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INCY - Q1 2015 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 1Q15 YoverY total revenue growth of 77%.

CORPORATE PARTICIPANTS

Michael Booth *Incyte Corporation - VP of IR*

Herve Hoppenot *Incyte Corporation - CEO*

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

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

Dave Gryska *Incyte Corporation - CFO*

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

CONFERENCE CALL PARTICIPANTS

Cory Kasimov *JPMorgan - Analyst*

Salveen Richter *Canaccord Genuity - Analyst*

Matt Roden *UBS - Analyst*

Steve Byrne *BofA Merrill Lynch - Analyst*

Michael Schmidt *Leerink Partners - Analyst*

Ian Somaiya *Nomura Securities Co., Ltd. - Analyst*

Eric Schmidt *Cowen and Company - Analyst*

Masha Chapman *JMP Securities - Analyst*

PRESENTATION

Operator

Greetings, and welcome to the Incyte Corporation first-quarter 2015 earnings conference call.

(Operator Instructions)

As a reminder, this conference is being recorded. It is now my pleasure to introduce your host, Michael Booth, Vice President, Investor Relations. Thank you, sir, you may begin.

Michael Booth - *Incyte Corporation - VP of IR*

Thank you, Jessie. Good morning, and welcome to Incyte's first-quarter 2015 results conference call.

Herve Hoppenot, our CEO, will begin with a few words summarizing our recent accomplishments; and Jim Daly, who leads our commercial organization, will then provide a commercial update on Jakafi. Rich Levy, who is in charge of Incyte's drug development activities, will update you on our clinical portfolio; and Dave Gryska, our CFO, will describe our first-quarter financial results. We will, then, open up the call for Q&A, for which we will be joined by Reid Huber, our Chief Scientific Officer.

On the call today, we will be discussing Jakafi, which is FDA approved for patients for intermediate- or high-risk myelofibrosis and for patients with polycythemia vera who have had an inadequate response to, or are intolerant of, hydroxyurea.

In addition, we would like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for the commercialization of Jakafi, our development plans for Jakafi in other indications, and for other

compounds in our pipeline, and our planned European expansion. 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-K for the year ended December 31, 2014, and from time to time in our other SEC documents.

Herve?

Herve Hoppenot - *Incyte Corporation - CEO*

Thank you, Mike. Good morning, everyone. We have had a very productive start to 2015, and I will just briefly summarize some of the highlights. Firstly, ruxolitinib sales in the US and the rest of the world are growing very well, reaching a growth rate above 60% in Q1 on a year-on-year basis. We also received a $25-million milestone payment from Novartis during the quarter, related to the European approval of Jakavi for PV, and we are very pleased, also, that the Phase III RESPONSE trial of ruxolitinib in patients with PV was published in the New England Journal of Medicine.

Now, turning to baricitinib, during the first quarter, we announced with Lilly the successful outcome of the second consecutive Phase III trial of baricitinib in rheumatoid arthritis. And, for epacadostat, our IDO1 inhibitor, we continue to progress very well with our combination studies in multiple tumor types.

During the first quarter, we finalized our immuno-oncology alliance with Agenus, which adds therapeutic antibody capability to our proven small-molecule discovery expertise. It also expands the landscape of potential immuno-oncology targets available to us, and it strengthens our ability to identify and possibly advance novel therapeutic combinations. Such novel therapeutic combinations were also the subject of our presentations last week at the AACR conference where we presented 11 abstracts. As well as highlighting the FGFR, BRD, and PIM inhibitors from our discovery research, these abstracts also included data on the potential immuno-therapeutic activity of our portfolio of JAK and PI3K delta inhibitors.

Also, we announced an important step in our corporate evolution, just a couple of weeks ago, with our intention to establish our European headquarters in Geneva, Switzerland. Incyte Europe will become the base from which we will conduct our European clinical development operations, and we are excited to begin to build our Company outside of the US.

Of course, a primary driver of our financial performance is revenue from Jakafi here in the US. I will now pass to Jim to give some additional details on the strong commercial performance of Jakafi in MF and the launch progress in PV. Jim?

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

Thank you, Herve. Good morning, everyone. With 2015 marking our fourth full calendar year post launch, first-quarter net product revenues of Jakafi reached $115 million. This represents an annual growth rate of 66% over the first quarter of 2014 and was driven by steady growth and underlying demand in MF, coupled with a meaningful contribution from our newly launched indication in PV.

On a quarter-over-quarter basis, net sales grew 9% with the following components of change relative to the prior quarter. Underlying demand as measured by bottles dispensed to patients grew 8%. Net price declined by 3%, reflecting a temporary increase in gross-to-net discounts driven largely by seasonal increases in Medicare Part D donut-hole rebates, partially offset by a 4.75% list price increase taken in early March. Inventory had a 4% positive relative impact, with weeks on hand increasing from the lower end of the normal range of 3 to 3.5 weeks at the end of the fourth quarter, to the middle of the normal range at the end of the first quarter.

Breadth and depth of prescribing in MF continues to grow in a consistent manner, with continued benefit from the overall survival data and updated safety and dosing information that was incorporated into the product label in the second half of 2014, which we believe is driving new patient starts.

While we will be providing more detailed overview of the PV launch performance -- based upon six months of findings -- on the second-quarter call, at this point, we can confirm that the launch is proceeding as planned, and we are pleased with early trends and performance indicators. We are already seeing some patients, who have received samples, transition to commercial supply. And, based upon early feedback from both physicians and patients, the product appears to be performing well and meeting or exceeding expectations.

We believe this foundation of successful early trial should enable us to continue to expand breadth and depth of prescribing over time, and to enable us to positively impact a significant proportion of the estimated 25,000 PV patients who have had an inadequate response to or intolerant of hydroxyurea.

On the reimbursement front, most of the large payers have made coverage decisions and are managing to the PV label. And patients are able to access the product in a timely manner, with reasonable out-of-pocket costs. Looking forward in PV, our primary opportunity and challenge is to reinforce with physicians the medical imperative to improve PV management, and to translate the Jakafi prescribing information and Phase III clinical data into appropriate and specific PV patients in their practices who require additional disease control.

We look forward to providing you with additional detail on our progress on the second-quarter call. With that, I'll turn it to over to Rich to give us a clinical update.

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

Thanks, Jim. 2015 has begun very well for the development group. We've significantly expanded our clinical portfolio, and our key projects are moving forward. We've also hired Dr. Steven Stein as our new Chief Medical Officer. Steven came to us from Novartis where he was Senior Vice President of Novartis Oncology in the US. He's already making key contributions to the development of our clinical portfolio.

I'll now walk you through the key pipeline updates beginning with the pivotal programs. During the first quarter, we announced, with Lilly, that the second pivotal Phase III trial of baricitinib in rheumatoid arthritis, the RA-BUILD trial, met its primary endpoint. With Lilly, we look forward to presenting these data, as well as those from the RA-BEACON study, at an upcoming scientific meeting. We also look forward to results from the additional two Phase III studies later in 2015.

We also continued to make good progress in the pivotal program for ruxolitinib in second-line pancreatic cancer. As a reminder, given our previous discussions with the FDA during the SPA process, we believe that, if results of JANUS 1 are sufficiently robust, it could support registration. We have, therefore, prioritized enrollment into JANUS 1 over enrollment into JANUS 2 by allocating the faster recruiting sites to the JANUS 1 trial. Recruitment to JANUS 1 is, therefore, running ahead of JANUS 2, and while we continue to expect data from JANUS 1 in 2016, results from JANUS 2 are now expected at a later date.

Moving now to epacadostat, our IDO1 inhibitor, recruitment into all four of the Phase I/II trials in epacadostat in the either anti PD-1 or PDL-1 therapies from Merck, BMS, AstraZeneca, or Genentech is progressing well. Once we've determined the doses to be used in each combination, we expect enrollment in the expansion cohorts to be rapid. If these trials generate positive proof-of-concept data, we would anticipate moving swiftly into potential registration studies.

Recruitment into the Phase II studies of ruxolitinib in colorectal and breast cancer is as expected, and these trials remain on track for data in 2016. Because of competition in lung cancer patients with immuno-oncology therapies, recruitment of the Phase III trial of ruxolitinib in lung cancer is somewhat behind our expectations at this time.

Moving to compounds in our emerging portfolio, we've initiated clinical development of INCB54828, our FGFR inhibitor. And, later in the second quarter, we're on track to initiate clinical development of INCB54329, our bromodomain inhibitor, which has already cleared the IND process. We presented full characterizations of these two molecules, along with the science, strategy, and data behind our emerging pipeline for potential cancer therapies, at the recent AACR annual meeting.

Looking now to ASCO, in our view, the key data from Incyte will be from the trial of our PI3K delta inhibitor, 40093, in combination with our JAK1-selective inhibitor, 39110. We will be presenting both 40093 mono-therapy and combination data with 39110 in the treatment of Hodgkin's lymphoma, as well as safety and summary efficacy data in other B-cell malignancies. We look forward to discussing these data after they have been presented at ASCO.

With that, I'll now turn the call over to Dave to give us the financial highlights of the quarter.

Dave Gryska - *Incyte Corporation - CFO*

Thanks, Rich. Good morning, everybody. We recorded $115 million of first-quarter net product revenues and $16 million in Jakavi royalties from Novartis for sales outside the United States. We also received $25 million in milestone payments related to the European approval of Jakavi for PV.

Our total revenue grew at 77% in the first quarter of 2015 over the first quarter of 2014. This compares well with the 47% growth in total operating expenses that we reported over same the period.

Our cost of product revenues of $3 million for the first quarter includes the payment of royalties to Novartis on Jakafi sales. For the first quarter of 2015, R&D expense was $118 million, and this includes a $20.2-million one-time payment to Agenus related to our immuno-oncology alliance. SG&A expense was $44 million in the first quarter. And we ended the quarter with $585 million of cash and cash equivalents.

During the first quarter of 2015, we moved the ex-US intellectual property rights of our early-stage assets to our newly formed subsidiary in Geneva, Switzerland. Subsequent to the end of the quarter, some holders of our 2015 convertible notes converted a total of $46.9 million in aggregate principal amount. This was converted into shares of our common stock, aggregating 5.3 million shares. At April 30, our total common shares outstanding are 179 million.

Operator, that concludes our formal remarks. Please open up the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator instructions)

Our first question is coming from the line of Cory Kasimov with JPMorgan. Please proceed with your question

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Cory Kasimov - *JPMorgan - Analyst*

I have two of them for you. First of all, Jim, I realize we'll get a more detailed update on PV this summer, but thus far in the launch are you able to comment on what you see as the key gating factor to get a doc to initiate treatment, and how you think that might change going forward? Then the second question I have is probably for Dave. It's on the longer-term tax rate for the Company and how that might be impacted by your new European operations? I'm just curious, outer years, how we should be thinking about that? Thanks a lot

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

Hey, Cory, this is Jim. Cory, I think the key gating factor to getting a physician to prescribe Jakafi for their PV patients is translating the clinical data and the indications statement in the label to a specific patient in their practice. I want to give a hat's off to our sales force, because quite frankly, it is -- there's no substitute for an effective sales force in accomplishing that. Because it requires a discussion with the physician of particular patient characteristics, and they're doing an outstanding job.

As you would expect, the patients that we're getting right now tend to be the "and" patients. These are patients who tend to have elevated counts and substantial symptom burden and they tend to be at risk for thrombosis. The sales force is having that constructive discussion. They're able to identify that patient as an appropriate candidate for Jakafi. The results are positive. With that successful experience, they earn the right to go back and ask for other additional patients, who may not be as obvious, may not be the "and" patient but maybe the "or" patient.

I think that process is taking place. I think our sales force is doing an outstanding job. There is no substitute for an effective sales force in achieving that gating event. As we look at new patient starts on a weekly basis, we're pleased and it's very consistent with our expectations.

Dave Gryska - *Incyte Corporation - CFO*

Cory, this is Dave. On your second question, we have no long-term guidance at this time on the tax rate. We're still working on other strategies, and we'll update you at a later point on that

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Cory Kasimov - *JPMorgan - Analyst*

Okay. Understood, thank you.

Operator

Thank you. Our next question can coming from the line of Salveen Richter with Sun Trust. Please proceed with your question.

Salveen Richter - *Canaccord Genuity - Analyst*

Thanks for taking my questions. Just with respect to physician education for PV, do you see any difficulties translating the spleen response into patient benefit? I think there was a question in the New England Journal of Medicine. Then a second question on the JANUS trials, just wondering if there was an FDA input as to why JANUS 1 would be sufficient for approval here? Are the PRO feedback just not required here? Thanks.

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

Yes, with response to splenomegaly, some of the early patients that are going on Jakafi do tend to have enlarged spleens. We see that becoming less important as trigger to treat over time. At this point, we're not seeing that as a barrier to identifying new patients for Jakafi.

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

Salveen, your second question, when we first were in discussions with FDA during the SPA period, going back about a year and a half, it was clear that if the results were robust in JANUS 1 that would be all that was necessary. JANUS 2 was designed in case the results weren't as robust as we expected. When I say robust, there's no specific definition of what that means, but the expectation is clear that if we were even close to the data that we saw in the RECAP study, that would be a robust study. So we just have to wait and see on that.

With respect to the PRO that's in JANUS 2 and not in JANUS 1, that's still only an exploratory endpoint in JANUS 2 and would have no impact on approval. That was there to demonstrate that that tool was "fit for purpose", as they say in regulatory terminology these days, to potentially be used in an additional study at later point to get a label and claim based on symptoms, so that has no impact on the potential for approval.

Salveen Richter - *Canaccord Genuity - Analyst*

Helpful, thank you.

Operator

Thank you. Our next question is coming from the line of Matt Roden with UBS. Please proceed with your question.

Matt Roden - *UBS - Analyst*

Jim, I wanted to ask you about the sustainability of the current run rate for Jakafi? I'm tempted to infer from the components of growth that you broke out in your prepared comments that this trend, in fact, is sustainable, possibly even with an upside because of the donut hole here. Also just wanted to get a sense for -- the inventory, you mentioned, has climbed up into the normal range. It sounds like there should not, then, be a give back in the second quarter? Then related, Jim, can you comment on what percentage of the sales in the quarter came from PV and whether or not there's any evidence of a bolus of patients coming on that may impact sequential trends later this year?

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

Let's knock those off. First, let's start with the last, because I remember that most vividly. No bolus of patients with PV. We should not see an inventory give back in the second quarter. If you look at the sustainability of the trends, there is a natural seasonality to our business. If you look at the last two years, we had single-digit dispense growth in the first quarter for both 2014 and 2013, followed by robust double digit in the second quarter. Not making a forward-projecting statement, but I would bet the trend on that. We are very confident that we can maintain a robust growth trajectory for Jakafi both in MF, and you'll see the compounding effect of our success in PV over time.

Matt Roden - *UBS - Analyst*

So in the absence of a real bolus - I mean, it sounds like you've definitely got patients on drug in PV, but this is something you would see as more of a slow and steady gain as opposed to a step up and then sideways?

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

Absolutely, no step changes with PV. PV is -- you have to go out and earn it everyday, patient by patient, and we're doing that. Again, based on very early data, we're pleased with the rate of new patients going on for PV. We're also pleased with the fact that, again based on very early data, that they seem to be staying on Jakafi in PV to a greater extent than what we saw with MF. We think this is a slow, steady build that will compound very nicely over time

Matt Roden - *UBS - Analyst*

Great. Then, if I may do a quick question for Rich here? You have the IDO and Yervoy combination data. If I'm not mistaken, that's to be presented at ESMO. We understand that this combo with Yervoy isn't strategically as important to you, but can you give us a sense of what we may expect to learn from those data about IDO itself?

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

The number of patients from which we'll have data as ESMO is about twice the number that we had data when the data was first presented at ASCO last year. Secondly, the duration of therapy in the patients who have been on therapy for a while, is longer. That's all I really feel comfortable saying about the data at this point in time. And I don't really know how to answer the question as to how you would translate the data in combination with Yervoy to expectations around the data with PD-1s or PDL-1s other than to say that we're seeing that this is an active drug in immuno oncology in combination with Yervoy and that gives us confidence, the same way as it has before, that we will see that it remains active and adds benefit to other immuno oncology combinations, including PD-1s and PDL-1s.

Matt Roden - *UBS - Analyst*

Thanks, Rich, and thanks for taking the question.

Operator

Thank you. Our next question is coming from the line of Steve Byrne with Bank of America Merrill Lynch. Please proceed with your question.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Jim, with respect to the results in MF, looks like maybe you're in the near 30% penetration or something in that range. Would you say that, looking forward, that the opportunity is more to drive up that percentage of patients within the oncology community or do you think that there's more opportunity by reaching docs that are currently not using rux in their MF patients?

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

That's a very fair question and I hate to sound like I'm hedging, but I think the answer is both. I think with the overall survival data inclusion in the label, we saw an increase in both the breadth and depth of prescribing. We saw physicians who had never prescribed the product begin to trial and adopt, and we saw greater depth of prescribing. Now with the second indication in PV, we're actually seeing physicians going back and evaluating some of their watch-and-wait MF patients and some of the later adopter physicians seeing that as a motivation to initiate their first patient in MF. Actually, as you look at the prescribing for PV, 25% of prescribers in PV had never prescribed the product before in MF. With positive experience in PV, we think there may be a halo effect for them to go back and use the product in MF. I think we're optimistic that we can see an expansion in both breadth and depth in MF going forward.

Steve Byrne - *BofA Merrill Lynch - Analyst*

And is the doc feedback so far in PV suggests support for that prior estimate of 25% of PV patients who could be eligible for Jakafi, is that -- do you still feel comfortable with that?

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

I think we feel more confident in that estimate today than we did last year when we communicated it. The patients are definitely there, without a doubt, and it's simply a matter of establishing successful trial, making sure the physician and the patient has a positive experience and then asking for the next patient.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Then, just one for either Reid or Rich, and that is based on the data that you presented last week on the mechanism of action of rux, specifically on effector and suppressor cells, do you see the longer-term opportunity in combinations with other specific therapies, I would say in contrast to the JANUS studies, which are simply an add-on to Capecitabine? Where do you see that opportunity longer term?

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

This is Reid, Steve. I think we've always been interested in exploring the JAK inhibitor franchise we have in combination with both cytotoxic chemotherapy as well as targeted therapies. But biology, I think, has instructed us pretty well over the years that there's a clear opportunity for

JAK-STAT pathway inhibition to augment and improve the effectiveness of both of those agents. You're asking quite different clinical questions, and you're talking about different patient populations, but I think as you see in the emerging solid tumor development program and as you'll see going forward in the development program with new studies starting over the rest of this year, this will continue to be two important themes that we'll emphasize, targeted combinations as well as combinations with cytotoxics.

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

Just to add to that, we're studying both. We have clinical data with Jakafi added to Capecitabine and emerging data with other agents, both targeted outside of immuno oncology as well as other cytotoxic agents. We have very interesting pre-clinical data suggesting that it will work in combination with immuno therapies, but we need to first start exploring that data in the clinic before we can really make prioritization decisions

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Steve Byrne - *BofA Merrill Lynch - Analyst*

Okay, thank you.

Operator

Thank you. Our next question is coming from the line of Michael Schmidt with Leerink. Please proceed with your question.

Michael Schmidt - *Leerink Partners - Analyst*

Good morning and thanks for taking my question. I had one regarding your comment on the IDO PD-1 inhibitor combination studies. You said you may go directly into pivotal studies following the ongoing Phase I/II trials. I'm just wondering in the context of the evolving PD-1 inhibitor landscape and some indications, in particular in lung cancer, and with some of your partners such as Roche and Bristol, now, also working their own idea? I was just wondering if you could just talk about your overall strategy with regards to accessing a PD-1 inhibitor, either A, are continuing to broadly look at this in on-indication basis, in respect of this specific PD-1 antibody, or are you actually evaluating a possible -- pursuing a specific PD-1 antibody in the future as opposed to a broader scheme? Thanks.

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

We believe we have an IDO1 inhibitor that has no issues with it and that is pretty far ahead of the competitive IDO inhibitors there are going to follow. And that is the reason why we continue to move forward, quickly, to maintain our advantage in terms of timelines, which is critical. Our strategy remains to work with a range of drugs, not just across companies with different PD-1s and PDL-1s, but also potentially to look at other combinations as well and not to have those decisions be driven by the potential that other IDO inhibitors that are further behind are going to be either licensed to or available to some of the same companies that we've been working with.

Michael Schmidt - *Leerink Partners - Analyst*

Okay, great, thank you.

Operator

Thank you.

(Operator Instructions)

Our next question is coming from the line of Ian Somaiya with Nomura Securities. Please proceed with your question.

Ian Somaiya - *Nomura Securities Co., Ltd. - Analyst*

Congratulations on a great quarter. My question relates to the Galapagos and AbbVie Phase II results in RA. I was just hoping to get your thoughts on the data we've seen from their compound and how we should think about a selective JAK1 inhibitor versus more of a JAK1 tumor friendly based on the efficacy profile we should expect for baricitinib?

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

Sure, so I'm not going to try to get in to and dissect the limited details that have been put in the public domain on the Galapagos results in DARWIN 1 and DARWIN 2. All I would say is that at this point we don't see any types of strong evidence for differentiation between that product and baricitinib, which is several years ahead. We look forward to sharing the Phase III baricitinib data with everyone in more detail soon.

Ian Somaiya - *Nomura Securities Co., Ltd. - Analyst*

This doesn't motivate you in any way to maybe evaluate some of your JAK1 inhibitors in the RA setting or autoimmune setting?

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

Our JAK1 since we've put 39110 into a relatively small three-month study and showed quite interesting results, but we decided the 39110 was going to be an oncology drug. We then took a second JAK1 inhibitor and put it into the clinic for RA and had a tox finding that wasn't necessarily drug related but one that made the development more difficult. So now we'd be talking, potentially, about another JAK inhibitor that's even further behind, and so you need to look not only at JAK1 versus JAK1/2 but also the timelines to bring forth another JAK1 inhibitor into this competitive space at this time.

Ian Somaiya - *Nomura Securities Co., Ltd. - Analyst*

Okay. If I may, just one other question I had. Just some of the increased productivity we're seeing on the R& D side, is that a function of new process, new personnel or just a willingness to invest in your pipeline drugs?

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

I think we've always been highly productive, but the size and scope that we have available to do as many projects as we're doing, just -- pound for pound, I'm not sure that we're any stronger than we were before, but we've always been strong. We're building and we're building with the same quality of excellent people that we've had in the past to be able to maintain, not only how rapidly we've progressed things but to put in strong, strategic thinking into what we do, so that we're not having to redo our plans on a constant basis. So I'm very pleased with the growth of the development organization, and as I said in my prepared remarks, really happy to have Steven Stein with us to lead the clinical group.

Ian Somaiya - *Nomura Securities Co., Ltd. - Analyst*

Okay. Thank you very much.

Operator

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

Eric Schmidt - *Cowen and Company - Analyst*

One quick question left for Rich. It's on ruxolitinib and the lung cancer trial. You've been saying that it's been slow to enroll now for a couple months, and obviously, the PD-1 aren't going away. Do you need to rejigger the protocol there or what are your plans for trying to accelerate and execute in the day and age where there's so many ongoing changes in the IO space?

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

Right. It's an ongoing process to evaluate what the next steps should be. And being realistic not only about the competition for enrollments in the studies but the changing landscape over the way lung cancer is likely to be treated by the time these studies read out, so we're continuing to look at that, but we don't have anything specific to say at this point in time.

Herve Hoppenot - *Incyte Corporation - CEO*

I think it's important to realize the field we are operating in, in cancer for certain indications is moving extremely fast with big steps happening with some new strategies. So the idea that in general there will be changes in direction, depending on how data are emerging from other strategies, something we have to live with now for the next 10 years. In general, what we see in lung cancer, where there was a sort of a transition for 20 years of taxol/carbo followed by gemcitabine or something like that, is changing completely as we are, at the same time, developing our own portfolio. Obviously, it is going to challenge as the standard of care is evolving. And it's not only true in lung cancer, I think there are a number of tumor types where we see the immuno-oncology wave being very successful very rapidly where we would observe the same type of things. I don't think there should be any surprise that there are some of our programs that are going to change directions. It could be the case depending on what we see in our early data there, but in general it's something we need to get used to for the future.

Michael Booth - *Incyte Corporation - VP of IR*

Jessie, the next question, please.

Operator

Yes, we'll move onto our next question, which is coming from the line of Liisa Bayko with JMP Securities. Please proceed with your question.

Masha Chapman - *JMP Securities - Analyst*

This is Masha for Liisa. Question for Rich. Can you, please, discuss rationale for evaluating a lower dose of JAK1 inhibitor in first-line pancreatic? I guess more specifically, do you have any additional data on what side effects or reasons for patients discontinuing? Is that a function of chemo? What are the implications for evaluating 110 in other solid tumors? Thank you.

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

Okay. First, in terms of the dose, as I've said previously, we saw a higher than expected discontinuation rate in first-line pancreatic cancer patients in the expansion of the existing study in months two, three and four. And we could not find any pattern among them. I don't think there were necessarily any two reasons for discontinuation that were the same and none of them appeared to me to necessarily be related to the drug and necessarily be related to the dose.

That said, because the discontinuation rate was higher than we expected, we didn't want to go into a large registration study taking the risk that the discontinuation rate early was going to inhibit our ability to see a positive result in the end. So, we had essentially two choices, one was to just get more patients at the dose that we've already been studying or to study a lower dose, or potentially we could have continued to do both. But we wanted to be not so exhaustive in what we did such that we would be adding too much time to this, so we decided that let's look at a lower dose, a dose that should still provide levels of JAK1 inhibition as high or higher than ruxolitinib provides in the positive RECAP study analysis. We feel comfortable with that lower dose.

With respect to whether this has any impact on our JAK1 in terms of other solid tumor combinations, I don't think that it does. I think that we don't even know that this has anything to do with the JAK1. We don't know that it has anything to do with the combination with gemcitabine and Abraxane, and we don't even know that this just isn't because the numbers of patients was relatively small in this lead-in to just by chance get a higher discontinuation rate. We're being prudent but I wouldn't look at as impacting anything else.

Masha Chapman - *JMP Securities - Analyst*

Thank you.

Operator

Thank you. It appears we have no further questions at this time. I would like to turn the floor back over to Herve for any additional concluding comments.

Herve Hoppenot - *Incyte Corporation - CEO*

Thank you. And thank you, all, for your time today. As we said at the beginning, I think it was a very successful first quarter with a fast-growing top line. As you heard, also, a fast expanding portfolio of clinical projects. We are looking forward to a series of important and exciting events over the next several months, and I just want to thank you for your time on the call today. We look forward to talking to you at the second-quarter conference call in early August. Thank you.

Operator

Ladies and gentlemen, this does conclude today's teleconference. We thank you for your participation, and you may disconnect your lines at this time.
