THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

INCY - Q3 2013 Incyte Corporation Earnings Conference Call

EVENT DATE/TIME: OCTOBER 31, 2013 / 12:30PM GMT

OVERVIEW:

Co. announced 3Q13 results.

THOMSON REUTERS

CORPORATE PARTICIPANTS

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

Paul Friedman *Incyte Corporation - President and CEO*

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

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

Dave Hastings *Incyte Corporation - EVP and CFO*

Eric Siegel *Incyte Corporation - EVP, General Counsel*

CONFERENCE CALL PARTICIPANTS

Thomas Wei *Jefferies & Company - Analyst*

Salveen Richter *Canaccord Genuity - Analyst*

Rachel McMinn *BofA Merrill Lynch - Analyst*

Matt Roden *UBS - Analyst*

Brian Abrahams *Wells Fargo Securities, LLC - Analyst*

Navit Singh *Goldman Sachs - Analyst*

Ying Wang *Barclays Capital - Analyst*

Matt Lowe *JPMorgan Chase & Co. - Analyst*

Eric Schmidt *Cowen and Company - Analyst*

David Friedman *Morgan Stanley - Analyst*

Drew Purgotic *JMP Securities - Analyst*

Skip Fine *- Analyst*

PRESENTATION

Operator

Greetings, ladies and gentlemen, and welcome to the Incyte Corporation third-quarter 2013 earnings call.

(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 and Communications. Thank you, Ms. Murphy, you may now begin.

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

Thank you, and good morning. Welcome to Incyte's third-quarter 2013 conference call. On the call today are Paul Friedman, Incyte 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 a brief overview of the quarter; Jim will follow with an update on the ongoing commercialization of Jakafi; Rich will then highlight progress made in our lead clinical programs; and Dave will describe our third-quarter financial results. Paul with then open the call up for Q&A.

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; our development plans for Jakafi and other indications, and for other compounds in our pipeline; and our expectations for net product revenue. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended September 30, 2013, and from time to time in our SEC documents. Paul.

Paul Friedman - *Incyte Corporation - President and CEO*

Good morning, everyone. Incyte's third quarter was a highly productive one. As expected, with Jakafi, we are continuing to establish a strong commercial foundation in myelofibrosis.

In the third quarter, Jakafi experienced solid, consistent growth, with steady new patient adds and new prescribers. And we are starting to see physicians become more appreciative of the need to treat patients earlier in the course of the disease. We also continue to see a modest yet meaningful increase in persistency rates. And we believe physicians are hearing and understanding the message that dosing should be individualized for each patient, and they are changing their behavior accordingly.

We are confident that we will reach the high end of our 2013 guidance for net product revenues, which we increased last quarter to a range of $220 million to $230 million. In his remarks, Jim will provide more color around Jakafi and myelofibrosis, as well as the anticipated launch of Jakafi in polycythemia vera. With the potential approval in PV on track for late 2014, we see a significant opportunity to continue to grow revenues and to position Jakafi as best in class among emerging MPN treatments.

If Jakafi shows potential beyond MPNs, recent data from the Phase II RECAP trial in second-line pancreatic cancer suggest a significant growth opportunity for Jakafi in pancreatic cancer among a well-defined patient subgroup and provide a strong rationale for use in other solid tumors. The growing potential of Jakafi is just one part of our story, however. Our core competency in medicinal chemistry, tightly integrated with biology, has been a primary driver of our productivity and drug discovery, and we now have a growing, robust pipeline that extends far beyond one product.

In his remarks, Rich will discuss several of these clinical programs, but there are a few I'll highlight briefly now. The strong alliance with Lilly provides optimal potential value for our second JAK1/JAK2 inhibitor baricitinib. Lilly is evaluating baricitinib in rheumatoid arthritis, psoriasis, and diabetic nephropathy, and we believe the compound has the potential to be best in class.

We have a broad portfolio of JAK1 inhibitors that gives us the option to pursue oncology and chronic inflammatory conditions with distinct compounds, an approach that has worked well for us with the JAK1/JAK2 program. With our lead JAK1 inhibitor, INCB39110, we recently presented very positive data from our proof-of-concept trials in psoriasis and in rheumatoid arthritis.

You'll see additional proof-of-concept data in myelofibrosis at ASH. We're also evaluating the compound in other malignancies in combination with established chemotherapeutic agents, in particular, those that are more highly myelosuppressive. A second JAK1 inhibitor is under clinical trials, and the data from these studies and other trials that we are planning will help us determine which compounds to pursue, and in which indications.

Beyond our JAK programs, we have other compounds in the clinic, including our indoleamine dioxygenase, or IDO inhibitor INCB24360, which is a novel oral compound being evaluated for its potential to enhance immune responses to tumors. We are evaluating 24360 both as mono-therapy and in combination with multiple -- for multiple oncologic indications. We've also advanced our first PI3K Delta inhibitor, INCB40093, into clinical development. With the PI3K Delta inhibitor and our portfolio of JAK inhibitors, we believe we are particularly well positioned to leverage both classes of molecules in areas of high unmet medical need to potentially improve treatment outcomes for patients.

With that I'll turn the session over to Jim.

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

Thank you, Paul, and good morning, everyone. Our third-quarter results reflect continued solid progress in executing our strategy to grow Jakafi in patients with intermediate or high-risk MF.

In terms of quarter-over-quarter growth, net sales grew 11%, with the following components of growth -- underlying demand, as measured by bottles dispensed to patients, grew by 8%; net price accounted for 3% of growth; inventory levels remained relatively constant; and third-quarter inventory remains within the normal range of 3 to 3.5 weeks.

Our third-quarter performance is consistent with our expectations for steady growth in underlying demand. Based upon the trends we are seeing in new patient starts and persistency, we expect to see continued solid growth in the fourth quarter, and as Paul indicated, to achieve the high end of our current net-product revenue guidance of $220 million to $230 million.

New patient starts remain consistent with previous quarters, and the number of prescribers continues to increase. Through the third quarter, more than half of our target prescribers have prescribed Jakafi at least once. We believe these dynamics are driven by a growing recognition of the disease-modifying effects of Jakafi in MF, as evidenced by survival data and fibrosis data. Physicians are becoming increasingly aware of the medical imperative to treat patients earlier in the disease.

With respect to persistency, the expanded dosing guidance in the label for patients with low platelet counts, approved by the FDA in June, has been well received by physicians, and we continue to see 5- and 10-milligram strengths representing a growing percentage, nearly 50%, of dispensed bottles. While we originally expected to expand our oncology sales force for the PV launch, we've accelerated our plans to capitalize on what we see as sustainable longer-term growth remaining in MF. We are currently recruiting for 20 new positions, which will bring our total number of sales representatives to 80. We are encouraged by the tremendous volume of qualified applicants we are receiving for these openings and expect to have most of these positions filled and trained by January 1.

Novartis is also experiencing solid growth for Jakavi in Europe and rest of world. They reported third-quarter sales of $48 million, as compared to the $33 million sold in the second quarter. Novartis also reported reimbursement approval in a second major European country, Germany, in the third quarter, and we continue to expect the third approval, which triggers a $60 million milestone payment, in the first half of 2014.

And while the MF market continues to grow at a healthy rate, we have an exciting opportunity to build on that growth with a potential new indication in PV next year. We believe the addressable PV population is substantially larger than the addressable MF population.

When hemotologic oncologists are surveyed about their PV patients, they typically think about the 70% to 80% of their patients who are generally well controlled with phlebotomy or HU treatment and report relatively high satisfaction with current treatments.

However, when reviewing patients charts, these same physicians readily recognize the 20% to 30% of patients in their practice who suffer with uncontrolled PV while on best-available therapies. Uncontrolled PV includes elevated hemotocrit and debilitating symptoms. These patients represent the unmet need and a major commercial opportunity for Jakafi.

We've always said MPNs are just the beginning. As Rich will describe, we have a number of potential opportunities in solid tumors that could significantly increase the number of patients who benefit from Jakafi.

We have a stable of JAK1 selective compounds, with potential applications in oncology and inflammation. And finally, we have a broader pipeline of innovative molecules in the clinic that together represent an outstanding opportunity for Incyte to make a meaningful difference for patients. I will turn it over to Rich.

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

Thanks, Jim. As Paul said earlier, we've made considerable progress with our compound from development during the most recent quarter and emerging results show great potential for our portfolio in oncology and inflammation. First, with respect to our development in myeloproliferative neoplasms, we submitted a number of abstracts for ASH which we expect to reinforce Jakafi's position as what we believe is the best-in-class treatment for patients with intermediate or high-risk myelofibrosis.

Earlier this month, we submitted an sNDA for inclusion of survival data into Jakafi's labeling for myelofibrosis. Based on prior discussions with FDA, I continue to believe the agency is amenable to some display of these data.

For our Phase III registration study for polycythemia vera -- it is being conducted under an SPA -- we expect to release top-line data in the middle of the first half of 2014 and to submit the sNDA in June. Assuming a six-month review, we would have potential approval before the end of 2014.

The companion study in PV, entitled RELIEF, is a double-blind study focused on symptomatic improvement. While the study is nearly fully recruited, the results of this 16-week study won't be included in the original submission for the PV indication. But we expect to submit an sNDA for inclusion of the symptom data into the package insert shortly after the anticipated original approval for PV. Our goal is to present data from both RESPONSE and RELIEF at a scientific session in the second half of 2014.

Moving to our other oncology indications for JAK inhibitors, in August, we released top-line results from our Phase II study of ruxolitinib in combination with capecitabine in second-line pancreatic cancer. It was a hazard ratio for overall survival of 0.47 in a prospectively defined subset of patients preselected as most likely to benefit from JAK pathway inhibition.

Based on our confidence in these data, we are moving forward aggressively in pancreatic cancer and other solid tumors. We submitted a Phase III registration study for pancreatic cancer to FDA for review and anticipate that we will begin randomizing and dosing patients in the first half of 2014.

We are also planning to initiate three additional randomized Phase II trials to evaluate ruxolitinib in non-small cell lung cancer, colon cancer, and breast cancer starting in the first half of next year. Each study will focus on the selected subgroup identified from the study in pancreatic cancer and will combine ruxolitinib with therapies with low to moderate myelosuppressive effects. While powered as pilot studies, each will have overall survival as a primary endpoint.

As Paul mentioned, we're also evaluating our JAK1 inhibitors in oncology, focusing initially on combinations that may not be as well tolerated with ruxolitinib as a result of the myelosuppressive potential of JAK2 inhibition. We have an ongoing study in advanced cancer patients, evaluating our lead JAK1 inhibitor, 39110, in combination with a highly myelosuppressive regimen of gemcitabine and nab-paclitaxel.

Additionally, we plan to initiate two randomized Phase II studies with 39110 in solid tumors, also starting in the first half of 2014. The first of these is expected to be similar to the Phase II pancreatic study with ruxolitinib to confirm our hypothesis that similar survival benefits can be seen with a selective JAK1 inhibitor. The second study is expected to include patients with non-small cell lung cancer in combination with a more myelosuppressive regimen.

Results of these three studies will help guide our future plans for use of JAK1 inhibitors in solid tumors. We believe our JAK1 inhibitors also have a role in additional hematological tumors in combination with established and investigational therapies. For example, we have advanced our first PI3K Delta inhibitor, Incyte40093, into a Phase I mono-therapy dose escalation study.

Upon completion of this study, we plan to initiate a safety-and-efficacy study of 40093 in combination with a selective JAK1 inhibitor, and this is expected to start around the end of this year and will focus on patients with B-cell lymphomas. These two distinct mechanisms exhibit synergy in pre-clinical studies, and this early-development program exemplifies our interest in exploring novel cross-portfolio combinations in areas of unmet medical need.

I'll now turn to the progress made with our JAK1 inhibitors for inflammatory indications. During the last four weeks, we presented results for our first proprietary JAK1 selective inhibitor, 39110, in psoriasis at EADV and in rheumatoid arthritis at ACR. For psoriasis, after four weeks of treatment with a top dose of 600 milligrams once daily, 46% of patients had cleared or almost cleared their psoriadic lesions.

In the three-month study in rheumatoid arthritis, presented three days ago at ACR, the top dose, also of 600 milligrams once daily, showed an ACR20 response rate of 91%; an ACR50 of 64%; and an ACR70 of 55%. While these studies were small, and it is difficult to compare the results to other established and investigational therapies, I believe the magnitude of effect in both psoriasis and RA studies of 39110 would compare very favorably.

In both studies, all dose levels are generally well tolerated without apparent myelosuppressive effects. The results show promise for 39110 or possibly one of our other orally administered JAK1 inhibitors in inflammatory diseases. While it remains our intent to develop a JAK1 inhibitor for selected inflammatory disorders, possibly with a partner, our top priority for our JAK1 inhibitors is in hematology and oncology. Data from ongoing and planned studies should help us to decide which of our portfolio JAK1 inhibitors are best suited to combinations with myelosuppressive chemotherapy and which are best suited for use in inflammatory indications.

We are also excited about the potential opportunities with Incyte24360, our IDO1 inhibitor in oncology. Like CTLA4, PD-1, and PD-L1, IDO1 is emerging as a novel checkpoint mechanism which may allow cancers to escape the host immune response. We have a combination study with ipilimumab in melanoma ongoing. We are encouraged by the early data and look forward to presenting the results of the open-label, dose-finding, run-in portion of the study, probably at ASCO next year.

Combined checkpoint inhibition looks to be an important new treatment option -- new treatment approach for solid tumors. Based on the emerging data for 24360, we believe it may offer an exciting advance in the immuno-oncology space and we are in discussions to collaboratively explore relevant combination regimens.

We also have ongoing studies of 24360 mono-therapy in ovarian cancer and are supporting an ongoing investigator sponsored study of 24360, again, as mono-therapy in myelodysplastic syndrome as well as a cooperative study in combination with a melanoma polyvalent peptide vaccine. And while we have a very robust development-stage portfolio with JAK inhibitors, our PI3K Delta inhibitor, and an IDO inhibitor, we also have several active programs directed at new oncology targets which we'll look forward to describing to you after these programs reach the clinical stage of development. With that, I'll turn it over to Dave.

Dave Hastings - *Incyte Corporation - EVP and CFO*

Thanks, Rich. Good morning, everybody. Let's start with product revenue. We recorded $60.2 million of Jakafi net-product revenue in the third quarter.

Our gross-to-net adjustment for product revenue recognized was approximately $5.6 million, or about 8.5% for the third quarter. We still expect that our full-year gross-to-net adjustment will range from 8% to 9%. In addition we recorded $8.2 million in product royalties from Novartis for sales of Jakavi outside the United States.

Now moving to operating expenses, our cost of goods sold for the third quarter was immaterial as our starting finished-goods inventory was previously expensed as R&D prior to FDA approval. Both R&D and SG&A expenses were within our expectations.

Now moving to the balance sheet, in terms of cash, we ended the third quarter with $291 million of cash and equivalents. In addition, during the third 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 $37 million in aggregate principal amount of the notes, for the 4.2 million shares of the Company stock into which the notes were convertible.

The holders also received $1.5 million, which was recorded as debt-exchange expense in the third quarter. Now importantly, this amount is significantly less than what we owed in future interest expense on the exchange bonds, had those notes remained outstanding. In total, of the

original $400-million principal balance of these notes, we have now completed separately negotiated exchanges of approximately $181 million of the notes in 2013.

So, in conclusion, we continue to make solid progress on multiple fronts, and I believe we are in a strong financial position. So with that, Paul, I will turn it back to you.

Paul Friedman - *Incyte Corporation - President and CEO*

Operator, let's please go straight to Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question is from the line of Thomas Wei of Jefferies.

Thomas Wei - *Jefferies & Company - Analyst*

Hello, thanks. I have a couple of questions on slightly different topics.

The first -- just wanted to find out if you are able to provide any more granular detail on persistence rates and new patient starts on Jakafi. And then, on the solid tumor program that you are expanding into, can you give us a little bit more detail on what percent of non-small cell lung cancer, colon, and breast cancer would qualify for this study based on the criteria from the pancreatic subgroup? That would be helpful in terms of sizing those opportunities.

And based on the pancreatic press release that you would put out, where there's mention of durable tumor responses, I guess I wanted to understand, do you think that Jakafi is working predominantly through a direct anti-tumor effect? And would there be actually a potentially big difference between JAK1 and JAK2 in that way? Thanks.

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

Hello, Thomas. This is Jim. I will take the first part of your question.

Regarding a patient starts, they have been remarkably consistent quarter over quarter. So we have not seen a deceleration in the absolute number of new patient starts quarter over quarter.

With respect to persistency, we really don't want to get into specific metrics around how long patients are staying on product, only because it is a moving target. Our best indicator of improved persistency is really looking at the dosing practice of physicians starting at lower doses and titrating as appropriate. So we are using 5- and 10-milligram tablets as an indicator of physicians individualizing dosing. And we continue to see that move very nicely upward quarter over quarter.

So with respect to the specific metrics of persistency, there's a number of different ways you can measure that. You go to the patient to stay on 12 months after initiation. You can look at the number of patients who drop off in a given month. We do have some variability in the data sources, particularly as patients switch from plan to plan, so we would prefer to really look at underlying demand as measured by total dispensed bottles, and then really let you triangulate between new patient starts and total patients in order to back into the persistency.

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

So with respect to the clinical questions that you ask, first on solid tumors in terms of what percent would qualify. Based on what we saw on the pancreatic cancer, where we said it would be approximately 50% of patients, we believe that's also true in these other solid tumors, within a ballpark. Now the other thing you have to consider in terms of looking at the size of the opportunities there, is line of therapy. We have really disclosed where we are looking, but it should be pretty clear that we're not focusing initially on first-line therapy. So when we talk about the approximately 50% of patients, that applies often to the lines of therapy that we're going to be focusing on initially. And as we move towards first-line, those numbers could come down a little bit.

With respect to the effects within pancreatic cancer. We are seeing survival benefits that I think are beyond what you might expect. Based simply on response rates, even though there were durable responses seen only in the patients that received ruxolitinib in addition to capecitabine. And in terms of the differences between JAK1 and 2, our hypothesis is, based on everything that we know, that the mechanisms should be equally applicable to both JAK1 selected inhibitors as well as JAK1/2 inhibitors.

However, the proof of concept that we have right now is, with ruxolitinib, which inhibits both JAK1 and JAK2; and that is part of the reason why one of the studies that we are planning to start in the first half of next year is looking at one of our selected JAK1 inhibitors to make sure we can reproduce those results before we make an even larger investment for our JAK1 selected inhibitors in other solid tumors.

Operator

Thank you. Our next question comes from the line of Salveen Richter of Canaccord. Please proceed with your question.

Salveen Richter - *Canaccord Genuity - Analyst*

Thanks for taking my questions.

I'm just wondering -- if you could just elaborate on the overall strategy with JAK1, how do we think about that strategy in inflammatory space? And then how is it de-prioritized relative to the hem-oncology opportunity? And how would you think about solid tumors versus hem opportunities, especially with 110? And then, just a competitive question -- so Gilead just started their Phase III trial with their JAK versus rux -- what are your expectations there? And how do you think, if this drug should come to market, it will play out in the marketplace?

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

With respect to our overall strategy for JAK1, we believe that the strongest opportunities and those that we have a clear competitive advantage and lead on, are in oncology; first of all solids and liquid tumors. We have multiple JAK1 selected inhibitors, two of which are already in the clinic. And our first goal is to figure out which of the drugs is best suited for use with more highly myelosuppressive chemotherapies. And once that decision has been made, then pursue the inflammatory indications with the one that is best suited to inflammation, either alone or possibly with a partner.

Was the next question simply the question on the competition, or was there another question in between?

Solid versus liquid. I think the opportunities are excellent in both places. With the data that we have besides myelofibrosis right now is in pancreatic cancer with ruxolitinib, which happens to be a solid tumor. So we are certainly planning to pursue solid tumors with both ruxolitinib and in other cases with a JAK1 selective inhibitor.

But as we said we are starting a combination study with a JAK1 inhibitor with 40093, our PI3K delta inhibitor, because we believe there will be synergy in the clinic there. And there's no reason why the same drugs cannot be approved and developed and then approved for both solid tumors and liquid tumors, so we don't feel that there's a need to have separate molecules for both, and we plan to pursue both.

Paul Friedman - *Incyte Corporation - President and CEO*

Salveen, with respect to competition, we've always expected competition; our view is that competition is good for patients, it is good for the market. Ultimately, more patients will be treated with a JAK inhibitor, so the question really comes down to which product will they be treated with. That's a function of product profile. We absolutely convinced we have the best-in-class profile with Jakafi.

With respect to Gilead, having just started their Phase III, they're a long way off the market. If you look at the study design, they seem to be with a secondary endpoint looking at transfusion independence. From our point of view, cytopenia is a non=target affect with JAK1, JAK2 inhibition. It is predictable, it is manageable, and we think between now and when Gilead were to come to the market, cytopenia will be an issue that physicians are very comfortable dealing with through individualized dosing. With Jakafi.

Salveen Richter - *Canaccord Genuity - Analyst*

Thank you.

Operator

Thank you. Our next question is coming from the line of Rachel McMinn of Bank of America. Please proceed with your question.

Rachel McMinn - *BofA Merrill Lynch - Analyst*

Yes, thanks very much. A couple of questions.

One, Rich, I was hoping you could flesh out a little bit more helping to set expectations for your IDO inhibitor at ASCO. Are we looking for just a response in there? Would we have any PFS or overall survival data that we could begin to look at?

And then -- I don't know, either Rich or Paul -- if you could talk about the PV read through from Sanofi discontinuing their Phase II monotherapy study. I think that kind of spooked some people. I don't know if you have any futility analysis that was already built into your Phase III that you could speak to, that gives you confidence beyond just the obviously the strong data you have in the Phase I/II study?

And then lastly, how do we think about all of these studies with regards to 2014 R&D? It sounds like you're making a really big push in solid tumors, not surprisingly, but just want to make sure that we are well prepared to think about how model expenses next year? Thanks.

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

Okay. With respect to IDO, what we are going to likely present in 2014 are the results of an open label run in, where everyone is getting both our IDO inhibitor 24360 and ipilimumab. This is a dose escalation to find the proper doses for the randomized study that will be definitive. What we would expect to be able to show, based on what we are seeing now, are our response rates, the duration of maintaining therapy before they have to change to something else, likely as a result of progression; and how long those individuals are living. And we're fairly confident, based on the data that we have right now, that, that will compare favorably to historical controls with ipilimumab alone. And that is the basis of our level of excitement right now. But in terms of actually having robust data and comparison to ipilimumab alone, that will be coming in later years after we really get into the randomized portion of the study.

Now, with respect to PV, we have only read the brief statement in the Sanofi press release from yesterday saying that they've halted that study and plan on looking at combination therapy. We have no idea and we'd be interested in finding out (inaudible).

Rachel McMinn - *BofA Merrill Lynch - Analyst*

They said it doesn't live up to their internal expectations, was the comment that I understand. I'm assuming that's just a failure to have robust efficacy.

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

I don't know exactly what their issue is, and we will still try to find out more about that. But let me just talk about our place.

First of all, the PV data from the Phase II study 256 was just published online yesterday in Cancer. So that is out there for people to look at. Secondly, our registration study, the RESPONSE study, not only has been fully enrolled for almost a year, but all the patients are past the primary endpoint now; we just to wait for -- which is basically at 32 weeks; all patients need to have 48-week data before we then have last patient/last visit and look at the data. But we know from a pharmacovigilance perspective that there are no issues with the study in terms of safety, and we have no indications from the study that there will be a lack of efficacy.

I cannot imagine why the results would be particularly different from what we saw in Phase II, where we had like 97% of the patients become phlebotomy-independent; patients had profound reductions in spleen size, at least as measured by palpation. Patients demonstrated symptomatic improvement in that study. So we remain confident in our study, and are curious when eventually the data comes out from Sanofi as to where they ran into problems with their drug.

And with respect to R&D expense in 2014, I'll turn that over to Dave.

Dave Hastings - *Incyte Corporation - EVP and CFO*

Thanks, Rich.

I think, Rachel, you had it right; it is an aggressive plan, and rightly so. We are very confident and optimistic about our portfolio. I think it is pretty consistent with what we've said in the past, that the return on investment as we invest in our R&D pipeline is very strong. As I mentioned in my prepared remarks, we're in a strong financial position. We continue to focus on optimizing the capital structure of the Company as evidenced by the recent exchanges we performed. So I think we are in a good position to fund an increased R&D investment next year.

Rachel McMinn - *BofA Merrill Lynch - Analyst*

Thank you.

Operator

Our next question comes from the line of Matt Roden of UBS. Please proceed with your question.

Matt Roden - *UBS - Analyst*

Great. Thanks for taking my questions as well. Happy Halloween.

On the IDO program, can you talk about the evidence that suggests that this should be additive or synergistic with the checkpoint inhibitor? Just try to give us a sense for why you think this approach should work.

And then related, we all know that Charlie Sawyer has been pushing this idea that combinations of investigational agents in cancer should be pursued; but operationally, can you talk about the path forward in combining IDO with PD-1 or PD-L1 inhibitors? And if I may, a follow-up.

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

Okay. So first as I mentioned in response to an earlier question, just with respect to our drug and the checkpoint inhibitor ipilimumab which is a CTLA-4 inhibitor, we are seeing response rates, we are seeing how long patients are taking to progress, and we are seeing survival data that is early and small numbers, but looks to us quite different than the early data with ipilimumab monotherapy in similar patient populations. There's also animal models and in vitro data that suggests synergy between our drug and PD-1 inhibitors and PD-L1 inhibitors, but there's no clinical data there.

With respect to the logistics of how this can work, I think companies in several areas have now become much more amenable to working together at the investigational stage prior to the approval of either of the drugs. FDA is making that easier, to recognize the benefits in cancer as well. So we have started discussions with other companies, not to partner our program or to sell it to them, but to maintain the program ourselves while looking at combination therapies. I don't want to get into any specifics about that until things have matured, but right now we are reasonably optimistic that one or more studies might start next year in combination.

Matt Roden - *UBS - Analyst*

Okay, and then from the regulatory perspective, are they on board with the combinations as well?

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

So, we have had experience with FDA in terms of combinations of investigational drugs. At this stage, where we have no specific agreements with any company, no protocols have actually been submitted to FDA or other health authorities to say that those studies can go forward, other than the fact that -- not that ipilimumab isn't an approved drug -- but they had no issues with combining those; and that data will help us justify dose selection and other things for combinations with PD-1s, PD-L1s or whatever we end up doing. So I don't have specific FDA or other health authority feedback, but I don't think it is going to be a major problem.

Matt Roden - *UBS - Analyst*

Okay. Then, Rich, you also mentioned the JAK1/PI3 Kinase combinations, and I think you said B-cell lymphomas. Quite heterogeneous group here. Can you help us where you think this combination might be best applied, and the rationale for addressing those. particular subsets?

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

So, the first part of the study will look at a range of B-cell lymphomas as we try to establish the doses of the two drugs in combination and establish what safe combination can be looked at. That study may also give us further hints as to where we would likely focus in the future. Certainly with respect to either the more established or further along in development PI3K deltas or BTK inhibitors, there are their places where those drugs are active but we think there's a lot of room for improvement, either in terms of the number of responses or the duration of those responses. So that need for increased benefit is the key driver now, and I can tell you that our in vitro synergy studies suggest the potential for benefit in those same indications where you are seeing sub optimal benefit with either be BTK or another PI3K delta inhibitor.

Matt Roden - *UBS - Analyst*

Thanks for taking my questions, and congrats on the pipeline success.

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

Thank you.

Operator

Thank you. Our next question is from the line of Brian Abrahams with Wells Fargo Securities. Please proceed with your question.

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

Thanks for taking my question, and congratulations on all the progress on multiple fronts.

Question on the pancreatic study. I realize a lot of the data you're going to preserve for ASCO, but I was just wondering if you can give us any sense as to the number of pre-specified subgroups that you looked at? And maybe how the hypotheses that these were testing deferred or perhaps overlapped? And then can you give us any sense in terms of the bar for label expansion, potentially based on those three Phase II solid tumor studies that you're going to be running for ruxolitinib, given the overall survival endpoint there? Thanks.

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

Okay. With respect to the number of subgroup analyses we actually had, as we've said in the past, more than one and less than five pre-specified analyses based on the potential mechanism of action. There were other subgroup analyses that were routine, like age, gender, things like that, that were not included in the mix because those are just always there. And with respect to how those differed, I really would rather not go into what the other two or three or one additional subgroup analysis was, until such time as we actually present the data.

Now, with respect to -- I think your next question is about the Phase IIs and expectations from that. The studies are really designed not to be registration studies. But if the results are robust, and this time already backing up the same group that was identified in pancreatic cancer, I cannot say there's no possibility we couldn't go directly to a label expansion. But I think the expectation for the most part should be that these are Phase IIs which would then lead to larger Phase III registration studies in any of a number of these indications.

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

Thanks, Rich; and congrats again.

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

Thanks.

Operator

Thank you. Our next question is from the line of [Navit Singh] of Goldman Sachs. Please proceed with your question.

Navit Singh - *Goldman Sachs - Analyst*

Good morning and thanks for taking my question.

I understand you can't provide much color on the bio marker for Jakafi in solid tumors, given the competition. But when do you plan to release that information? And second, how confident are you that, that bio marker will resonate with the scientific community?

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

In terms of release of the information, it would certainly be no later than when we expect to present the data at ASCO. But we recognize that holding it out for that long may not either be possible or appropriate, depending upon what information seems to be leaking. Various other things that could come about, where we just feel obligated to do something. So I'm not going to put a specific timeline on it.

With respect to how well it is going to resonate, I think it is going to resonate, but I think that there are so few people out there that we've actually -- community-type oncologists, that sort of thing, that are aware of what's going on, that I don't have any data to support it one way or the other. Other than to say that it is consistent with the mechanism of action of JAK1 or JAK1 and 2 inhibition, and therefore it should not come across in any way as, oh, they just got lucky, they just found some random thing. I think that's the best I can put it at this point in time.

Navit Singh - *Goldman Sachs - Analyst*

Okay. And a quick follow-up on your JAK1 inhibitor. I noticed that you are evaluating the JAK1 inhibitor in Phase I trial in solid tumors. And I think that trail was initiated in June. When do you think we can get some data on that? Is ASCO 2014 realistic? Thanks.

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

It is hard to say exactly when we are going to present data from dose escalation Phase I studies, because you never know exactly how many cohorts you are going to end up doing before you reach the maximally tolerated dose. They are largely safety studies; and so, yes, certainly it is possible that there will be data out there, and there is more than one study going on with JAK1 inhibitors right now in solid tumors. There's the combination with gem and nab-paclitaxel as well as just a general solid tumor dose escalation study. So it is reasonable to expect that you will see something in 2014; but, for example if that was to be submitted to ASCO, that means submitting the data in the first quarter of 2014 and we are just not sure yet how robust that data set will be. So we don't want to make specific predictions and then not follow through on them.

Navit Singh - *Goldman Sachs - Analyst*

Okay, thanks, Rich, and congrats on the progress.

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

Great. Thanks.

Operator

Our next question comes from the line of Ying Wang of Barclays. Please proceed with your question.

Ying Wang - *Barclays Capital - Analyst*

Good morning. Thanks for taking my question.

I have two relating to the RECAP trial in pancreatic cancer. First one is, when you conducted this subgroup analysis did you spend any [alpha] in conducting the analysis? And then secondly, I'm sure Novartis has done a lot of looks into the data here. When do you think Novartis would opt in? And when is the latest timeframe they could do that?

And then on INCB39110, we just saw the data from ACR which looks pretty encouraging. But I'm not sure whether we see clear dosage (inaudible) amount of three lower doses; and we did see (inaudible) lipids elevation at 600 qd dose. I was wondering what your thought is in terms of taking this compound forward, which dose will you likely select? Thank you.

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

Okay, thanks.

First of all, in terms of prospective planning of this study, which was 120 patients, approximately. There was no pre-specified alpha control for subgroup analyses. However, if you do a Bonferroni correction, which is the most aggressive correction for multiple looks at subgroups, based on the two to four other groups, the statistics of the subgroup does held up with the corrected P-value still of less than 0.05.

So again, we don't see this as an issue of chance. We see this as a pretty clear finding that's also supported by the mechanism -- action makes sense as opposed to just the statistical rigor.

With respect to Novartis, they have no limitations as to when they can decide to opt in to a program. So we cannot speak to when they may or may not decide to do that. And with respect to the Phase II data of 39110 in RA, we agree there wasn't much of a dose response seen, other than with a 600-milligram dose. That was clearly -- I shouldn't say clearly -- which in this study was clearly better than the 100 BID, 200 BID and 300 qd. I think that you just would need larger numbers of patients to really be able to see that, as well as potentially studying a lower dose than either 100 BID or 300 once a day to really see the full view of that dose response.

With respect to lipids, all of the drugs that are being developed in the IL-6 space, the JAK space, as well as, to a lesser extent, other anti-inflammatory, increase LDL and HDL. And so far this has not been a problem for any of them. We're aware that Galapagos has put out data saying they don't increase lipids, but they actually do at the 300-milligram qd dose, which is one that they have said they are not going to take forward into Phase II. But clearly the effect is still there when you reach levels of inhibition of the JAK1 target, which is related to then inhibiting the signaling of IL-6. So I don't think there any exceptions to this mechanistic role.

Ying Wang - *Barclays Capital - Analyst*

That's fair. Thanks for the color. Very helpful.

Operator

Thank you. Our next question is from the line of Cory Kasimov of JPMorgan. Please proceed with your question.

Matt Lowe - *JPMorgan Chase & Co. - Analyst*

It's actually Matt Lowe, in for Cory today. You mentioned during [tarus] with the early data in the open label study for IDO. I was just wondering if you can characterize that at all, and what you're looking at in this study?

And then also at ASH, I believe you're going to present the 3-year survival data for Jakafi. I was wondering -- is there still a meaningful number of physicians who need to be convinced of your overall survival data? If you can comment on that, that would be great. Thanks.

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

Okay, I don't really have much more to say on the IDO plus ipilimumab that I've said before. But let me just reiterate the bottom line. So the things that we are looking at now in this small-dose escalation open label study is comparison to historical controls. And what we are seeing are response rates, the duration before someone has a progression event, and the duration that those patients are living, which we believe, compared to published data on ipilimumab monotherapy in melanoma are better.

But it is not a statistical comparison, it is not even a head-to-head comparison yet. It is a comparison to historical control based on a relatively small number of our patients compared to a larger number of patients in a Phase II and III studies with ipilimumab. But this, along with some of the pre-clinical data that suggests synergy between these things, gives us confidence that this is a real effect, and gives us our interest not only in following the study with ipilimumab, but with other checkpoint inhibitors including PD-1s and PD-L1s.

With respect to the impact of 3-year survival data, I will turn it over to Jim.

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

Yes, there is still a significant proportion of physicians who are not aware of the survival data with Jakafi. So certainly publication and scientific meetings is incrementally helpful. But alternately we think the major catalyst would be inclusion of the data in the package insert. And again, we are hopeful for that sometime next year.

Matt Lowe - *JPMorgan Chase & Co. - Analyst*

Okay, thank you.

Operator

Our next question is from the line of Eric Schmidt with Cowen and Company. Please proceed with your question.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks. Three questions --maybe first for Jim -- having a little trouble reconciling the unit volume growth -- 8% in the quarter down from 15% last quarter, given the comments you made about steady new starts, and maybe even increasing persistence. Maybe you could clarify that?

And for Rich, I think you indicated earlier that initial focus here with the JAKs in solid tumors is later lines of therapy? Is that based on some mechanistic rationale? Or is that just because that's where you were fortunate enough to get the first early read?

And then lastly for Dave, just wondering if you have tax planning strategies in place for some of these newer assets -- I guess the JAK1s in particular that you own the world-wide rights to.

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

This is Jim.

There is an actual rhythm to the business in terms of our demand pattern. If you remember, we did 7% dispensed bottles in the first quarter. We did 15% in the second quarter, 8% in the third quarter. And what you will find is typically the first quarter in oncology, particularly before orals, tends to be one which you got the wind in your face with respect to deductibles, donut hole, et cetera.

There's also an issue of the number of shipping days; and we had fewer shopping days first quarter. More shipping days second quarter. And the third quarter tends to be impacted more by, quite frankly, vacations, whether it be patients or physicians. There is a reluctance to put patients on new products during the summer period. And typically we see a relatively strong fourth quarter.

So that's the natural rhythm of the business. We would expect it to repeat this year. So that really is the explanation for the 7% to 15% and the 8%.

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

With respect to lines of therapy -- with respect to ruxolitinib we particularly looked for lines of therapy where the current treatment could include an option that was not very highly myelosuppressive. And that was the lead basis for making those decisions.

With respect to the JAK1s, that's been less of an issue, but it's still very hard to get directly into first-line therapy. I'm not saying we are starting each of our studies in last line, by any means. I'm saying that first line is hard to get to initially. And it just happens that, there are in some of these diseases at least, the percentage of patients who would fit into the category where we work very well in pancreatic cancer is a little bit higher in later lines, maybe because the prognosis is not that good in the first place.

But the number of patients who exist in first line is larger, so the total number of patients that might be available for treatment in the end could still be as large or larger in first line even if the percentages are little but lower. So that was not really a key decision-maker in how we selected our Phase II studies.

Dave Hastings - *Incyte Corporation - EVP and CFO*

And Eric, yes, we are working with our outside professional service providers on those strategies. In addition we are actively recruiting internally for a Tax Director who will lead that role. Of course I will remind you in the meantime we have a $1.3 billion NOL that can be utilized as well.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks a lot.

Operator

Our next question is from the line of David Friedman of Morgan Stanley. Please go ahead with your question.

David Friedman - *Morgan Stanley - Analyst*

Thanks for taking the question. Just wanted to get a sense of two things.

One is, of all of the Phase IIs, these randomized Phase IIs that are starting in lung and colorectal, what is the rough timeframe to get data from those? Is that 2015 or is that 2016?

And then the other question is just around some of the pre-clinical work that supports the tumors. And was wondering if you could just talk about what you've seen pre-clinically for pancreatic and how that is similar or different to what you see in lung or colorectal, but also prostate and myeloma, where you've had trials as well? Thanks.

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

Okay. We are not going to get specific about the timelines for the Phase IIs yet, in part because we have not selected centers yet for all these studies, haven't completed feasibility to determine how many patients might be enrolled per month or how many at each of those centers. The only thing I'd say is that these are pilot studies like the Phase II RECAP study; and the RECAP study; from start to finish was about 2 years. So I think, assuming we start in first half of 2014 with some of these studies, I think seeing data in 2015 is optimistic, and seeing data in 2016 is quite reasonable at this early stage of evaluation.

With respect to the pre-clinical work, I would really suggest that we have a follow-up call with you and the scientists who have done that work, because I don't have all the information at hand to go into detail, other than to say that there were clear pre-clinical models suggesting benefit in terms of pancreatic cancer; and some of the other tumors have been well studied and have similar results. But that's not directly my line of responsibility, and I don't have that information at hand today.

David Friedman - *Morgan Stanley - Analyst*

Okay. Thanks.

Operator

Thank you. Our next question is with the Liisa Bayko of JMP. Please proceed with your question.

Drew Purgotic - *JMP Securities - Analyst*

This is [Drew Purgotic] for Liisa. I had a couple questions for you.

One is, if you can talk a little bit about how the choices were made for the solid tumors you are developing first, including colorectal and breast? And second question is, where in the inflammation space you see the best opportunity for a JAK1-specific inhibitor?

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

Okay. So in terms of the choices with respect to ruxolitinib, which is the place where we already have clear proof of concept in pancreatic cancer. We will looking for major solid tumors and the ones that we announced that we are doing -- lung, colon, and breast are major solid tumors -- but also where there was an opportunity to combine with something that was not very highly myelosuppressive.

And with respect to the JAK1 inhibitor at this stage, again the first thing is to try to reproduce the RECAP results of the JAK1 inhibitor; and the second, in non-small cell, is because it is a very large opportunity -- large unmet need -- along with similar levels of evidence that this mechanism should work in these patients; and about 50% of the patients would qualify into the subgroup that we think we work best in.

With respect to choices in inflammation -- this is really -- a couple things I would say. One is that one of the potential benefits of the selective JAK1 inhibitor is to go to levels of inhibition that you cannot get to necessarily with a JAK1 and 2 inhibitor, because at that point you would start to get into myelosuppression.

And so there are certain diseases -- psoriasis being one, but certainly not the only one, but place where we have data -- where the data suggest that you do want higher levels of inhibition that is necessary for maximal effect and something like rheumatoid arthritis. But obviously, something like rheumatoid arthritis is a very large opportunity and nothing to be dismissed of out of hand. So we have not decided exactly what we would do in terms of this. Our main priority right now is figuring out which molecule would go for inflammation. And if we decide to partner the program, then our partner would also have a lot of influence probably on the choices that would be made in terms of which indication's first and which indications would come later.

Drew Purgotic - *JMP Securities - Analyst*

Thank you.

Operator

Our next question is from Skip Fine with (inaudible) Capital Advisors. Please proceed with your question.

Skip Fine - - *Analyst*

Maybe I should start by trying to soften you up by sincerely thanking you for all the good progress and execution. In sales, balance sheet, clinical front -- there's a lot going on, and you guys are really executing.

So then on to the question. I guess it is really for Jim. I'm working on a triangulation that he suggested, and I'm not sure, Jim, whether you know that I answer to a higher authority. There' s some ladies that play mah-jongg who are big fans of Doctor Friedman, and they honestly pester me more than I've ever been pestered in my investor life.

And here's what I've told them, and I guess I'm just wondering whether you could tell me whether I'm in line or out of line. I've told them that the Company has treated about 5,700 patients in myelofibrosis out of about a 12,000 available population. I'm telling them you have about 3300 on therapy. You're adding about 120 to 125 patients a month on a net basis.

So I'm telling them you're about halfway through the MF opportunity; PV is to follow, and is a bigger available patient population. And telling them I have peak sales in 2025 and they remind me that they are not going to be alive then, but I tell them it is going to be $1.8 billion in peak sales at that point, with a pancreatic probability of technical success of about 60% to 70%. So that's a lot, but am I roughly in line? Because these ladies -- I don't really want to embarrass my mother, and they play mah-jongg with her.

Eric Siegel - *Incyte Corporation - EVP, General Counsel*

Skip, we haven't been that precise in communicating our patient numbers. But I think you may be misleading the ladies with respect to the total addressable population. Again, we see an addressable population of basically 85% of the total MF population of 16,000 to 18,000. So let's call that 15,000 patients. You can segment them pretty much into three groups -- high risk, 5000; intermediate 2, 5000; intermediate 1, 5,000.

To date, I'd say we have less than, considerably less than 5,700 patients who have [touched drug] for MF. So the way we are looking at it, we are probably in the third inning -- third or fourth inning with respect to our MF game. I think we are in a good position to be almost 2 years into launch and we are still characterizing our growth in terms of sequential quarter over quarter.

Most oncology products experience a relatively rapid peak and then a plateau, and they are often talking about year-over-year growth rate at this point. We are still talking about double-digit sequential quarter-over-quarter growth, and I think that's because of the nature of the disease. It is a heterogeneous disease with a spectrum of severity, and it is also managed by community physicians. And when you have a low-prevalent disease manage by community oncologists, it takes them some time to get comfortable with a new therapy and a disease they don't see that often. I think we're seeing that with a solid consistent growth with Jakafi. But I think we have a lot of growth ahead of us with Jakafi in MF.

Skip Fine - - *Analyst*

Great. And then I greatly appreciate your handling the fact that I was high on the treated patients. How about 3,300 on therapy and adding about 120 a month? Because this one lady that kind of focuses on that.

Eric Siegel - *Incyte Corporation - EVP, General Counsel*

Yes, I don't want to get into the new adds per month. What I can say is that's been relatively consistent. If you look at the number of patients who are on therapy, I would just suggest you really use your calculator. If we have $60 million in net sales for the third quarter, and right now we realize about $7,600, assume 8% discount off the list of $8,300; and then divide by 3 months -- you will get closer to about 2,600 to 2,700 patients on therapy.

Skip Fine - - *Analyst*

Okay. Thank you very much. And I guess the most important is peak sales, but I guess I can't expect anyone really to comment on that. But is that way out of line as things go right, to think that peak sales could be $1.5 billion to $2 billion for Ruxo?

Eric Siegel - *Incyte Corporation - EVP, General Counsel*

Well, I wouldn't want to comment on anything outside of MPNs, but I think as we've said in the past, we see Jakafi being a $0.5 billion opportunity in MF. And we see the PV opportunity being at least as big if not bigger than the MF opportunity. Then obviously the programs that Rich has discussed -- that's all incremental.

Skip Fine - - *Analyst*

Great. Thank you very much.

Operator

Thank you. We are nearing the end of our question and answer session and time for one final question. That will be a follow-up from the line of Matt Roden with UBS. Please proceed with your question.

Matt Roden - *UBS - Analyst*

Actually it is been answered. Thank you very much.

Operator

Thank you. I will not turn the floor back to Management for closing comments.

Paul Friedman - *Incyte Corporation - President and CEO*

This is Paul.

Thank you all for dialing in and for the dialogue we had this morning. I think we are making really good progress and the Company looks forward to our next quarterly call. With that, I will be signed off. Goodbye.

Operator

This concludes today's teleconference.