm wondering how necessary you think that even is? And then the second question is how much off label use are you currently seeing in PV? Thanks.

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

So I'll answer the first question, this is Rich. We recently had a meeting with FDA in July to talk about the potential of adding the results of survival, the analysis of survival from COMFORT-I and COMFORT- II to the package insert. And they are quite amenable to some display of that, the details of which will be worked out after they review the dossier. And that is planned to be submitted mid-second half and we just don't know how long yet that review will be. So we do think that will be added. In terms of its importance, I think it's always good to be able to have something in the package insert so that the sales reps can directly speak to something. Jim may add on to that as he also addresses your second question.

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

Yes, no I think having a Kaplan-Meier curve in the label is powerful and clearly that would support the rationale to treat early with Jakafi. Now with respect to our current usage by indication, 90% plus of our usage is for MF. Of the remaining 10%, about half of that is for PV and the remaining portion is small numbers but you're looking at MDS and ET largely.

Cory Kasimov - *JPMorgan Chase & Co. - Analyst*

All right, that's helpful, thank you.

Operator

Matt Roden, UBS.

Matt Roden - *UBS - Analyst*

A question on the pancreatic trial upcoming, similar to what I have asked before. The Phase II trial is smallish for a randomized survival trial and accordingly doesn't have the most robust power. If the bar is high for the primary endpoint, can you talk about the way you think about the other endpoints? What do you need to see to further develop Jakafi or other JAK inhibitors for improving survival? I guess it's a way of asking in the case of a grey result, how do you think about that in taking this forward? Thanks.

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

Yes so when we look at this field a number of years ago, there were a lot of companies trying to get into cancer cachexia and constantly running into issues with FDA as to what the surrogates were and whether they were truly established surrogates. And we decided to just study those things but put the emphasis on what is the survival data because that is in fact the bottom line here in terms of advanced pancreatic cancer. I mean it's one thing to make people feel better, which I think you probably will find that it does based on no analysis of pancreatic data but just on our experience with the drug, but when you're talking about survival within months, I think survival does become important.

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So the study is powered not necessarily to look at a two-sided p-value of less than 0.05 though it has the potential to show that. But it doesn't have -- it wasn't initially designed with 80% or 90% powered to demonstrate that because we wanted to get an answer on survival without doing eventually a Phase III trial at the start. But we'll just have to look at the remainder of the data and decide in the end, is the next study a survival study? Is it something else? And what is the impact of this initial study in pancreatic cancer in terms of other types of cancers that have a cancer cachexia component. And we'll have the results soon enough, sometime this quarter. And so it's premature for me to try to speculate without seeing any of the data from this trial and knowing that's coming pretty soon.

Matt Roden - *UBS - Analyst*

Thanks for that, Rich. And then when you think about advancing 110 and 986, these are coming into a space where there's already one JAK approved in RA and maybe by the time these guys get into Phase III there might be another. Trying to get a sense for what you think the clinical and regulatory path would be for those and whether or not you would need head-to-head trials in the various indications you're looking at?

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

So those are really difficult questions. I think it really is going to depend upon the data and the differentiation as to whether or not the strategy is to just be another JAK inhibitor with some improvements over what's out there versus going to slightly different indications where we might be first or potentially second, something like that. Clearly it's not our goal to just have a me-too third potentially JAK inhibitor for indications with nothing additional to offer.

Matt Roden - *UBS - Analyst*

Thanks very much.

Operator

Thomas Wei, Jefferies.

Thomas Wei - *Jefferies & Company - Analyst*

Was wondering if you could give some extra color around the contribution of new patient starts versus persistency improvements during the quarter? And for the 46% at the lower doses, when you take a look at your overall clinical database and model out what the ratio should be based on efficacy, safety parameters, what do you think is ultimately going to be the stable ratio of lower doses versus higher doses? Thanks.

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

Sure, thanks, Thomas. Well Thomas our initial guidance was predicated on the fact that we would see a gradual meaningful improvement in persistence as well as a gradual deceleration in new patient starts over the course of the year. Now we're certainly seeing the improved persistence and the favorability to our initial guidance expectations is really attributable to the fact that we're not seeing any slowing in new patient starts. So that's the major driver, the fact that we're seeing continued strong new patient starts month over month that's driving our ability to increase the guidance.

In terms of the lower doses mix, interestingly, we're still well behind Jakavi in Europe in terms of the use of lower doses. So they certainly went to school on us. I think it's very hard to quantify, but I would be surprised Thomas if we weren't well above half of our units being in 5 and 10 milligram strengths.

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

Can I just add then in terms of the clinical trial experience, what we have found in for example the COMFORT studies is that those patients who started at a dose of 20 milligram BID, because they had baseline platelet counts of greater than 200,000, those patients tended to either remain at 20 BID or go down to 15 with the mean over time being 15, so higher than the 5 to 10. Whereas those patients who started with 100,000 to 200,000 platelets and started at 15 tended to average down to doses around 10 milligrams BID. And then from the separate study of patients with starting platelet counts less than 100,000 who started at 5 BID, those patients tended to end up at 10 BID. So it really depends upon the patient mix as to what the eventual doses are going to be. And so I think that you wouldn't necessarily expect to get much over the 50% to 60% of patients on doses of around 10 over time because some patients can tolerate and may receive additional benefit from doses around 15 BID.

Thomas Wei - *Jefferies & Company - Analyst*

Thanks.

Operator

Brian Abrahams, Wells Fargo.

Unidentified Participant - - *Analyst*

Hi this is Shannon calling in for Brian, thanks for taking my questions. You've mentioned cachexia as one of the potential mechanisms of actions for improving survival in pancreatic cancer. Could you talk in a little more details about the mechanistic rush now behind targeting JAK2 in pancreatic cancer such as intrinsic factors mediated by IL-6 signaling axis, intrinsic factors involving GMCSF mediated immunosuppression and whether you think the fact that Jakafi had an effect on bone marrow fibrosis translates to an impact on desmoplasia in pancreatic cancer and whether you have tested these hypotheses in pre clinical models?

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

Okay. So let's -- let me -- rather than answering each of your individual questions go through how we think about this. So first of all, in myelofibrosis, we see the patients are cachectic, they gain weight and they live longer. And there have been plenty of animal models where in cachectic models IL-6 is a key driver and if you inhibit IL-6 signaling through whatever mechanisms reduce IL-6 levels use siRNA, any of those things. In animal models, that reverses the cachexia and leads to greater survival. Additionally, there are animal models that look at IL-6 inhibition in pancreatic cancer that has benefits. And in our xenograft models of pancreatic cancer, even without necessarily having a cachexia component, we see that our JAK1 and 2 inhibitors inhibit, excuse me, lead to tumor growth delays, reductions in tumor mass et cetera. So we have not looked specifically at impacts of fibrosis within -- and various things like that as part of our rationale. And we look forward to seeing actual clinical results soon.

Unidentified Participant - - *Analyst*

A quick related question is how confident are you that dosing used in MF should translate to an effective dose in pancreas, are there any mile markers that you're tracking to access whether you have reached that effective dose?

Paul Friedman - *Incyte Corporation - President and CEO*

Well I mean we know by following ex vivo STAT (inaudible) that the blood levels that we get in these patients are sufficient to inhibit the JAK pathways to the degree that we want to inhibit them. And we certainly do have measurements that we're making in the study but all of that data is blinded at this point.

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

Yes and the dose, the starting dose here is 15 mg BID. And because these patients do not have bone marrow disease, they're able -- they're virtually all of them as far as I know are able to maintain that dose which is a highly active dose.

Unidentified Participant - - *Analyst*

Great, that's very helpful, thank you very much.

Operator

Ying Huang, Barclays.

Ying Huang - *Barclays Capital - Analyst*

So the first question I have is on the volume change from this quarter for Jakafi shipments because I know you guys took a pricing increase. So can you give us basically the volume change for Jakafi (inaudible) from 1Q to 2Q? And then second question I have was regarding to a new drug you guys just put into the clinic, I think it's code named INCB40093, it was in Phase I for B-cell malignancy. I was wondering if you could clarify what mechanism of action this drug has, is it a PI3K inhibitor? And what your thoughts are in terms of getting into this PCR malignancy given there are probably four drugs are already on the -- in the clinical phase now? Thank you

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

Hi, Ying, this is Jim. In terms of quarter-over-quarter price volume, volume grew 15% and price -- 15% unit growth, and price contributed 1% and that was really a function of our gross to net going from 9.5% down to 8.5%. And we burned off 4% of growth in inventory. And that netted us the 12% net sales quarter-over-quarter growth.

Paul Friedman - *Incyte Corporation - President and CEO*

Second question, 40093 is a selective inhibitor of PI3K delta. We're currently exploring its safety and biological activity in the Phase I trial. We're not going to provide at this time greater detail on the compound or our development plans. We'll disclose those details at the appropriate time as the program matures.

Ying Huang - *Barclays Capital - Analyst*

Great, that was very helpful. Thank you very much.

Operator

Eric Schmidt, Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

It sounds like Jim has been doing some work on the PV opportunity you mentioned that you think the duration of therapy is going to be longer there. Does he have any estimate for the percent of patients with PV who might be appropriate for second line Jakafi type therapy?

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

Yes Eric, we believe that 20% to 30% of the 100,000 patient population would fit the criteria for being refractory to or intolerant of hydroxyurea.

Eric Schmidt - *Cowen and Company - Analyst*

Okay. And then just a quick one for Dave on cost of goods. Can you update us on how much left has been -- how much pre-expense inventory is left to be sold and when that does work its way through the channel, what the gross margins going to be?

Dave Hastings - *Incyte Corporation - EVP and CFO*

Sure. So certainly for 2013 Eric, we'll continue to use the validation batches that we had clinically, so I would expect sometime in 2014. And what we've guided for in terms of overall cost of sales the summer between 4% and 6%.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

Josh Schimmer, Lazard Capital Markets.

Josh Schimmer - *Lazard Capital Markets - Analyst*

As the top line grows now going forward, you're so close to profitability, do you expect starting next year to be profitable and growing the bottom line or is the strategy to more use the top line growth to broaden R&D efforts? How do we think about modeling going forward?

Paul Friedman - *Incyte Corporation - President and CEO*

I think it's important to note that we really believe that the pipeline and Incyte is developing and investing in it offers a very high return on -- potential high return for shareholders and we're going to continue that investment, Josh. So we're not giving any guidance in terms of when we'll be profitable. But certainly we believe that the Company is in excellent shape financially, strong cash position with multiple sources of cash flow now including royalties and strong milestone flow to come, we've reduced our leverage and we're really in a strong position to continue our investments in the pipeline.

Josh Schimmer - *Lazard Capital Markets - Analyst*

Then may be a quick question on 39110, why do you feel you need three different Phase III studies to explore the difference in the JAK1, 2 versus JAK1 as opposed to maybe adding some new innovative indications where there's a reasonable either proof of concept or expectation for success?

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

You said Phase III, did you mean Phase II?

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Josh Schimmer - *Lazard Capital Markets - Analyst*

I'm sorry, yes of course Phase II, thank you.

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

Well we wanted to go to places in which there were data already in the public domain on JAK1, 2 to be able to see how this may differentiate. But not necessarily committing to developments in those same indications that were there. So as we move into the next stage of development, we may not be limited or even focused necessarily on those same indications. But it was going to be harder I think in a relatively short term with relatively small studies to start exploring indications for which we didn't know what the effect of JAK1, 2 inhibitors where. Now there are some other indications, for example Pfizer has data in inflammatory bowel disease for which there was some data out there. But those trials are hard to enroll quickly and we wanted something where we could get results in the 2013 timeframe.

Josh Schimmer - *Lazard Capital Markets - Analyst*

Understood. Thank you.

Operator

Ian Somaiya, Piper Jaffray.

Ian Somaiya - *Piper Jaffray & Co. - Analyst*

First question was for you, Jim. Curious about the sensitivities your (audio difficulties).

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

This is Jim, you're pretty garbled coming through on your cell phone. I'm guessing that the question was, talk about the sensitivity you have in distinguishing between a new patient and a repeat patient.

Ian Somaiya - *Piper Jaffray & Co. - Analyst*

That's correct.

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

Okay. I think that's a good question, Ian. There is some noise in the data. We have become increasingly more sophisticated in how we try to separate signal from noise. So we believe that our assessment of new patient starts is directionally consistent over time. And therefore, when we say that new patient starts have been consistent, we have good reliability on that. As you point out there is a sensitivity between new patients and repeat patients to the extent that we overstate new patients we would be understating repeat and therefore understating persistence. So it is a closed system and there is some compensatory factors there. But as we look at total bottles being sold, clearly with the 15% quarter over quarter, we're seeing very nice, very nice growth both in persistence and in new patients.

Operator

Navdeep Singh, Goldman Sachs.

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Lisa Zhang - *Goldman Sachs - Analyst*

Hi, this is Lisa Zhang in for Navdeep Singh. Thanks for taking my question. Do you believe you still match the Jakafi growth seen and now expected in 2013 also in 2014 given a potentially new entrant in 2014? Thank you.

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

It's too early for us to be giving specific 2014 guidance. But as we look forward to 2014, clearly we do have a competitor. I think the share that that competitor will take will be a function of the data and the profile that they present at ASH. And it will also be a function of how well they execute. We think we're in a very strong position. Our data continues to build very nicely, whether it be survival, whether it be fibrosis. And we'll let the competitor speak about their product, but we'll be looking very closely at off target GI toxicity. We'll be looking at durability response and we're confident that it'll be very difficult to displace Jakafi as first-line treatment in MF. Having said that, we think it will be helpful to market growth to have a second entrant. Having more people talk about the need to treat should expand the overall market and we think whatever share impact we have should be more than offset by market growth.

Operator

Skip Klein, Gauss Capital.

Skip Klein - *Gauss Capital - Analyst*

Yes, two quick ones, please, thanks. One for Dave, the $9.8 million kiss to the convertible debt holders, was that paid in cash or stock? And can you give me a rough estimate with the savings were versus the interest over the life of the convert?

Dave Hastings - *Incyte Corporation - EVP and CFO*

Yes, Skip, we paid that all in cash and the interest savings are little bit over $7 million over the life of the convert.

Skip Klein - *Gauss Capital - Analyst*

That's nice, that's great And then for Jim, is there any way you can help me, I mean I wake up at night thinking about the duration of therapy believe it or not. And I was wondering if there any [meets] or bounds that you could give us on duration of therapy in MF, what could it be, what are the ranges? And the same thing in PV. And if you don't feel real comfortable with specifics, is there an example of an oncology compound that we can look at that's on the market that you use as an exemplar?

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

Yes, Skip, to answer that question I think it's important to separate the idea of discontinuation rate or persistence versus duration of treatment. And duration of treatment, assuming you have a patient successfully benefiting from the drug and tolerating the drug, that's a function of how long they live. So I'll defer to Rich to comment on survival of MF patients versus survival of PV patients and what we've seen in Phase II studies with the extension. But if you look at persistence or discontinuation rate, what we said in the past and we believe it today, is that we should be able to keep 70% to 80% of the patients on the product for the first 12 months. Now if you looked at the Phase III COMFORT-I, COMFORT-II, you had a 14% discontinuation rate at 6 months, 18% at 12 months. That's probably an unrealistic hurdle. But having a 20% to 30% discontinuation rate at the end of 12 months, we think that's achievable and we're working toward that goal. So I ask Rich to comment on the overall duration of treatment that you may see in MF versus PV.

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

Yes, so Jim basically gave you the key data in terms of what we've seen in the clinical trials remembering that those clinical trials didn't include patients with the lowest platelet counts. So the very sickest patients were not necessarily included in those trials making them really hard to absolutely meet those numbers. But what we did see as an example, and Jim made reference to this I think in his prepared remarks, was that we expect longer duration of therapy in PV. And so last year at ASH, we presented a three-year follow up in PV, and again in the clinical trial setting, 75% of the patients were still on drug at three years as opposed to about 50% still on drug at three years in the comparable Phase II MF trial. Indicating that whereas the absolute numbers may never be matched in the clinic, the ratio of about twice as long duration of therapy at least as measured at three years in PV versus MF probably is a realistic estimate. But again we'll have to launch the product and see how that goes over time.

Skip Klein - *Gauss Capital - Analyst*

But fair to say the patients feel better, they don't feel worse, it's not like in any hypertension and the data supports them feeling better and supports the position and the payer being willing to pay for it. I guess the other piece that you didn't really comment on is the treating earlier aspect. What are you gaining at the front end do you think over time? Is it as much as 6 months or 9 months of 12 months by giving them earlier and convincing the doctors and the patients, the patients going to the doctors I want to be put on this drug, there's survival benefit, there's fibrosis benefit, put me on the drug. So is it 6 months or 12 months?

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

So if you look at the reasons for discontinuation in the marketplace, a fair number of those are because of anemia and thrombocytopenia. It wasn't the case in the clinical trials where they were very well managed and the doses were adjusted. But as you start earlier that in a sense means less anemia and thrombocytopenia at baseline which would give those patients a better chance to be treated longer. And of course in PV, where they don't have anemia and thrombocytopenia, they have too many red cells and in most cases more platelets than they need. Those are actually benefits and not reasons to discontinue. So starting earlier should lead to quite a bit longer treatment but have it quantified that they can start six months earlier, are you just going to get six more months of treatment or are you going to get many more years of treatment? That I really couldn't speculate on.

Skip Klein - *Gauss Capital - Analyst*

Great, thanks for your help.

Operator

Salveen Richter, Canaccord.

Andrew Goldsmith - *Canaccord Genuity - Analyst*

This is Andrew Goldsmith on the line for Salveen. I had a couple of related questions on Europe. I was wondering if you could talk at all about the one-time issues in Q2 that led to a small decrease in revenue? And then similarly, what went into the delay in getting that third [contributor] for pricing? Thanks.

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

Yes well I think Novartis is the definitive source on that, but what they have shared with us is with respect to the nonrecurring events, one of those was destocking in Germany. And that is pretty typical for a product launch in Germany. And the other was a one-time accrual reversal in France. And then with respect to the reimbursement, I think as you know right now, Europe is a very difficult marketplace in terms of reimbursement. And I think we've just had not unexpected bureaucratic delay with the second major market and we're confident that we'll get the third major market in the first half of next year.

Andrew Goldsmith - *Canaccord Genuity - Analyst*

Are you seeing any other one-time event coming in the second half or you think those are mostly behind us?

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

I'm sorry.

Andrew Goldsmith - *Canaccord Genuity - Analyst*

I'm sorry, do you see any other of these one-time events coming in the second half?

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

Again, I would defer to Novartis on that. But to the best of our knowledge, we've got these one-time events behind us.

Andrew Goldsmith - *Canaccord Genuity - Analyst*

Great, thanks so much.

Operator

Boris Peaker, Oppenheimer.

Boris Peaker - *Oppenheimer & Co. - Analyst*

I had a question on clinical studies that are ongoing. You've highlighted a number of upcoming data releases, but you also mentioned that there's a number of investigator sponsored trials. I'm curious if you could summarize some of the investigator sponsored trials and when we may see some of that data?

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

Yes, so with ruxolitinib there are a number of things going on, some of which are higher on our radar screen than others. We have a couple of studies going on in breast cancer including triple negative breast cancer and inflammatory breast cancer. We have a study ongoing in lymphoma. And there are a reasonable number of other things going on, but I don't even necessarily keep them all in my head. Certainly some of them are still related to myelofibrosis including combination therapies and uses in myelofibrosis and other settings such as pre-transplant. But in terms of new potential indications, those are the ones that come to mind there.

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We also actually do have some ISTs with some of our other products including the IDO inhibitor. And it was mentioned in the prepared remarks there is an IST starting in late stage MDS with our IDO inhibitor. So a number of interesting things. Timeline wise, boy that's really something that is very hard to predict. I mean that's the down -- the upside of ISTs is lot of things you can do without our spending a lot of money on them. But the downside is we really don't have anywhere near the control of the timelines that we have when we do studies ourselves.

Boris Peaker - *Oppenheimer & Co. - Analyst*

Is there any particular maybe IST that is high in your radar that may inform some kind of an internal development decision? Or most of these are early exploratory at this point?

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

Well I think they're all geared toward helping us make investment decisions to do further development ourselves. And I do think that solid tumors with ruxolitinib for example, a lot of that is going to also depend upon the results of RECAP as well as the ISTs that are reading out. And in terms of liquid tumors, I think that the lymphoma study is one of particular interest to us.

Boris Peaker - *Oppenheimer & Co. - Analyst*

Great, thank you very much for taking my questions.

Operator

Matt Roden, UBS.

Matt Roden - *UBS - Analyst*

I want to come back to this PV prevalence question. Jim you mentioned that you're sticking with your numbers 100,000 prevalence in the US, 20% to 30% addressable. When you think about the addressable numbers, did -- when you -- I guess it's just a methodology question. Do you get to that percent based on an estimate as how many patients are hydroxyurea refractory or intolerant? Or is it -- do you think of it in terms of a proportion or an absolute number? Because if the number is really 150 than that has implications. Thanks.

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

We do it as a proportion, Matt. It's based on an extremely large -- we did a 1,000 patient chart audit and that's how we derived the 20% to 30% estimate. So it is proportional to the overall universe. So if it's 150,000 then we have upside and so that's one estimate that we wouldn't mind being wrong on.

Matt Roden - *UBS - Analyst*

Great, thanks so much for the clarification.

Operator

Ian Somaiya, Piper Jaffray.

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Unidentified Participant - - *Analyst*

Hi, thank you, it's actually Matthew on for Ian. Two quick questions, if I may. For Jim and Rich regarding 110, you keep focusing on differentiation and the need to focus versus other JAKs particularly on the efficacy front. But it seems like thinking about things from a safety point of view, the market is really wide open and so I'm -- we're wondering why not focus on safety? Why does there seem to be such a high bar internally in terms of differentiation?

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

So one of the issues with respect to Phase IIs is the size of the population in order to be able to really access what the long-term risks are of infrequent things. So if you look at tofacitinib as an example where they did 5,000 patients and they studied them for many years and now they're having some issues, particularly in Europe, those, unless you actually have a problem, is not something that you're likely to pick up in relatively small Phase II. So what we're doing right now is really focusing on the things that we can see within a Phase II trial and making sure that we're not running into any issues related to immunosuppression. Now of course we do avoid JAK3 with both our JAK1, 2 inhibitors as well as our selective JAK1 inhibitors which gives us a likelihood of having -- not having the same immunosuppressive issues that tofacitinib does. But we just don't have studies designed at this stage to be able to prove that.

Unidentified Participant - - *Analyst*

Okay. And if I could squeeze in one last one, please. Regarding pancreatic cancer, the pancreatic cancer Phase II, can you give us a sense or help set expectations for what you're viewing or how you're defining good data that would support advancement into Phase III verses say one of the other backup compounds? Thank you very much.

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

So we look at hazard ratios, and I think that's the most important thing, and hazard ratios tell us two things. One, they tell us what the likelihood of success is and whether it's worth the investment. And they also tell us what the size of the patient population -- what the size of the study you would need to do in Phase III in order to be able to adequately power the study. And so, I don't have any particular number in mind in terms of what it is that is our go hazard ratio. But if it was a barely -- if it was a small difference, not only would that take in to question the likelihood of success, but also the size of the study that would be necessary. So we would be looking for something that would be both high likelihood of success and manageable. And in terms of differentiation between other compounds, I mean I think that's more driven by the ability to combine ruxolitinib with various chemotherapies than it is based on hazard ratios.

Operator

Mr. Friedman, it appears we have no further questions at this time. I would now like to turn the floor back over to you for closing comments.

Paul Friedman - *Incyte Corporation - President and CEO*

Thank you. Thank you all for joining us this morning, we certainly appreciate your time. And we're looking to a busy second half of the year and we look forward to keeping you updated on our progress. Thank you, and with that we'll end the call.

Operator

Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.

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