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INCY - Q3 2019 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 3Q19 total revenues of $552m.

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PRESENTATION

Operator

Greetings, and welcome to Incyte Corp.'s Third Quarter 2019 Financial Results Conference Call. (Operator Instructions) As a reminder, this conference is being recorded. I would now like to turn the conference over to your host, Mike Booth, Head of Investor Relations. Please go ahead.

Michael Booth - *Incyte Corporation - Divisional VP of IR & Corporate Social Responsibility*

Thank you, Brock. Good morning, and welcome to Incyte's Third Quarter 2019 Earnings Conference Call and Webcast. The slides used today are available for download on the Investor section of incyte.com.

I'm joined on the call today by Hervé, Barry, Steven and Christiana, who will deliver our prepared remarks, and by Dash, who will join us for the Q&A session. (Operator Instructions)

Before we begin, however, I'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 2019 guidance, the commercialization of our products and our development plans for the compounds in our pipeline as well as the development plans of our collaboration partners. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended June 30, 2019, and from time to time in our other SEC documents.

We'll now begin the call with Hervé.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Thank you, Mike, and good morning, everyone. Incyte continues to execute well across all aspects of the business. We have delivered multiple positive updates from our late-stage portfolio in recent weeks, and our product and royalty revenues continue to grow at a remarkable rate for a company of our size. Product and royalty revenues in the third quarter grew at 24% over the same period last year, totaling over $530 million and including $433 million in Jakafi sales, which increased 25% in Q3. Sales of ICLUSIG in Europe as well as royalties from Jakavi and Olumiant also increased year-over-year.

At the beginning of 2019, we set out an ambitious list of R&D goals for the year, and I am pleased to report today that we have already achieved the majority of them. The NDA for pemigatinib seeking approval as a treatment for patients with FGFR2-driven cholangiocarcinoma has been submitted to the FDA and the positive updated data that supported the submission were presented in September at ESMO. We recently reported that REACH2, the Phase III trial evaluating ruxolitinib in steroid-refractory acute GVHD, met its primary endpoint of superiority over best available therapy. This data further reinforced the efficacy of Jakafi as the start of care treatment option for these patients following FDA approval in this indication in May. We were also pleased to provide 52-week follow-up data from our randomized Phase II trial of ruxolitinib cream in vitiligo at EADV. These data showed that patients treated with higher concentration of rux cream experienced continued improvement in their disease with additional time on therapy, and we have already launched a global Phase III program for rux cream in vitiligo with results due in 2021.

We still have some key items we expect to deliver before the end of the year. But for now, I'll turn the call over to Barry for an update on Jakafi.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Thank you, Hervé, and good morning, everyone. Net product revenues for Jakafi were very strong in the quarter, totaling $433 million. This is an increase of 25% when compared to the same period last year. Growth was primarily driven by patient demand, which grew 18% year-over-year, and there were no appreciable effects of inventory in the quarter. Because of the strong demand for Jakafi today, we are very pleased to be increasing both the bottom and top end of full year 2019 guidance for net sales of Jakafi to a new range of $1.65 billion to $1.68 billion. We are seeing good demand for Jakafi in all 3 approved indications. More than 50% of eligible myelofibrosis patients in the U.S. are currently on Jakafi, and total patients on therapy increased approximately 5% year-over-year. We continue to be encouraged by the growth we see in this indication, especially in its eighth year since approval. Patient growth in polycythemia vera continues to be higher than myelofibrosis and within the eligible population, Jakafi has reached more than 20% penetration. We saw an opportunity to increase disease awareness in both PV patient and physician community. In an effort to augment the patient voice, we recently launched a pilot television and social media disease awareness campaign. This pilot was conducted in several key target markets where it has been very well received, and we have now expanded the education campaign nationwide. This is the first full quarter of sales since approval in steroid-refractory acute GVHD, and while early, the launch is currently outpacing our internal expectations. Importantly, we're seeing comprehensive access in both the inpatient and outpatient treatment settings, and we continue to see strong uptake and broad utilization across bone marrow transplant centers.

I'll now turn the call over to Steven for the clinical update.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Thanks, Barry, and good morning, everyone. Continuing with graft-versus-host disease, we were pleased to report the positive outcome for REACH2, the randomized trial of ruxolitinib versus best available therapy in steroid-refractory acute graft-versus-host disease. We plan to share these data with the FDA for inclusion in the Jakafi label, and we look forward to sharing the detailed data with you at an upcoming scientific meeting.

REACH3, the randomized trial evaluating ruxolitinib in patients with steroid-refractory chronic graft-versus-host disease, is ongoing and has almost completed recruitment. A recent interim efficacy and safety analysis conducted by an independent data monitoring committee recommended that REACH3 should continue without modification with results expected in 2020.

Moving on to pemigatinib for cholangiocarcinoma. Slide 11 shows the data that we presented at ESMO and which formed the basis of our recent new drug application. As you can see, in cohort A, the overall response rate was 36%, median progression-free survival was 6.9 months and median overall survival was 21.1 months. Importantly, the vast majority of patients have some degree of tumor size reduction, as evidenced by the 82% disease control rate and as illustrated in the waterfall plot on Slide 11.

We believe that pemigatinib offers a meaningful improvement over the current standard of care in the second line, which typically results in single-digit response rates, median progression-free survival of 3 months and an overall survival of approximately 6 months. The most common adverse event of all grades was hyperphosphatemia, which is an on-target effect of FGFR inhibition that can be managed with a low phosphate diet, phosphate binders and diuretics. Hypophosphatemia occurred in 23% of patients, which was likely due to the treatment for hyperphosphatemia. Serous retinal detachment was seen in 4% of patients, which was mostly grade 1 or 2.

If you recall, the only potential curative therapy for cholangiocarcinoma is surgery, but approximately 70% of patients are diagnosed with unresectable disease. So the need for new therapeutic options for these patients is clear.

My third slide summarizes updated data from the randomized Phase II trial of ruxolitinib cream in vitiligo, which were presented a few weeks ago at EADV. These data showed continued improvement in repigmentation with additional time on therapy as objectively measured by VASI scores. For example, in patients dosed with 1.5% BID and followed for 52 weeks, the facial VASI75 was achieved in 52% of patients, up from 30% of patients at 20 weeks -- 24 weeks, sorry, and the facial VASI90 was achieved in 33% of patients, up from 12% at 24 weeks. The global Phase III program of ruxolitinib cream in patients with vitiligo is already enrolling with the facial VASI75 at 24 weeks being the primary endpoint, and we expect the result to be available in 2021.

With that, I would like to turn the call over to Christiana for financial update.

Christiana Stamoulis - *Incyte Corporation - Executive VP & CFO*

Thanks, Steven, and good morning, everyone. The financial update this morning will include GAAP and non-GAAP numbers. For a full reconciliation of GAAP to non-GAAP, please refer to Slides 19 and 20 in the backup section of the deck and to the press release we issued this morning.

Our third quarter results reflect continued strong growth with total product and royalty revenues of $534 million, representing an increase of 24% over the third quarter of 2018. This is comprised of $433 million in Jakafi and $21 million in ICLUSIG net product revenues, $58 million in Jakavi royalties from Novartis and $22 million in Olumiant royalties from Lilly. We also recognized $18 million in contract revenues under our collaboration agreement with Zai Lab resulting in total revenues for the quarter of $552 million.

Our total cost and expenses for the quarter on a non-GAAP basis of $365 million decreased by 1% from the prior year quarter. Ongoing R&D expenses for the quarter was $251 million on a non-GAAP basis, unchanged from the prior year period, reflecting our decision to reallocate capital from the co-funding of baricitinib and the development of epacadostat to our other late-stage development programs.

SG&A expenses for the quarter was $90 million on a non-GAAP basis, representing a 6% increase over the prior year quarter.

Moving to our guidance for 2019. Given the strong performance of Jakafi in the first 9 months of the year, we are increasing Jakafi full year guidance to a range of $1.65 billion to $1.68 billion. Our guidance for both R&D and SG&A remains the same as we continue to invest in our commercial operations and our clinical development portfolio, and we expect certain of these expenses to be more back-end loaded into Q4 2019.

I will now turn the call back to Hervé.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Thank you, Christiana. So our last slide reminds you of our progress to date in 2019 as well as the remaining key news flow events we expect during the year. These expectations include the NDA submission by Novartis for capmatinib in patients with MET exon 14 skipping mutations in non-small cell lung cancer. Capmatinib is another development candidate discovered in Incyte's laboratories and has the potential to be an important product in lung cancer. It was recently positioned in the Novartis third quarter material as a key approval for them in 2020 and for Incyte, capmatinib also has the potential to be a meaningful contributor to our top line with over $500 million in potential milestone and 12% to 14% royalties on global net sales.

We are also looking forward to having the results of the GRAVITAS-301 trial of itacitinib in first-line acute GVHD in-house at the end of the year. Itacitinib has the potential to be another key contributor to near-term revenue growth.

With this strong execution across our late-stage development program, we are making significant progress towards our strategic goals of adding diversification to the top line and further accelerating revenue growth.

And that concludes our prepared remarks, and we are now happy to take your questions. Operator, please give your instructions and open the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question today comes from Salveen Richter of Goldman Sachs.

Salveen Jaswal Richter - *Goldman Sachs Group Inc., Research Division - VP*

So with regard to the early uptake in feedback for Jakafi and GVHD, what does that suggest for the trajectory here and have there been any gating factors? And then a follow-up for Hervé, given the progress of your pipelines in both oncology and IAI, how are you thinking about business development opportunities?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure, Salveen. So GVHD, as I said, the uptake has been very good since the beginning. We think the opportunity for itacitinib is ultimately where the opportunities lie. Jakafi is giving patients benefit right now. We believe it will get benefit in acute GVHD as we are now and then in the future for chronic GVHD and we await the results of GRAVITAS-301 for itacitinib and a potential worldwide for that drug.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

So Salveen, on the progress of the late-stage portfolio, obviously, I mean, you know our strategic goal of diversification and growth. I mean that's really what we are aiming at. And obviously, a lot of it is now starting to take place with pemigatinib. We spoke a little bit about capmatinib, which

is not always the most known of our pipeline products that Novartis has been licensed to Novartis. So we are on a good track to succeed on getting these products to market over the next few years. At the same time, we are obviously looking at BD opportunities that would fit with our portfolio. We are mostly looking at oncology/hematology type of assets. And it's a continuous process where we are reviewing opportunities, and we should -- we are expecting -- we hope to be able to gain some additional products to fuel the growth of the top line in the next few years.

Operator

The next question is from Marc Frahm of Cowen and Company.

Marc Alan Frahm - *Cowen and Company, LLC, Research Division - VP*

Maybe this is for Barry. In the prepared remarks, you mentioned that the awareness campaign PV is having some success. Can you maybe define that a little bit better? Are you already seeing an uptick in sales within those regions or is it more qualitative measures? And then what type of budget are we talking about now that you're expanding it nationally and trying to broaden that success?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Well, the way we measure uptake, it's very early. As we said, we did it in 5 key markets across the country first, and what we saw there was really the uptake in our -- in social media sites. For example, "take action PV" is what we direct patients to go to, our health care professionals to go to, to get more information. There's education materials there, materials they can download to track their symptoms, and we saw spikes in those first 5 key regions. Now as we expand it across the nation, which only started October 1, so we don't really have all that much data yet, but it certainly has grown dramatically on those sites that we're sending patients to. And the -- the budget nationwide is relatively small. This is a 30-second commercial. We're placing it at time periods that we think patients will see it, but at the same time don't cost a fortune. So it's not going to the Super Bowl, but it is, in fact, we think, being very effective as an educational tool for patients and health care professionals.

Marc Alan Frahm - *Cowen and Company, LLC, Research Division - VP*

Okay, great. And then maybe a short follow-up on kind of the market dynamics for Jakafi. Maybe some comments on what the initial impacts of fedratinib's launch that you may or may not have seen yet?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Yes, well I think it's early. We haven't really seen much of an impact yet. We know that Celgene is really positioning it as a second line agent just by their pricing strategy that they came out with. And then very particularly, their marketing materials that we have seen are positioning it as a second line drug. Maybe you also are aware that the only 2 clinical trials that they have ongoing now a single-arm trial and a Phase III trial compared to best available therapy are both after Jakafi. So clearly, they're positioning it for a second-line drug, and we haven't seen the impact yet on Jakafi, and we're fully confident because we have long-term follow-up data, 8 years of data, more than 50,000 patients treated in the United States with the drug. So the safety profile is there. And of course, an overall survival advantage that I don't think that fedratinib will ever be able to achieve, particularly with their Jakarta study because it was never followed up on.

Operator

The next question is from Tyler Van Buren of Piper Jaffray.

Tyler Martin Van Buren - *Piper Jaffray Companies, Research Division - Principal & Senior Biotech Analyst*

Great to see the solid results on the quarter. Just had a couple of follow-up questions to Marc's line of questioning. As you look at Jakafi in MF and PV, can you give us an update on duration of treatment for both of those indications? Also, as we think about long-term in terms of PV, could we see ultimate penetration of the patient population to reach kind of that 50% level that we're seeing with MF? And perhaps just some updated thoughts on the long-term guidance that you guys gave last year? I believe, it was $2.5 billion to $3 billion by 2027. And if we see the continued growth in PV and GVHD that seems exceedingly achievable. So it would be -- be interested to hear your updated thoughts.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure, Tyler, this is Barry. We're still confident of the $2.5 billion to $3 billion long-term guidance. So that's clear. In terms of persistence, it's what we've said all along. To be honest with you, I think we have to turn to the clinical trials for persistence when you look at PV, when you look at this RESPONSE data, you saw 80-plus, 83% of the patients were still on therapy at 2 years and in the COMFORT trial, you saw that 50% of the patients were still on at 3 years. So that's still our touchstone for persistence. In PV, we continue to grow year-over-year. This year, we grew total patients in PV 15% year-over-year and that continues to exceed the continued growth in patients in MF. So we see that in PV, we'll catch up to the MF patients sooner or later, and we certainly are confident that the clinical profile of Jakafi and polycythemia vera patients could hit the 50% mark at some point.

Operator

The next question is from Brian Abrahams of RBC.

Brian Corey Abrahams - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

Congratulations on the strong quarter. On GVHD, can you provide any perspectives on the REACH3 stopping rule at the interim and maybe frame expectations now that, that readout's been pushed out to next year? And related to that, I'm curious your latest views on the potential impact of JAK1 versus pan-JAK inhibition on the potential for efficacy in GVHD and the bar for the itacitinib readout, now that you guys have more clinical and commercial experience in the space?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes, it's Steven. So in terms of REACH3, we don't normally guide to interim results. But this time, working with our partner, Novartis, we obviously did expect to potentially have some results by the end of 2019. As you can see, the study at interim made it through the interim analysis by the IDMC and they recommended to continue the study to completion without modification. The recruitment itself is about to finish. We literally have only a few patients left. There is always a higher -- by the nature of an interim, there's always a higher bar to achieve an interim analysis to close the study because you have to be very careful that you do it appropriately. So we're not at all worried. We remain extremely confident in the data sets. The primary endpoint in the chronic graft-versus-host disease study is an overall response rate at month 6, but there are numerous secondary endpoints that are important here, including failure free survival, symptom improvement, overall survival and others. So sometime in 2020, we'll get those results. We remain extremely confident in that. And as I -- just to reiterate, it was a little unusual for us to guide to an interim, but again working with a partner, that's what we did.

In terms of reading through to itacitinib and a more JAK1 agent or relatively more -- hits JAK1 more than the other JAKs. We saw our proof-of-concept data for itacitinib. It was strong across the spectrum of disease, but it was even stronger in steroid-naive acute graft-versus-host disease, which is why which led to GRAVITAS-301.

In addition, patients with steroid-naive acute graft-versus-host disease are immediately post bone marrow transplant to allogeneic transplant tend to be sicker, tend to have cytopenias, particularly low white cell counts and low platelets. So to have a relative JAK2-sparing agent that doesn't

cause as much cytopenia as the others, is potentially beneficial from a therapeutic ratio point of view. But in terms of the biology of the disease, it ameliorates the biology appropriately, and again we remain confident in that.

Operator

The next question is from Michael Schmidt of Guggenheim.

Michael Werner Schmidt - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

I just had a follow-up on GVHD as well. I think you said the launch is outpacing your internal expectations. Just wondering if you could help us with a little bit more information around what treatment share do you have at this point? And maybe what percentage of top line sales was contributed by GVHD?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure, Michael. Well, treatment share, I'm not exactly sure. I think that we're the most used agent maybe already in the second-line setting, but I can't be sure of that. Trying to get information on GVHD is a little bit harder than MF and PV since it's all hospital used. So that's it. So I think last year, I said something like with spontaneous use and then with the approval, we'd hit somewhere around $80 million for this year. I think we're ahead of that, but I can't give you an exact number for that, but we're very pleased with the uptake in GVHD. And we think with now the REACH2 data it will even be stronger in the future.

Michael Werner Schmidt - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

Great. And then maybe a bigger picture question for Hervé. Regarding the earlier stage pipeline, I guess you're pursuing both new immunotherapies as well as targeted oncology drugs and obviously, there's been some very interesting data generated in the last couple of years, specifically with TKIs going after driving mutations, including pemigatinib, obviously, but there are other targets as well. On the other hand, I think many would agree that the success rate for new immuno-oncology drugs has been rather mixed, I guess, in that context, I was just wondering how do you see your bigger picture pipeline strategy evolve longer-term going after both areas?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Yes, I think -- so thanks for the question because, obviously, it's very important. And it's a field where the effect of the decisions we made over the past few years are always seen with the delay. So we were, obviously, with a very heavy share of the research effort in immuno-oncology and immunity in general, which led to a number of other projects beyond oncology. And what has been happening over the past 2 years is a rebalance where we have now more targeted therapies -- or targeted -- I mean, targeting oncogenic mutation type of projects that are a larger part of our portfolio.

At the same time, we are keeping immuno projects today. So it's -- I would say it's a balance that is probably in the 60:40 or 40:60 kind of ratio, where maybe in the past it was more heavy on the immuno aspect. And Dash, if you want to speak about it?

Dashyant Dhanak - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Yes. Thanks for the question, Michael. Just to sort of echo what Hervé was saying. I think you're right, at some level, the promise of immuno-oncology is being tempered by clinical data. However, we still think there's particularly plenty of opportunities out there in both the targeted and the immuno-oncology space. You'll remember or you'll know from our sort of access to modalities that we have both for molecule and biologics capabilities. So having both of those options open to us does keep the entire area open. And we have a number of programs that we think will

enter the clinic in the coming months that target both going after a very sort of traditional targeted therapeutic approach as well as an immuno approach and then combinations thereof.

Operator

The next question is from Cory Kasimov of JPMorgan.

Cory William Kasimov - *JP Morgan Chase & Co, Research Division - Senior Biotechnology Analyst*

First one for you is on expenses. So SG&A and R&D both came in pretty meaningfully below expectations for the quarter, but guidance was unchanged, which would imply a decent step-up in 4Q just to get to the low-end of your range. So is that something we should be anticipating and maybe to the extent you're willing to qualitatively comment on trends into 2020? Do you have any kind of preliminary big picture expense thoughts going forward? And then I have one follow-up.

Christiana Stamoulis - *Incyte Corporation - Executive VP & CFO*

Cory, it's Christiana. Thank you for your question. First of all, big picture in terms of R&D and SG&A cost, we continue to invest -- aggressively invest in our clinical development portfolio as well as on our commercial operations. What you are seeing with R&D this year and the expenses coming on the lower side is that we were able to reallocate expenses that were previously for epacadostat and baricitinib to our other late-stage development programs. So that allowed us to be able to push forward the other development programs without seeing an increase in R&D. Going forward, however, as we have discussed in the past, we are looking to invest in R&D based on the quality and the progress of the program. So based on data and merits of the programs if those programs progress, through later stage of development, you would expect that to drive R&D expenses.

In terms of Q4, we reiterated the guidance that we provided on both R&D and SG&A because there is a timing factor for some of the expenses on both lines that we expect to be more back-end loaded into Q4 of 2019. And therefore, we continue to be comfortable with the initial guidance that we had provided.

Cory William Kasimov - *JP Morgan Chase & Co, Research Division - Senior Biotechnology Analyst*

Okay, that's helpful. And then my follow-up is a quick one for Steven. How much patient follow-up will you wait for in that FIGHT-201 pemi bladder study before potentially top lining that data?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Cory, it's Steven. So typically, across the board, ballpark follow-up in these sort of studies required by regulatory agencies is around 12 months, but that's for your last responder. So what I'm saying is you complete recruitment, if that last, very last patient is responding, you typically require about 12 months. So if you think we've just recently completed recruitment on the study, we're looking at data sometime mid-2020 or beyond to get a complete view of that picture across the board on that bladder data.

Operator

The next question is from Evan Seigerman of Crédit Suisse.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

Congrats on the progress. So Christiana, one for you. How would you characterize your capacity to transact? I know Hervé mentioned some high-level thoughts on BD, and then I have a follow-up on that. Just basically, what are some characteristics of assets that you would consider bringing in-house? So one for you, Christiana, and one for you, Hervé.

Christiana Stamoulis - *Incyte Corporation - Executive VP & CFO*

So in terms of the capacity, as we have discussed in the past, we have a strong balance sheet. We currently have $2 billion of cash on our balance sheet. So that gives us the opportunity to consider bringing in external assets to add to our internal portfolio. In terms of the nature of the assets, we are looking at programs that could contribute to revenue diversification and growth in the midterm time frame. So continuing to add to growth as we're getting closer to the Jakafi potential patent expiry period. So bringing additional growth drivers, then obviously, makes a lot of sense for us.

So do you want to take...

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Yes, I mean the type of assets are fairly -- is very clear. I mean, the first is obviously hematology/oncology, anything that would be good science, that would be innovative, that would provide a benefit that is unique in the field of cancer treatment, could fit with our portfolio where we have a very strong hematology franchise, both in Europe and the U.S. and where we have emerging solid tumor franchise also in the U.S. and a little bit later in Europe. So that makes sense.

In terms of timing, we are looking at the window between 2025 and 2030 and it's fairly obvious why because that's where we will need more diversification. The second aspect is to complement our MF and PV franchisees where there are new mechanisms that can be complementary to what we have in our portfolio. And where, obviously, our leadership in MF and PV could be reinforced by external assets, if any benefit could be shown from this.

And then we have a little bit of a longer view on the non-oncology aspect. As we said, we will be commercializing our rux cream in the U.S. We may have partnership, if needed, but we would be leading the commercialization in the U.S. We will be partnering our dermatology assets outside of Europe and U.S., and we are still looking at what the best strategy for Europe.

So there, there could be also potential BD aspect to the dermatology franchise. We are very confident in the benefit we are showing both in atopic dermatitis and as you saw in vitiligo, it's a fairly striking data with the long-term follow-up. And we believe there is a true value in this franchise, and complementing it with external assets could be an option. It's not absolutely mandatory because we believe in the U.S., we can build the team to successfully commercialize, but there could be some complement to it. So it's fairly clear. It's hematology/oncology for 25 to 30, where that's where the contribution to the top line will be the most valuable. It's life cycle management of MF and PV, and potentially, if we find the right assets in dermatology or somewhere in the immuno -- non-cancer immunology, it could be also another dimension.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

Okay. And then I just -- follow-up there. I mean, are we talking $1 billion, $2 billion or really have you -- can you give color on that in terms of what you'd pay?

Christiana Stamoulis - *Incyte Corporation - Executive VP & CFO*

So the main focus is on what I would characterize as, tuck-in type of assets that we could bring in either through licensing or M&A. So we are agnostic in terms of the structure, whatever makes sense.

Operator

The next question is from Jay Olson of Oppenheimer & Co.

Jay Olson - *Oppenheimer & Co. Inc., Research Division - Executive Director & Senior Analyst*

Congrats on the quarter and all the progress. I had a couple of questions. Could you comment on what were the best available therapies that Jakafi beat in REACH2? And is there overlap between those best available therapies in REACH2 and REACH3? And then just a follow-up on pemigatinib. Could you provide some additional color on how the enrollment is going in FIGHT-205 and FIGHT-207, and also the bladder cancer continuous dosing cohort?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes, Jay, it's Steven. Thank you for your questions. So both REACH2 and REACH3 are randomized studies against best available therapies. Just to mention, REACH2 that we've just said and reported out as positive and will be presented at an upcoming medical meeting, to our knowledge, is the first randomized study in graft-versus-host disease that is reported out as positive. So that's really good news, obviously, for patients and for us.

Then the therapies themselves are listed on clintrials.gov. But just to give you a sense, there are slight differences because they're different disease entities. For REACH2, they include things like antithymocyte globulin, extracorporeal photopheresis, there's mesenchymal stromal cells, low-dose methotrexate, mycophenolate and even mTOR inhibitors like everolimus can be used. For REACH3, there's some overlap, but they also, in addition, because chronic graft-versus-host disease include therapies like rituximab and imatinib as well as ibrutinib which is approved in chronic graft-versus-host disease. The complete list is available on clintrials.gov.

Enrollment -- to the second part of your question on the studies you mentioned for the entirety of the pemigatinib program obviously includes our completed first part in cholangiocarcinoma and then the ongoing first-line study there, then the large bladder cancer program and then the tumor agnostic as well as a smaller entity that we don't speak about much, but very important to patients, is an 8p11 myeloproliferative neoplasm. We don't guide to exact dates in terms of enrollment other than when we start and sometimes when we end the studies. But just to give you a sense that the agnostic study, 207, which you mentioned has started enrollment, and we'll be looking at different driver mutations there. And then we expect to complete, as I just alluded to, the second line bladder study before the end of this year and have data latter part of next year. And then we're about to start the first-line bladder study. So that gives you a sense of the cadence of enrollment in the entirety of the program.

Operator

The next question is from Ren Benjamin of JMP Securities.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Senior Research Analyst*

Congratulations on a great quarter. I guess, just as a follow-up, regarding the REACH2 data, Steven, is there anything there that kind of increases your confidence in regards to REACH3 or are the 2 diseases really separate and distinct, acute versus chronic?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Ren, thank you. It was great to see a randomized study against best available therapy being positive. And again, as I just said, we look forward to sharing those results to you. So it further does increase our confidence in what we already know per se that ruxolitinib is a really good drug for steroid-refractory acute graft-versus-host disease. Chronic does have a slightly different pathophysiology as it's more a disease of fibrosis with

more skin manifestations as opposed to more apoptotic disease in acute where there's more sort of cell death in the liver and GI tract, but there's enough overlap, and our proof-of-concept data was strong enough that we remain confident in chronic graft-versus-host disease. We do think, although the pathophysiology, there's a little bit of a difference. There's a good read through, and we're confident in getting that data next year.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Senior Research Analyst*

Got it. And then just as a follow-up. The vitiligo studies have started. Can you give us any sort of a sense of if its enrollment is on track or -- and have a schedule and have all the sites opened?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. So you're correct. The vitiligo studies have started. As you saw in my formal presentation, we just presented the 52-week data at EADV with continuing improvement, quite dramatic in patients through 1 year. The studies have just recently started. But I will tell you, it's a pleasant surprise to us working in dermatology. These studies accrue really, really well. So we start to open quickly. We've dedicated dermatology centers across the globe. We're good at doing clinical research to put patients on quickly, and we're up and going with gusto and very positive about it.

Operator

(Operator Instructions) Our next question is from Alethia Young of Cantor Fitzgerald.

Alethia Rene Young - *Cantor Fitzgerald & Co., Research Division - Head of Healthcare Research*

Congrats on the quarter. Two -- one, maybe, Steve, can you talk a little bit about best supportive care for REACH3 and how it varies across the world? And do you think there's any kind of variability there that you should consider in the trial that's ongoing?

And the second question probably is more for maybe Hervé. I guess, I'm just curious how you think about kind of long-term margins for the business and where we are exactly in kind of the peak cycle for Jakafi? It seems like there's still a lot of room to move and you're building in PV, kind of an awareness and there's penetration that could be had. But maybe if you can frame that from a high-level perspective, that'd be helpful.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Alethia, it's Steven. So you do allude to something we see in graft-versus-host disease not only across the world, but even within the United States and even within cities themselves. There are treatment differences in patterns at bone marrow transplant centers and how people have treated this condition to date and continue to, both in terms of preparative regimens and actual regimens, which is exactly why for best available therapy we have to account for a number of therapies. So there's no dramatic differences across the world compared to just, as I said, even within the U.S. itself. We always, as a matter, of course, do analyses that look at differences, if there are any between different parts of the world to explain response rates, et cetera. So those analyses will be done. Typically, you do the U.S., Western Europe and rest of world analyses, and we'll look at those. But there's nothing that we're concerned about.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Regarding the cycle, I mean, the sort of medium- to long-term cycle of the business. Obviously, the growth of Jakafi in the U.S. is very key to the entire P&L of Incyte. As you can see, I mean, this quarter, in fact, is growing even faster than the previous one versus last year. Now Q3 last year was a little bit lower maybe than it should have been. So the ratio of the 25% growth for Jakafi U.S., maybe slightly higher than the true trend over the year. I think we are more in the 20%, but which is still very, very strong for a sort of a seventh or eighth year of commercialization. And we see a lot of potential for continued growth of Jakafi in the U.S.

In MF, it is still volume growth, patients volume is increasing in MF. And in PV, as we said, there is larger potential for 2 reasons. It's because the treatment rate is still on the low-end, below 50%, and the duration of treatment for every patient studied on Jakafi is very much longer than what we have in MF.

So what we see is a sort of a chronicization of the disease in MF that is leading to this growth potential that is obviously higher. We are not changing the long-term guidance very frequently, but we have made a lot of progress towards the number that we gave a few years ago of $2.5 billion to $3 billion, and that's something we are very confident in.

Regarding the P&L itself and the margin, as Christiana said, I mean, we are investing in R&D based on the quality and the required work for the assets that we have. And so it may be fluctuating, as you have seen when epacadostat did not work as planned, to say the least. You could see that it has a positive impact on the R&D budget, which is obviously the paradox of our industry in that if you stop a project, it will improve margins. But obviously, our goal is not to manage the margin short-term proactively, but to maximize the value to the company and the shareholders by doing the right clinical development for each of the assets that we have in our hands.

At the same time, you may have seen from 2014 to today, is that we are in the trend of improving ratios in the P&L, where the growth of the top line has been not every single quarter, but if you look at it on a cumulative four quarters in a row, that margin has been improving over time. And that's why we are where we are today. The P&L has the shape that it has today. So that's something we'll continue to look for, but it may include quarters where investment will increase because some of the assets that we have are requiring an increased investment at some point.

So overall, the way we have been sort of looking at this is certainly, growth of the top line is driving our ability to invest in R&D, and they are the 2 components to create value that will be sustainable for the long-term for Incyte.

Operator

Our next question is from Vikram Purohit of Morgan Stanley.

Vikram Purohit - *Morgan Stanley, Research Division - Equity Analyst*

So I wanted to go back to long-term Jakafi and the tail on that franchise. And I had 2 questions on Jakafi life cycle extension program. So I believe, earlier you had alluded to possibly getting some extended-release data in 2020. So I just wanted to see what the status of that program was? If it's in the clinic yet or not? And then secondly, I believe the last time we saw some Jakafi combination data was at ASH last year in combination with the PI3K molecules. I just wanted to see when further data from that combination could be available as well as from other combinations like PIM and itacitinib, in the MF setting?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Vikram, it's Steven. So thank you for your question related to ruxolitinib life cycle management, which we view as something for ruxolitinib itself as well as for myeloproliferative neoplasms in general, there are 3 pillars to the program and you mentioned all of them.

So firstly, in terms of formulation work which you brought up, that's been ongoing this year. It involves an extended-release approach in terms of formulations and bioavailability and bioequivalence work that is underway. It's been going. And well, as you just said, complete in 2020 at some point. And then we'll use it to have regulatory discussions probably through the middle of '21. We'll find an appropriate meeting to present it that. But I'll remind you that we actually presented some RUX XR data in 2011 with the 25-milligram XR tablets. So we have already, and that work is ongoing and progressing well.

In terms of the second pillar, combinations. We are running, as you said, the PI3-kinase delta combination, that's the most mature of them. We also have a RUX plus PIM combination and a RUX plus itacitinib combination ongoing. We'll have ourselves data in-house to look at ourselves with RUX

plus delta in approximately end of this year and we'll find an appropriate meeting to present to that in 2020 and make decisions -- go-forward decisions or not in either first or second line myelofibrosis when we look at the completeness of the data.

We'll also -- should have enough data with PIM and itacitinib, also to present in 2020 at an appropriate meeting. And then the third pillar, and very important, is new targets to look at in MF and PV in collaborations with academia and different vendors, including epigenetic screens to look if there are any new targets there. And we haven't announced anything publicly yet. But that's a very, very active endeavor as well.

Operator

The next question is from George Farmer of BMO Capital Markets.

George Farmer - *BMO Capital Markets Equity Research - Analyst*

I was wondering if you could comment a bit on pemigatinib? And how you believe this molecule differentiates from other FGFR inhibitors?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So it's Steven, I'll go first. Dash, may want to add something to it. We're an FGFR 1, 2, 3 specific inhibitor. We know the PK and PD effects of this compound really well. We've done both intermittent dosing as well as continuous dosing. And we've got a very good PD marker, pharmacodynamic marker, in hyperphosphatemia. So we can dose to that, and as I said earlier, manage appropriately. All compounds, obviously, chemically are different. Obviously, the only approved FGFR inhibitor currently is erdafitinib, the Janssen compound, and that does hit FGFR4 as well and may explain some of the difference in safety profile that we've seen, but we'll wait for the full data sets to bear that out.

As regards to the other compounds, I just -- I don't know enough to comment on and if Dash wants to add anything.

Dashyant Dhanak - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Yes. I mean, I think you covered the major points there, Steven. We feel that pemigatinib is probably the most selective FGFR inhibitor out there. We are focused on FGFR 1, 2 and 3. We don't really touch the other isozymes whether it's in biochemical assays or cellular assays, et cetera. We have what we think is a great PK profile clinically. So overall, we feel it's a balance of optimal selectivity for our target proteins as well as the clinical profile to sort of leverage that selectivity in an optimal way.

George Farmer - *BMO Capital Markets Equity Research - Analyst*

Okay, great. That's helpful. And then I know it's early days, but do you have any sense for duration of therapy in the steroid-refractory acute setting with Jakafi?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Well, we can only go on, again, the REACH1 trial. And we believe, in fact, in the duration of response of 173 days. That's in our label where therapy isn't changed or -- and the patients don't come off for whatever reason. So that's what we're going by. But we don't really have, from a commercial standpoint, a follow-up yet on what the true nature is, but we do know that it's successful, that patients seem to be staying on it for a long time. As you know, in graft-versus-host disease in general, but it's particularly in acute graft-versus-host disease, physicians -- bone marrow transplant docs want to taper off drugs like steroids, and then even like Jakafi over a period of time, but just so they can do it safely and make sure they fully managed the effects of GVHD before they do so.

Operator

The next question is from Mara Goldstein of Mizuho.

Mara Goldstein - *Mizuho Securities USA LLC, Research Division - MD of Equity Research Department*

Great. Just a couple of questions. And 1 is on the promotional sensitivity on Jakafi in the PV indication. You mentioned that you thought that, that category could get 50% penetrated. So I'm wondering where the resistance is among the prescribing community? And is that something that is subject to also greater promotion? And then just secondarily, if you could update us on the status of the commercial organization for pemigatinib as you have that NDA filed for cholangiosarcoma?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure. So Jakafi is actually promotionally sensitive across all indications. It's both MF and PV can sometimes -- most of our treating physicians and health care professionals don't see these patients that often. Sometimes, they're often worried about some other patients that might have lung cancer or pancreatic cancer. So they don't pay enough attention to the symptoms, in fact, that these patients are experiencing and other indicators that their disease may be getting worse. So we have oncology clinical nurse educators, we have obviously our MSLs, and we have our sales representatives are continuing to try to educate health care professionals that they need to look more closely at these patients, particularly at PV patients who are suffering, and that's one of the reasons we do our educational campaign, obviously, to encourage patients themselves to go out and, in fact, advocate for themselves if they don't feel like they're getting the appropriate treatment.

And your second question was -- oh, the commercial footprint for pemigatinib. So we do plan, in fact, to add a few more people in 2020 to get ready for the pemigatinib launch. So we do -- we're going to keep the full amount of current FTEs against Jakafi for MF and PV. We're going to increase slightly the number of FTEs that we have that are targeting graft-versus-host disease in bone marrow transplant centers, and then a few FTEs that will be concentrated on pemigatinib. We also have a couple of oncology clinical nurse educators. And obviously, our market access people that are, in fact, fully ready for -- and fully trained on pemigatinib and cholangiocarcinoma for the launch in 2020.

Operator

Our final question is from Christopher Marai of Nomura Instinet.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Just maybe touching upon some of the RUX life cycle management plan. If I recall previously, Incyte had a BRD inhibitor in the pipeline looking at that target. And at EHA -- there was some great data for launch of CPI 0610 in myelofibrosis, has the potential to potentially work in the second line but also augment ruxo in first line, that's myelofibrosis. And I was wondering if perhaps you could comment on your conference there with BRD inhibitors that you might be looking at that at that particular target?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Christopher, it's Steven. So I'll just remind you, we ourselves had a BET/BRD programs. So obviously, we had preclinical data that showed that RUX plus that target had enhanced or potentially enhanced efficacy in myelofibrosis, and we ran into toxicity in terms of -- an on-target toxicity in terms of thrombocytopenia and currently put ourselves, the program on clinical hold with the regulators. The company -- you allude to a competitor BET/BRD program which showed, you're right, some interesting data and have an abstract in for future medical meeting as they make sure more and will follow that closely. We are interested in anything that enhances RUX activity, and we'll keep looking across that. Our own programs are there for us to use should we need to resurrect them.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Okay. So the toxicities, I think, it sounds like the competitor had, but as you noted that's something you're still investigating an improvement on the therapeutic index there. Maybe any mechanistic reason why do you think yours might be different from the competitors?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. So I won't address there's directly, but it's knowing that bit BRD inhibitors have on target, thrombocytopenia that can be profound. So you have to weave the therapeutic ratio carefully in terms of potentially dosing to get there. I can't speak to the competitor compound there.

Operator

There are no additional questions at this time. I'd like to turn the call back over to Hervé Hoppenot for closing remarks.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Okay. Thank you. Thank you all for your time today and for your questions, and we look forward to seeing you at upcoming investor and medical conferences. But for now, we thank you again for your participation in the call today. Thank you, and goodbye.

Operator

This concludes today's conference. You may disconnect your lines at this time. Thank you for your participation.