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INCY - Q2 2018 Incyte Corp Earnings Call

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OVERVIEW:

INCY reported 2Q18 GAAP revenues of $522m.

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PRESENTATION

Operator

Greetings, and welcome to the Incyte Second Quarter 2018 Earnings Conference Call. (Operator Instructions) As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Mike Booth, Vice President of Investor Relations. Please go ahead, Mike.

Michael Booth - *Incyte Corporation - VP of IR*

Thank you, Kevin. Good morning, and welcome to Incyte's Second Quarter 2018 Earnings Conference Call and Webcast. The slides used today are available for download on the Investors section of incyte.com. Steven is not able to join us this morning, as he is currently recovering after a bicycling accident this weekend. So I'm joined on the call today by Hervé, Barry, Reid and Dave, who will deliver our prepared remarks; and by Peter Langmuir and Lance Leopold from our clinical group, who will participate as needed in the Q&A session.

Before we begin, 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 2018 guidance, the commercialization of our products and the 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 March 31, 2018 and from time to time, in our other SEC documents.

We'll now begin the call with Hervé.

Hervé Hoppenot - *Incyte Corporation - Chairman of the Board, President & CEO*

Thank you, Mike, and good morning, everyone.

So on Slide 4, I'll start with the growth of the organization and the financial strength. So we have continued our strong start to 2018 in the second quarter by delivering 29% year-over-year growth in product-related revenues. This dynamic top line growth is driven by 4 sources of revenue, where second quarter sales of Jakafi increased 25% over last year and Iclusig grew by 27% year-over-year. Royalties increased by 61% over the same period last year as we begin to see the effect of Olumiant commercialization in addition to the strong ongoing performance of Jakavi, ex U.S. Today, we reported a balance of cash and equivalent of $1.2 billion, which allows us to progress our portfolio, while affording us the flexibility to be opportunistic in business development. Our reported cash balance at the end of June does not include the recently triggered $100 million milestone from Lilly following the U.S. approval of Olumiant for RA.

Moving to Slide 5. Jakafi and Jakavi have already provided significant benefits to thousands of MPN patients and maintaining our leadership position in MPNs is an R&D imperative for Incyte, as we seek to drive additional benefits in this patient population. We believe there are multiple avenues that we might be able to pursue to withstand our leadership in MPNs beyond the next decade. We are already working on new potential formulations for ruxolitinib monotherapy. We are assessing ruxolitinib-based combination strategies, and we are also working internally and with collaborators on MPN targets beyond JAK inhibition. An example of our approach to ruxolitinib-based combinations is our ongoing trial evaluating ruxolitinib plus '50465. We recently presented preliminary data for this combination, which showed that adding a delta inhibitor to ruxolitinib could bring additional benefits for refractory MF patients, and we have also filed patent applications for this doublet that would, if granted, provide additional patent protection for this treatment of myelofibrosis patients.

Slide 6 illustrates our vision for Incyte in the future, which is led by our diverse development portfolio with multiple candidates being evaluated in later stage clinical trials. We have several near-term opportunities such as ruxolitinib and itacitinib in GVHD and our FGFR inhibitor in cholangiocarcinoma and bladder cancer that, if approved, has the potential to add meaningfully to our top line growth in the next few years.

Looking a little further out, we are pursuing later-stage compounds across a total of 15 new indications and our earlier-stage portfolio could also provide us with additional important optionality. I'm confident that we have the right team in the appropriate geographies to deliver transformational revenue growth.

With that, 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. Jakafi continues to perform very well with net product revenue of $346 million in the second quarter of 2018, representing growth of 25% over the same period last year. Sales continue to be driven by robust prescription demand, and in the second quarter, we saw a year-on-year increase of approximately 16% in total patients being treated with Jakafi. We are very happy with our sales performance in 2018 to date and are pleased to reiterate our Jakafi net product revenue guidance for the full year of 2018, which is a range of $1.35 billion to $1.4 billion.

Following the positive REACH1 result we announced last month, we're preparing the sNDA submission to the FDA, seeking approval for Jakafi as a treatment for patients with steroid-refractory acute GVHD. The sNDA is expected to be submitted before the end of the third quarter. We have breakthrough designation from the FDA, which we expect to provide us with a shorter review period. If approved, we'll be ready to launch Jakafi

in this new indication immediately. Our field force has already been optimally sized and structured in anticipation of approval and the map on the left hand side of Slide 9 shows the areas where we will be focusing our efforts, should approval be granted.

Allogeneic stem cell transplants are largely concentrated across the top centers in the United States. For example, the top 10 centers by volume conduct nearly 30% of transplants and the top 50 centers, which are shown here, conduct about 70% of transplants. Our team is currently preparing for this potential launch by developing robust plans for these key accounts as well as appropriately engaging with payers and reimbursement authorities for coverage upon launch.

I'll now pass the call over to Reid for an update on our portfolio.

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Thanks, Barry, and good morning, everyone. I'd like to use my time today to briefly touch on some of the important takeaways from our recent investor and analyst event as a means of summarizing progress across the development portfolio.

We continue to work hard to satisfy the needs of MPN patients. We're addressing this through both discovery and development initiatives and have also partnered with key academic centers and companies in order to extend our efforts. The objectives here are to improve patient outcomes, reduce disease burden and, where possible, improve hematologic tolerability. Our collaborations with Syros, Moffitt and Vanderbilt seek to discover new targets and new combinations that may yield benefits to patients. And we are already aiming to improve outcomes through ongoing clinical trials of ruxolitinib-based combinations. Last month, we shared some early but interesting data from the ongoing ruxolitinib plus PI3-kinase delta trial in refractory MF patients, and we look forward to sharing additional data from this and other combinations when available.

PI3-kinase delta inhibition is a potent therapeutic mechanism with the potential for broad application across multiple diseases. At our investor event in June, we touched on multiple areas where '50465 could provide benefit to patients, both as monotherapy and in combination with other agents.

Slide 12 highlights 2 of our later-stage programs in oncology. Firstly, and as part of the COMFORT clinical trial program evaluating ruxolitinib-based combination in MPNs, we are testing ruxolitinib in combination with '50465 in patients with refractory myelofibrosis. We presented early data from 10 patients last month, which showed that most patients had improvements in both spleen lengths and in their disease-related symptoms. Updated data are expected later this year. The CITADEL program is evaluating '50465 monotherapy in follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma. In Phase I, we were encouraged to see rapid, deep and durable responses in these 3 diseases, but we also observed immune-related and likely on-target toxicities after several months of therapy. We have since adjusted the dosing regimen, which appears to enable patients to remain on therapy and hence continue to benefit from the potent activity of the molecule. We look forward to sharing these data as they become available.

In June, we announced that REACH1, the pivotal trial of ruxolitinib in steroid-refractory acute graft-versus-host disease met its primary endpoint. This trial was important for a number of reasons. First, it is the only prospectively designed pivotal trial of a JAK inhibitor in graft-versus-host disease to be completed. And second, these positive data add to the growing body of knowledge of the benefit of the inhibition of JAKs in GVHD. We are working with Novartis to recruit patients into REACH2 and REACH3, the 2 ongoing pivotal trials of ruxolitinib in steroid refractory acute and steroid refractory chronic graft-versus-host disease, respectively. At the same time, we are also recruiting patients into the GRAVITAS program, which is evaluating itacitinib, our JAK1 selective inhibitor, in newly diagnosed GVHD patients. REACH2, REACH3 and GRAVITAS 301 are all expected to readout next year.

On Slide 14, we summarized the clinical trial schema for our FGFR inhibitor, which is now known as pemigatinib. Last month, we presented initial data from the FIGHT-202 trial in FGFR2-mutated cholangiocarcinoma. These results showed a disease control rate of 82% and an objective response rate of 24%, which included 11 PRs as well as a 6.8-month median progression-free survival. With second-line chemotherapy generating an objective response rate of less than 10% and a PFS of approximately 3 months, we are excited about the potential impact of this compound in this setting. Should the data warrant, we are planning to file an NDA with the FDA in 2019. Therefore, pemigatinib has the potential to be the first selective FGFR inhibitor approved in cholangiocarcinoma.

As previously announced, we are also planning to adjust the FIGHT-201 study in FGFR3-mutated bladder cancer to include a continuous dosing arm. We expect that this regimen may enable a greater degree of patient benefit and data from the continuous dosing cohort are expected next year. FIGHT-201 may support an initial regulatory submission in the U.S. for second-line patients, and our ultimate intention is to develop pemigatinib as a first-line treatment for patients with FGFR2-mutated bladder cancer.

Development plans for our PD-1 inhibitor are detailed here on Slide 15. We have completed recruitment into dose escalation and initial dose expansions and recently declared our intent to run 3 registration-directed development efforts. The cohort of patients with microsatellite instability-high endometrial cancer will be further expanded at a 500-milligram every 4 week dosing schedule. And in addition, we are planning to open Phase II studies in merkel cell carcinoma and anal cancer later this year.

We're also planning to evaluate '012 in a number of combination settings. Leveraging our own portfolio, we are planning combination studies with both small and large molecules. We expect that having an in-house PD-1 antagonist will speed our decision making and could obviate the need to either buy supply from a third party and/or to share any plans or data with them.

By capitalizing on our drug discovery and immunology expertise, Incyte is establishing a specialty focused business in inflammation and autoimmunity. Following positive Phase II data of ruxolitinib cream in atopic dermatitis, which are expected to be presented at the EADV meeting later in September, we are currently preparing to initiate a pivotal trial in this indication. Additionally, a Phase II trial in patients with vitiligo is ongoing, and we expect to be able to announce data from this trial in 2019. We believe that '54707 is a differentiated JAK inhibitor due to its selectivity as well as its longer half-life compared to ruxolitinib or itacitinib. We've initially chosen to study 54707 in hidradenitis suppurativa, which is an inflammatory skin disease characterized by lesions in the axilla, in the groin and under the breast area as a result of inflammation and infection of the sweat glands.

Lastly, we are interested in studying delta inhibition across a variety of B-cell mediated and antibody-driven diseases outside of oncology. We feel that there is a potential to differentiate from CD20 antibodies based upon the mechanism of action and the ability for reversible suppression versus long-lasting depletion. We expect to begin proof-of-concept clinical trial work later this year.

Slide 17 shows our full portfolio, illustrating our 3 drug discovery platforms on the left, our 4 sources of revenue on the right and our robust group of post-proof-of-concept of assets in the later-stage portfolio. While most investor focus is rightly on these later-stage molecules, it's also important to recognize that the optionality inherent in our earlier-stage portfolio. I won't go through each molecule, but I will say that we are pleased with the progress that these programs are making. As expected, our LAG-3 antagonist recently entered dose escalation trials, and both TIM-3 and AXL/MER are slated to enter the clinic in the coming months. We continue to make data-driven clinical decisions being prepared to terminate programs, as we have done recently with both JAK1 in AML and our BRD program, while also being prepared to make rapid go-forward decisions where appropriate.

I'll now pass the call along to Dave to review the financials.

David W. Gryska - *Incyte Corporation - Executive VP & CFO*

Thanks, Reid, and good morning, everyone. The financial update this morning will include GAAP to non-GAAP numbers. For a full reconciliation of GAAP to non-GAAP, please refer to our press release.

Our financial performance in the second quarter was very strong. We recorded $522 million of total revenue on a GAAP basis. This is comprised of $346 million in Jakafi net product revenue, $20 million in Iclusig net product revenue, $47 million in Jakavi royalties from Novartis, $9 million in Olumiant royalties from Lilly and $100 million of contract revenues from the milestone earned from Lilly for the FDA's approval of Olumiant. Total revenue for the quarter on a non-GAAP basis were $422 million and excludes $100 million milestone from Lilly. Second quarter Jakafi net sales of $346 million represents 25% growth over the same period last year. In the second quarter, Jakavi royalties of $47 million represents 39% growth over the same period last year. Our gross to net adjustment for the quarter was approximately 13%, and we expect that our gross to net adjustment for the full year 2018 will be approximately 14%.

Our cost of product revenue for the quarter was $19 million on a non-GAAP basis. This includes the cost of goods sold for Jakafi and Iclusig and the payment of royalties to Novartis on U.S. Jakafi net sales. Our R&D expense for the quarter was $253 million on a non-GAAP basis, primarily driven by clinical development programs. The $13 million decrease in non-GAAP R&D expense from the first to second quarter is primarily due to lower costs associated with our epacadostat program. Our SG&A expense for the quarter was $96 million on a non-GAAP basis, which is lower than the first quarter due to donations to independent charitable foundations, which typically decline as the year progresses.

Moving on to non-operating items. We recorded GAAP to non-GAAP net interest income of $6 million in the second quarter. Our net income for the second quarter on a non-GAAP basis was $57 million. Looking at our year-to-date results, our net income on a non-GAAP basis was $54 million.

A quick comment on the balance sheet. We ended the second quarter with $1.2 billion in cash and marketable securities, excluding the $100 million milestone from Lilly for Olumiant, which we expect to receive in the third quarter. We expect to end the year with a slightly higher level of cash and marketable securities.

Slide 23 provides a summary reconciliation from GAAP to non-GAAP metrics. As I mentioned, a more detailed reconciliation is provided in this morning's press release. The next slide provides a summary of our current financial guidance, which is largely unchanged from the prior quarter.

And Hervé will now conclude our prepared remarks by summarizing our upcoming expected newsflow.

Hervé Hoppenot - *Incyte Corporation - Chairman of the Board, President & CEO*

Thanks, Dave. So Slide 26 summarizes our current expectations for data readouts for the remainder of the year. First, we are expecting Phase II data from ruxolitinib topical cream in mild to moderate atopic dermatitis to be presented in September at EADV, and we are expecting to report additional pemigatinib data in patients with cholangiocarcinoma and bladder cancer at ESMO. Later in the second half of '18, we are expecting to present the REACH1 data for ruxolitinib in patients with steroid-refractory acute graft-versus-host disease as well as updated data from the study evaluating '50465 in combination with ruxolitinib in patients with refractory myelofibrosis.

I'll close with our exciting schedule of projected regulatory submissions in the coming years. We have the potential to submit a total of 6 product candidates for approval in up to 15 indications over the next 5 years. And while we have a lot of work to do to execute on this plan, we are encouraged by the data we have shared with you so far, and we look forward to sharing additional data and updates from our programs as they evolve.

In the second quarter, we delivered strong product revenue growth, and I believe that we are very well positioned from both revenue and clinical perspective to build sustainable value for all our stakeholders.

Operator, that concludes our prepared remarks. Please give your instructions and open the call for Q&A. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question today's coming from Cory Kasimov from JPMorgan Chase.

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

Two of them for you. I guess, first I want to ask about the combination work you're doing in MPN, so bigger picture. So in addition to providing an improved option for your existing patients, do you believe this also opens up a material number of new patients to your therapies, while also, I guess, potentially extending your overall runway? I guess, I'm getting at how much of this market remains untapped at this point? And how far do you think you could possibly extend that runway? And then I have one follow-up.

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

Sure, Cory, it's Barry. So we think that we could, in fact, extend the duration of therapy for patients who are on Jakafi by combining with some of our pipeline products like our delta product, for example. Where patients who are getting an inadequate response perhaps to Jakafi or are progressing on Jakafi could now be recovered and get a better spleen response in MF, so [they] could certainly stay on for a longer duration of therapy and perhaps [it would] even provide them significant improvement, maybe even survival advantage for those patients if we can complete these studies with our PI3K-delta and itacitinib and so forth.

Hervé Hoppenot - *Incyte Corporation - Chairman of the Board, President & CEO*

Cory, maybe I can add something. I mean, the big picture here is that obviously Jakafi is the only FDA-approved product today for MF and PV. We believe there is still a lot of progress that could be made, and we see for us, as the leader in this field, an opportunity to expand duration of treatment, as Barry was describing, potentially to provide an option for patients who have today there is no option after Jakafi failure or where patients cannot be treated with Jakafi. And all of that together, as we are looking at new targets, as we are looking at fixed dose combinations, as we are looking at new formulations, is going to give us a position that will expand potentially our leadership in MPN beyond the Jakafi single-agent option that is available today.

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

Okay. All right, great. And then my second question is for Reid. You mentioned with regard to your FGFR program or pemigatinib, I think, you're calling it, that you would file in 2019, should the data warrant. I guess, I'm wondering what else you need to see in the data beyond what's been disclosed or maybe what kind of feedback you need from KOLs and/or regulators to move ahead with that filing?

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Yes, thanks, Cory, for the question. This is Reid. I'm going to hand it over to Peter for him to address the regulatory activities around FGFR.

Peter Langmuir - *Incyte Corporation - Group VP of Oncology (targeted therapies)*

Thank you for your question. Basically, what we've seen so far from the cholangiocarcinoma data or interim data, so basically, we need to complete recruitment to that cohort of 100 patients, evaluate the final response rate and then importantly, look at the overall duration of response in these patients as well. So that's sort of the main totality of the data that we'll need to support a potential file next year.

Operator

Our next question today's coming from Salveen Richter from Goldman Sachs.

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

The first question is around Jakafi and itacitinib. Just given you've got both these drugs targeting acute and steroid-refractory populations, how big do you think this GVHD opportunity could really be?

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

For Jakafi, at least in the United States, obviously, Novartis is going for the approvals outside of the United States for steroid-refractory acute and chronic GVHD. In the United States, for Jakafi for the acute and chronic, we estimate the steroid-refractory population is about 1,500 patients a piece. For the steroid naïve patients with GVHD globally, at least in the major markets, Japan, the United States and Europe, it's about 15,000 patients. So depending on the duration of therapy, you can imagine, you can calculate what the Jakafi value would be for GVHD -- steroid-refractory GVHD and then for itacitinib, it's a much larger opportunity for us.

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

Great. And then just in terms of topical ruxolitinib, I know we're going to get an update at EADV coming up. What additional data are we going to get versus the EASI score and the IGA responder analysis that you provided at the Analyst Day?

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Yes, Salveen, this is Reid. So we'll have a more complete description of all the trial results that includes those scores over time. There are some other scoring indices that are used in this space, we'll describe those. We'll be describing, I think, many of the components parts of those scores, which are important to patients and give you a sense of overall safety across the topical ruxolitinib as it relates to increasing dose versus both the vehicle cream and the triamcinolone cream. I think you'll have a good perspective coming out of that as the potential of the drug and the mild to moderate patient indication as well as the safety profile.

Operator

Your next question is coming from Ying Huang from Bank of America Merrill Lynch.

Ying Huang - *BofA Merrill Lynch, Research Division - Director in Equity Research*

I have a high-level pricing question. So in 2017, you took 2 price increase of 6% each for Jakafi. In your $2.5 to $3 billion piece sale of guide or estimate, how much price increase did you bake in? And do you think that's realistic in today's environment? And then, secondly, maybe for the clinical side, on PI3K-delta programs, given the data you have observed so far in the Phase II program, how differentiated do you think this compound is from existing PI3K drugs, such as Zydelig in toxicity?

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

So thanks, Ying. This is Barry. I'll take the first question. And going forward, we don't talk about or we've never talked about our strategy around price increases, but you could still figure for modest price increases going forward.

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Yes, and Ying, this is Reid. I'll take your question around PI3-kinase delta. We've described this a few times. '50465 is a very potent molecule and has a structure that is quite distinct from idelalisib. And one of the important features that, that structure modification is made is it's eliminated or significantly minimized any hepatotoxicity risk. And as you know, that's been a characteristic liability for idelalisib. It tends to occur over the first few months of dosing and leads to a discontinuation rate and a dose attenuation rate. We've yet to see that, and we think that's a testament to the structural modification of the molecule that's innate to the molecule. Second, the tolerability around on-target toxicity that tend to occur later in dosing. And these are typically GI toxicities manifesting as nausea and diarrhea and are believed to relate to an alleviation of immune suppression in the gut just through chronic PI3 kinase-delta inhibition. So what the team has done, I think, in a very clever way, very nicely, is constructed an induction and a maintenance regimen, where patients are treated at a reasonably high dose over the first 2 months of therapy and generally,

patients are brought into response during that time period. And then thereafter, they're shifted to a dose or a schedule-attenuated regimen, and that allows them, we think, to maintain response to be able to tolerate the therapy long term. So I'd say, in sum, the differentiation comes both from the intrinsic properties of the molecule, but importantly, also from the way that the team is gone about constructing this dosing schedule and developing the drug up to this point.

Operator

Next question is coming from Katherine Xu from William Blair.

Katherine Xu - *William Blair & Company L.L.C., Research Division - Co-Group Head of Biopharma Equity Research, Partner & Biotechnology Analyst*

Just wondering, what catalysts from the pipeline do you think could move the needle to improve investor sentiments, especially following the epacadostat setback? So the other question for Reid, for the PI3K-delta inhibitor, can you comment on the activity in ibrutinib failure?

Hervé Hoppenot - *Incyte Corporation - Chairman of the Board, President & CEO*

Maybe I can take the first part, and Reid can also comment on the catalyst question. You can see from the portfolio, the way it's developing that there is a lot of attention given to GVHD. We have the largest program in the field. It has a lot of potential from the medical standpoint to literally transform the practice of medicine in this field because it's a very important curative procedure for cancer patients and the largest drawback is GVHD. And we think that by transforming that, it can have, obviously, a positive effect for patients, but also, it can create a meaningful opportunity in terms of top line growth for Incyte, and we have short-term ruxolitinib ongoing with the filing in the next few weeks. And then we have, obviously, itacitinib data that would be available next year, so that's important. I would say, I mean, if you look at our FGFR inhibitor, our PI3-kinase delta, we spoke about it, it has a lot of different dimensions. It can go in multiple directions. And then, something that we have just disclosed, which is our efforts outside of oncology. So it's starting with atopic dermatitis, but it has a number of other indications where we are doing now the clinical research. And in the case of atopic dermatitis, we are planning to be in Phase III in the next few months and that can also have a very meaningful effect on our revenue growth over the next few years. So it is a situation where there are multiple opportunities, meaningful opportunities, for Incyte with a relatively short-term newsflow that will be driving the strategy there. So that's really the way are looking at it. I don't know, Reid, if you have any additional comments.

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

No. I'll take your second question on the delta inhibitor. So in short, we are studying both patient populations, both those that are naïve to ibrutinib and those that have progressed on ibrutinib or prior BTKs. I would say, up to this point, the data are relatively limited, so I can't say too much other than to make the point, and we think we've presented this in prior meetings that we have seen in responses post ibrutinib. As you know, that can sometimes be a very acute situation in those patients that progress often progress with some very aggressive disease, but we have noted some clinical benefit and even responses in those patients in both the marginal zone lymphoma as well as the mantle cell lymphoma trials that are ongoing as part of the CITADEL program. We're including patients that were previously treated either with or without a BTK inhibitor. So I think as those data mature, we'll be able to make a more definitive statement as to what the potential is for PI3-kinase delta inhibition post ibrutinib.

Operator

Our next question is coming from Geoff Meacham from Barclays.

Geoffrey Christopher Meacham - *Barclays Bank PLC, Research Division - MD & Senior Research Analyst*

I have 2, mostly on the pipeline. For rux for GVHD, I want to ask you about the strategy of filing on REACH1. Does this speak to the unmet need? Or do you think it's worth it to wait for a stronger profile when you have REACH2 data or even waiting for chronic patient data with REACH3? And then I have one follow-up on FGF.

Peter Langmuir - *Incyte Corporation - Group VP of Oncology (targeted therapies)*

Our feeling is that the data from REACH1 clearly identify a benefit and meet the unmet need in patients with steroid-refractory acute GVHD, and so our goal is to file on those data. The REACH2 study is, obviously, a larger study in the same setting comparing versus best available therapy that's being conducted in the rest of world. But again, we believe that the REACH1 data provide compelling evidence for activity in this setting. The REACH3 study is being conducted in steroid-refractory chronic GVHD. So that's a different, though related disease, and we hope that will be a separate file later on once we have data from that study.

Geoffrey Christopher Meacham - *Barclays Bank PLC, Research Division - MD & Senior Research Analyst*

Okay. And then on FGFR in bladder, can you guys talk about the opportunities for differentiation that you see thus far with erdafitinib, this is J&J's product. And how much of leading indicator do you think that cholangio could ultimately be when you look to the bladder on things like response rates?

Peter Langmuir - *Incyte Corporation - Group VP of Oncology (targeted therapies)*

So the bladder work is still ongoing. As we've reported, we have some interim analysis data looking at an intermittent dosing schedule, and we're now moving to a continuous dosing schedule to try to improve the outcomes in those patients with bladder cancer. So we'll need to wait for the data from that, which will be available next year, to see how we differentiate from J&J. But in cholangiocarcinoma, as we talked about, the interim data look promising, and so, if those data continue to look promising and we're able to show a good durability of responses, we should -- we have the potential for being first-in-class in cholangiocarcinoma.

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

And Geoff, just to add a little bit on the molecules. I think the selectivity profile of pemigatinib, it's a little bit cleaner across the isoforms, particularly for FGFR4. That may minimize any diarrhea or nausea risk that could come from spillover to that isoform, so we'll have to see how the safety profiles emerge over time. That's probably a little bit of a subtlety in the safety profile but one that could be meaningful for patients, especially if you think about ultimately this class of agents moving to the first-line setting. As Peter said, I think, we have a very good chance to be first-in-class in cholangiocarcinoma, and we're very excited about that. It's a meaningful opportunity in an area of unmet need, and I think, we're probably a little bit behind in bladder cancer. But with the moment to continuous dosing, we have every reason to believe that the merits of pemigatinib as a high-quality molecule may well show at the end of the day when we get the full efficacy and safety data in.

Operator

Our next question is coming from Jay Olson from Oppenheimer.

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

I had a question about the GVHD launch preparations. You mentioned that you've been having some preliminary meetings with payers. Can you just talk about sort of the feedback from payers that you've gotten from those meetings? And then I had a pipeline question.

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

Sure. We just had some market research with payers. We've had some advisory boards with payers, and we have to take a lot of time to explain GVHD, both acute and chronic steroid-refractory, steroid-naïve patient populations. But once they understand that this is an unmet medical need and a very limited patient population, we don't see any barriers that would be put in place from payers.

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

Okay. And then just a follow-up on pemigatinib in bladder cancer. Since PD-1 antibodies are not recommended in the first-line setting for PD-1 low bladder cancer patients, do you know what percent of bladder cancer patients with FGFR3 mutations are also PD-L1 low or negative?

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

So it's almost a mutually exclusive population. So patients with FGFR3 mutations are translocations, so that's the patient population that we would be targeting with pemigatinib. About 85% of those patients are either PD-L1 low or negative. It's only a minority of 10% or 15% of patients that actually have PD-L1 high status. Obviously, that has bearing for how we think about moving into the first-line setting and what kind of trial designs you could imagine. Some interesting dynamics that you just referred to as we now learn from regulators across the globe that the PD-1 axis blockade is not recommended for those patients. So I think that gives us some opportunities, but we haven't finalized any specific plans there, but we hope to share those details with you once they become available.

Operator

Our next question is coming from Brian Abrahams from RBC Capital Markets.

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

Couple of early stage pipeline questions, maybe for Reid. Wondering if you could provide any update on the partnered bispecifics programs and how those are progressing? And then, we also noticed you recently been filing a number of patents for a set of oral PD-L1 inhibitors with some interesting mechanistic and preclinical data. Just wondering, if you might be able to comment on the status of that program, when it might enter the clinic and perhaps, how it might be differentiated from the anti-PD-1 antibodies?

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

So I'll take your second one first, in terms of the patents that you referred to, looking at PD-L1 binders. So you are correct, we do have a series of patents that are out there that are available on the web. As you well know, we don't comment on our preclinical stage research. So I would leave it at that. I will say though with respect to our small molecule efforts as well as Merus, the first part of your question, we're very excited by the near-term products in our later-stage preclinical pipeline. And I think as we get through the coming months and quarters, I think, we'll have a few new agents that we'll be able to talk to you more about and describe. That'll include both the small molecule as well as the first bispecific coming from the Merus partnership. Both of those -- the Merus effort is just over a year old now, and I'll say that it's a very healthy collaboration. We have a robust pipeline of preclinical stage programs moving forward, one of, which is nearing the IND stage. And I think it's living up to all the hope and potential that we had going into the relationship, and I think for us, going forward, it's an area of significant innovation and kind of creative whitespace that we can access new pharmacology that otherwise wouldn't be able to be achieved through small molecule means or even through standard monoclonal antibody methodology.

Operator

Our next question is coming from Carter Gould from UBS.

Carter Lewis Gould - *UBS Investment Bank, Research Division - Large Cap Biotech Analyst*

I guess, first off, you touched a little bit on it earlier, but I was hoping you may be just zero in a little bit more on how you guys are thinking about the clinical -- the hurdle for '50465 plus rux and the hurdle for moving that into a Phase III study specifically on spleen volume and total symptom score? And then separately for Hervé and David, just your latest thoughts on how you guys are thinking about the importance of demonstrating EPS growth from here. I know, during the epacadostat days, you were more willing to (inaudible) investment, but maybe just now how that thinking has changed, particularly now as you've shifted clearly into profitability again?

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

So I'll start, and Peter may have some things to add on '50465 plus ruxolitinib. That trial design is studying patients who are refractory to ruxolitinib in the first-line setting. So these are patients that have had at least 6 months of dosing with ruxolitinib, have been on a stable dose for 8 weeks and still unfortunately have either a palpable spleen or significant disease-related symptoms. And so you can imagine, that's an area of unmet need right now. Fortunately, rux is a fairly effective drug and it's not an incredibly common situation, but when it is, we'd like to be able to bring to those patients a novel treatment. Obviously, that has the benefit not only of the patient being able to rescue their response, as Barry put it earlier, but also to able to extend the treatment duration of ruxolitinib. That doesn't preclude taking a signal there and even considering it into the first-line setting. If you have a beautiful benefit with a doublet, it's, of course, an interesting clinical question as to whether or not an upfront treatment that may be a more idealized treatment approach, and that's something that we would certainly pursue as well as a registration path in the second-line setting, should we have an actionable signal. I'll let Peter comment if he wants to -- it doesn't look like he does, so I'll turn over to the next question.

David W. Gryska - *Incyte Corporation - Executive VP & CFO*

So I'll -- the next question, I'll take the first part, Hervé will take the second part. But in terms of EPS, we did mention -- we gave our guidance today. If you take the guidance and run it through your model, you'll see that on a non-GAAP basis, we'll be between $225 million-$250 million net income. Obviously, that means that the Q3 and Q4 will be slightly higher than the Q2 non-GAAP net income. We really haven't talked much about -- Carter, about what EPS would be next year, we'll give guidance on that. But obviously, we're still going to make substantial investments in the pipeline next year. So I wouldn't expect that you're going to see a big amount of growth, and Hervé has some more comments on that.

Hervé Hoppenot - *Incyte Corporation - Chairman of the Board, President & CEO*

No. I just want to reiterate the sort of the principles we are following. One is the fast growth of our top line, because that's really what's driving our ability to develop the portfolio to ensure that the corporation will continue to grow fast over the next years ahead of us. And that principle applied to the IDO program where we were investing and planning to invest to create a leadership position there, and we would apply the same thing to the programs coming from our portfolio when we see the opportunity. So today, we have a number of Phase III studies ongoing, some of them were in GVHD. We spoke about cholangiocarcinoma. We have a program that we are planning in bladder cancer, obviously, with FGF. We have a number of programs at that stage of development. And as the portfolio is maturing, if we see opportunity, we will certainly invest in them to make sure that we realize the potential for this project. So that's sort of the driver. At the end of the day, over a long period of time, the goal is to have multiple growth drivers for the top line and to be able to be in a position where we would be profitable in a sustainable way and that's really a direction that we will be following in a window of 2 to 3 years.

Operator

Our next question is coming from Marc Frahm from Cowen & Company.

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

First on the FGFR, just the data expectations moving forward. In the past, you've mentioned a 20% hurdle that the FDA wants to see in response rate with reasonable durability in cholangio. Can you talk about what you think the FDA wants in bladder cancer to see? And then kind of related to that, how big of a differential do you think is acceptable -- if it's not necessarily differentiated versus erdafitinib either on the downside that you guys are still close enough to compete or on the upside that it's not a meaningful difference between the 2 of you?

Peter Langmuir - *Incyte Corporation - Group VP of Oncology (targeted therapies)*

I think for bladder cancer, we don't have a clear hurdle that we need to be at. Obviously, erdafitinib has showed data so far around 40% response rate. So we'd like with our continuous dosing to get up to that range. I think clearly, there is a potential we may be differentiated on our safety profile. So potentially, there could be differentiation there, if the response rates are similar, but we can show a better safety profile. But obviously, we'll have to wait for the data to come out with that. So we should have data from that continuous dosing schedule by next year.

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

Okay. And then maybe for Barry, on pemigatinib. Just can you talk about what the sales infrastructure -- your thoughts are there? What you're going to need for cholangio? And maybe if any of that process has started yet, where things stand?

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

Well, that's good question. We have 125 sales reps in the field now. Many of the customers they call on currently treat both hematologic malignancies and solid tumors. So we actually think we have a sales force in place that could actually handle cholangiocarcinoma, a relatively small patient population. But we do have plans to increase both on our medical affairs side and maybe on the commercial side, our understanding of the diagnostic market, so that we know exactly how to communicate to the health care professionals that are taking care of these cholangiocarcinoma patients of what testing they need to do and how to get that done quickly.

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

Okay. And then one last one for you, Barry. As you've started to do some market research in acute GVHD, in our checks, we've heard about a fair amount of off-label use in this refractory setting. So I mean, do you see much of an immediate growth opportunity? Or is this really laying the groundwork for the earlier lines of therapy that will come ultimately with the other REACH studies and the GRAVITAS studies reading out?

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

There is some spontaneous use in both acute and chronic GVHD in Jakafi today. But we do think that with the approval and with any barriers removed from payers, there is a significant opportunity in even the refractory patient population.

Operator

Your next question is coming from Peter Lawson from SunTrust Robinson Humphrey.

Peter Richard Lawson - *SunTrust Robinson Humphrey, Inc., Research Division - Director*

David, just you had a nice beat on Jakafi this quarter. Anything in that beat over the second half around pricing, volume or competition that kind of held you back from raising guidance?

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

Well, so the top end of our guidance is $80 million more than what we -- than what we sold in the first half, so we had $660 million in the first half. And if we get towards the top end of our guidance, that's another $80 million, that's 12% growth. We still think that -- half over half. We still think that's very nice, so there is nothing that's holding us back. We just think that's a prudent guidance to remain in place for today.

Peter Richard Lawson - *SunTrust Robinson Humphrey, Inc., Research Division - Director*

And how should we think about pricing going forward? So kind of in this kind of price-sensitized world, how should we think about moderate pricing? And how should we think about rux as it moves into other indications?

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

We think that we've been prudent in our pricing in the past and moving forward, we will continue to do that. Jakafi is in the same price range as other oral cancer drugs that provides the benefit to patients that we believe Jakafi provides to patients, and in fact, we're actually below the median or average price of oral cancer drugs. So we think the innovation, the fact that we're the only drug approved for myelofibrosis, the only drug approved for polycythemia vera and potentially, the first drug approved in acute steroid-refractory graft-versus-host disease and hopefully, the first drug approved in other areas of graft-versus-host disease, that the -- our price currently represents the value that Jakafi brings to these patients.

Operator

Our next question is coming from Matthew Harrison from Morgan Stanley.

Matthew Kelsey Harrison - *Morgan Stanley, Research Division - Executive Director*

I want to ask just more on the PI3K program. Can you just talk about given that all these are monotherapy studies and you've talked about them being potentially registrationable, what sort of the response rate bar that you need to be able to file these? And how you are thinking about that?

Peter Langmuir - *Incyte Corporation - Group VP of Oncology (targeted therapies)*

So we don't have a specific hurdle necessarily because I think a lot of it is also going to be related to the long-term tolerability and ability to sustain responses over a long duration. So clearly, we're going to look at this in the context of other therapies. But again, it's an overall risk-benefit profile that will be important when we're looking at this compound in monotherapy.

Operator

Our next question is coming from Tyler Van Buren from Piper Jaffray.

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

I guess, I want to ask a question on fedratinib. Celgene continues to talk about the potential for it to compete in the first-line setting. In the past, you all said that you're quite confident that they're going to just stay in ruxo failure. So just want to hear you may be reiterate your confidence that they won't compete in the first-line setting anytime soon? Or perhaps asked another way, what would they need to show in the first line in future studies in order to compete in your opinion?

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

I'll start, and I'll turn it over to Barry for any additional comments. We know quite a bit from the presented and published data for fedratinib in terms of its overall profile and it is a potent JAK2 inhibitor. I think one of the liabilities that it has showed is in its safety profile and that likely comes from off target kinase inhibition. Significant rates of GI toxicity are probably the most prominent for patients. And I think that obviously would be a headwind for any drug moving into the first line setting when you have an established agent without that liability in place for multiple years. There is also, I think, the possibility for Wernicke's risk, at least to my mind, still not fully characterized, but certainly, present in the Phase III data set. So we'll have to see how updated analyses there look. But from a profile standpoint, I don't think it has in any way the safety profile that you would want for a first-line agent to be able to compete effectively with Jakafi, and I'll let Barry describe more from the commercial perspective his thoughts around that.

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

So the only thing I could add is we've heard what Celgene has said about submitting their NDA by the end of the year. Maybe they can get a second-line approval, and if that is beneficial for patients who for some reason no longer are on Jakafi, that would be a good thing, but the safety profile so far, as Reid said, both in the first and second-line setting seems to be problematic. If they were to someday get an approval in the first-line setting in terms of competing in the marketplace, I think, that we would be not concerned about that since the safety profile and the efficacy of Jakafi has been proven in tens of thousands of patients around the world.

Peter Richard Lawson - *SunTrust Robinson Humphrey, Inc., Research Division - Director*

And just as a second question, Hervé, in the release, you mentioned later-stage development portfolio that may accelerate the growth in the near term and there were some exciting data at the Investor Day, and we'll continue to see more through the end of the year. But if you look at Slide 27, it suggests that some of the larger opportunities and some of these exciting programs won't really launch until 2020 or 2021. So I guess, as you think about near-term acceleration of growth other than the pipeline, is there anything else that maybe investors should keep in mind perhaps leveraging the ex U.S. oncology infrastructure? Or are there any potential smaller near-term accretive deals that could be interesting?

Hervé Hoppenot - *Incyte Corporation - Chairman of the Board, President & CEO*

Yes, absolutely. I mean, we -- as we said, I mean, we have a position where we have some cash in the balance sheet. So we have the optionality to do business development, and we are -- as we have done over the past years, we are always looking at potential opportunities. Now there is nothing today I can tell you on what's coming up. But we are looking at complementing what we have from our own pipeline, if any opportunity looks attractive enough to justify the cost.

Operator

Our next question is coming from Ren Benjamin from Raymond James.

Reni John Benjamin - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Maybe one for Barry in GVHD. Can you talk a little bit about any sort of competitive analysis you have regarding the ibrutinib launch in GVHD? And you talked about rightsizing the field force. Can you provide a little bit more color, are there people that are just designated for these transplant centers or are people splitting their duties? How does that really work? And switching gears to Reid, real quick. When we talk about the FGF program, can you just provide a little bit more color or just explanation regarding the selection and cut-off parameters that you are using and what you're learning there? And if I can squeeze 1 last one, an IP question regarding the current IP for Jakafi and the potential extensions?

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

Okay, So Ren, I'll start. So as far as the ibrutinib goes in steroid-refractory chronic GVHD, to be honest, any market research that we have or talking to external experts currently who are treating GVHD, they don't have much use for ibrutinib in that setting, so the uptick doesn't seems to be that strong. As far as our sales force goes, we have an arrangement where we have 82 territories and then we have another 40 people that overlap those 82 territories. So essentially, we have 1.5 persons. So we call 1 group oncology territory specialists and the other group oncology area specialists. So the oncology area specialists are going to be concentrating on those top centers that we highlighted during my presentation, so they'll be trained more deeply in GVHD and in how Jakafi works to help patients with chronic and acute GVHD. So that -- anyway, that's how we're handling it, so they're assigned to these particular centers. And just remember, more than 50% of these docs that are transplanters, we're already familiar with because they are already treating myelofibrosis in some way. I'll turn it over to Reid.

Reid M. Huber - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Yes, sure, Ren, so I'll take your last few questions. In terms of FGFR and patient selection, FGFR can be activated through amplification through a point mutation or through translocation, and all 3 have shown to be oncogenic in patients. It turns out that in cholangiocarcinoma and bladder cancer, the 2 areas that we're focusing on, FGFR is activated through mutations and translocations, and we can identify those through sequencing. And so we're using Foundation Medicine as our platform for identifying those events. And so just through deep sequencing, you either have it or you don't. If you have the mutation or translocation that activates the gene, then you're enrolled in the trial. So that would be akin to any ALK or BRAF inhibitor development than you would expect to see that in the label, of course. In terms of the IP, as you know, the late 2027 is the earliest expiration for composition of matter for the ruxolitinib patent. The cream could go several years beyond that, perhaps to the early '30s, 2031. And anything else on combinations, whether they be with delta or other agents and whether they're discrete agents or fixed dose combinations, would all be predicated on what that IP estate -- how that IP estate evolves, but would be anticipated to have the potential to go well beyond that.

Operator

Thank you. We've reached the end of our question-and-answer session. I like turn the call back to over to Hervé for any further closing comments.

Hervé Hoppenot - *Incyte Corporation - Chairman of the Board, President & CEO*

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

Operator

Thank you. It does conclude today's teleconference and webinar. You may disconnect your lines this time, and have a wonderful day. We thank you for your participation today.
