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PRESENTATION

Operator

Good day, and welcome to the Galapagos Q3 reporting webcast. Today's conference is being recorded. At this time, I would like to turn the conference over to Elizabeth Goodwin. Please go ahead, ma'am.

Elizabeth Goodwin - *Galapagos NV - VP of IR & Corporate Communications*

Thank you, and welcome all to the audio webcast of Galapagos' Third Quarter 2017 Results. I'm Elizabeth Goodwin, Investor Relations, and I'll be hosting today's event. This recorded webcast is accessible via the Galapagos website homepage and will be available for replay later on today. So that your questions can be included, we request that you call in to the following telephone number, which is also to be found on our web -- homepage. The number is 32 for Belgium, 240 459, and there's an access code 2890376.

I would like to remind everyone that we will be making forward-looking statements during today's webcast. These forward-looking statements include remarks concerning future developments of the pipeline and our company and possible changes in the industry and competitive environment. Because these forward-looking statements involve risks and uncertainties, Galapagos' actual results may differ materially from the results expressed or implied in these statements.

Today's speakers will be Onno van de Stolpe, CEO; Walid Abi-Saab, our CMO; Piet Wigerinck, CSO; and Bart Filius, CFO and COO. Onno, Walid and Piet will go through the operational highlights. Bart will explain the financial results. Onno will then close with the outlook for 2017. You will see a PowerPoint presentation on screen. We estimate that the talk will take approximately 20 minutes, and then this will be followed by a Q&A session.

So with that, I would now like to hand over to Onno to start the presentation.

Onno van de Stolpe - *Galapagos NV - Founder & CEO*

Thank you, Elizabeth, and thank you for attending the webcast. Q3 clearly has been a very exciting quarter for us, with 2 new model actions showing activity in patients. It's a big compliment to our discovery platform. We started this back in 2000, building our adenoviral library to come up with novel targets and the JAK1 filgotinib is clearly, the first one that made it to the patients with -- now with 1690 in idiopathic pulmonary fibrosis and MOR106 in atopic dermatitis. We have 3 programs, where we have shown activity against the novel target that we discovered. And that's quite unique and that is the basis of Galapagos and will remain the basis of Galapagos with many more programs to come. In the meantime, filgotinib is continuing its strong path forward with multiple trials. The Phase III trials underway, 8 trials already in proof-of-concept stage and more to come. Cystic fibrosis, very competitive area, where Galapagos is pushing ahead together with AbbVie. We just got the go-ahead from the Scientific Advisory Committee from the U.K. to file for the trials in the U.K. and other countries. And we hope to start dosing the triple study by the end of the year. So exciting times there to come. All that within a fantastic cash position, EUR 1.2 billion in the bank. And we are actually preparing for the next phase in the evolutionary model of the company, where after discovery and development, we are now starting to prepare for commercial operations, and we were very pleased to hire Michele Manto, as our Senior VP Commercial Operations. And he will be at the basis of creating the commercial operations for Galapagos. So if you look at the filgotinib pipeline, then that is quite a number of different diseases. These are all inflammatory diseases that we believe have a good chance to be treated with filgotinib. The 3 main programs, where the Phase IIIs are running in rheumatoid arthritis, ulcerative colitis and Crohn's disease are running its course. So then, we are now testing it together with our partner, Gilead, in 8 other diseases. So a very impressive number. And there's actually more to come. We are preparing more proof-of-concept studies with filgotinib. So blanketing the whole -- this inflammatory disease area. And Galapagos is clearly much more than just filgotinib. Here you see the pipeline of molecules that have passed the candidate stage and are now in preclinical Phase I or Phase II, where you see in idiopathic pulmonary fibrosis, where we have, at the moment, 2 different mechanisms. The autotaxin 1690 deferred as advanced show you the data today. But we also have a number of other numerous actions, some partners, some proprietary that are moving forward. Two are in an undisclosed area. We will shed some more light, not so far from here, but at the moment, we still remain that in undisclosed. In cystic fibrosis, we're preparing for 3 different triples to move into patients. The first one, as I said, starting by the end of the year. The other 2 planned for next year. In our osteoarthritis program, we have a collaboration with Servier, where we are moving ahead with 1972, and a molecule that hits the target ADAMTS-5, and we are planning a full Phase II study worldwide together with MorphoSys to start next year. And in the meantime, we are waiting the data for our Phase Ib study. Then we have programs in atopic dermatitis, a small molecule program that's proprietary to Galapagos in preclinical, and then the antibody program we have collaborated with MorphoSys that we released the Phase Ib data a couple of weeks ago. Further programs in inflammation and pain are still early, but extremely promising, especially, the inflammation program, 3121. I want you to keep that number in your mind because that will be quite exciting when we are going to show the data at a later point in time. Well, with all that information and excitement, I want to hand it over to Walid to talk us through our clinical programs.

Walid Abi-Saab - *Galapagos NV - Chief Medical Officer*

Thank you, Onno. So as you can see, filgotinib is really building up a consistently strong profile around safety in rheumatoid arthritis. Here, you see a comparative overview of safety that we showed at our R&D update back in June. I'd like to highlight a few points here. First, you see that we compare filgotinib in the green column with multiple JAKs plus tocilizumab and adalimumab. You should always exercise caution when comparing across studies. Secondly, you see the patient year exposures involved in the first trial, filgotinib already has an extensive safety database, with more than 1,300 patient years in RA. These results that we're showing here are based on the 16-week safety cutoff from our ongoing DARWIN 3 study. Consistently, across all parameters shown here, filgotinib exhibited a superior safety profile. Regarding thromboembolic events, such as DVT or PE in this dataset, I remind you there was only one patient, who experienced DVT followed by a PE in the study. This puts the range of thromboembolic events at a very low level, considering the background rate in this patient population.

Lastly, I'd like to highlight that at ACR in San Diego, Dr. Genovese will report on more than 1,700 patient years exposure with filgotinib from the same DARWIN 3 study based on the 84-week safety cutoff. And we invite you to listen in on his talk there. From the abstract for his talk, you can already see that continued experience with filgotinib reinforces its solid positioning on safety in RA. Moving on to the next slide. We turn to our autotaxin inhibitor, 1690. Here, we show data from the proof-of-concept study, FLORA, in patients with IPF. IPF is a serious orphan disease with high unmet medical need. On this slide, you can see the steep reductions in plasma LPA levels during the course of the study. This confirms target engagement in patients and it's consistent with the results we showed in our Phase I program. I remind you that FLORA was a double-blind

placebo-controlled trial in 23 IPF patients, who are naïve to treatment. These patients were randomized in a 3:1 ratio to 1690 or placebo for 12 weeks. Next slide. Here, we see that patients who received placebo lost approximately 90 mL in forced vital capacity after 12 weeks in the study, which is consistent -- which -- with what has been observed in similar trials. While we were very excited to see if that patients, who were randomized with 1690 managed to show no progress of their disease over the 12-week period as evidenced by no loss in FVC. In fact, the mean change from baseline was an increase of 8 mL.

Next slide. Using functional respiratory imaging or FRI, for short, a more sensitive technology combining high-resolution CT and fluid dynamics, we showed a statistically significant difference between 1690 and placebo, whereby patients on placebo continued to show progression of the disease as evidenced by an increase in airway volume and a drop in airway resistance. In contrast, disease progression appears to have been stopped in patients with -- on 1690. So these data demonstrate that 1690 is the first autotaxin inhibitor to show promise in patients in IPF. These exciting results, coupled with a benign safety and tolerability profile, strongly support moving 1690 into late-stage development. And with that, I will turn the presentation to Piet Wigerinck. Piet?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Thank you, Walid. During Q3, we also obtained the first patient data with MOR106, our antibody against IL-17C. IL-17C is a cytokine, we picked up as a target using our drugs discovery platform. And together, with MorphoSys, we decided to generate an antibody to block this cytokine. So in IL-17C, some work is published and that points to a dual mechanism of action. Meaning when there is IL-17C somewhere in the skin, it will activate its 17 cells and those cells will give more IL-17A and always on -- as a direct action as well on the epithelial IL-17C will activate the immune reaction. So we believe we are the first company, and so this is a first-in-class, that we developed in the autoimmune space. IL-17C in our model is really behaved as an local amplifier of the immune response. So independent or whether the trigger is Th1 or Th2, IL-17 for both of these triggers will locally amplify. So it's a novel mechanism of action with a potential broad application. Next slide. So in September, we released as part of the press data, the Phase Ib patient data. So we did an SAD in healthy volunteers, then went over to 24 patients in 3 different cohorts. So patients got 4 weekly infusions in a dose-escalating mode. So what we saw was very, very nice efficacy data, in the sense that we saw a fast onset of action. And after top dose after the last infusion, we once saw that the activity remains visible for over 2 months. And secondly, more than 80% of the patients showed a 50% improvement of the disease score. So over 2018, we, together, with MorphoSys, will start up a Phase II study IV; and in parallel, develop a subcu formulation in Phase I, allowing us to bridge into a late-stage subcu program for IL-17C. Let's now move to CF, where as you all know, we are developing multiple triples and the plan is to bring 3 triples into patients over the coming 12 months. So on this slide, I've depicted them, again. In gray, you see how the dual platform of Vertex compares in our in-vitro assays. And for each of our triples effect, we expect a significantly stronger activity compared to the dual platform of Vertex. So the first one that will move into patients is 2222, 2737, 2451. During Q3, we went for scientific advice to MHRA. Discussed with them our design for the first into patient study, discussed with them all our preclinical and clinical data and they agreed that we can move forward now and submit the trial application in the coming days. So the second triple that we'll move to patients is one with 2222, 2737 and 3067. So that triple currently we are doing -- we've completed the dual in healthy volunteers. In Q4, we will move and do the triple in healthy volunteers; and then early next year, this will move into patient. And then, finally, 3221 is a new C2 type of compound and that will move into Phase I in Q4 as well. If you now look to the patient studies, we have, in total, 6 studies on the books. So ALBATROSS is a Phase II study, where we dose 2222 on top of Kalydeco in G51D patients. And those data will read out over the coming weeks. So also the second Phase II study, which is a mono study of 2222 in delta 508 patients. We will have all the data around year-end. Then the first triple is in fact 2737 on top of Orkambi. We've got approval in the countries where we have submitted, and that study has started in the meanwhile. And then you see the first of our in full, in-house triples of 2451. We will file the application in the coming days and then start that study. 3067 base first triple will move into patients early next year, and then the triple base on 3221 will move later in second half of next year into patients as well. So that's the overview of our CF patient study up to now. Then in Q3 as well, we move forward in the field of osteoarthritis. There 1972, in fact, during Q3, Servier took the option on the rights on this program ex U.S. We own all of the U.S. rights. In the meanwhile, we had a Phase Ib study running in the U.S. In that study, we've included, for the first time, patients. We've included, for the first time, female adults. And currently that we have extended the typical dose range beyond the age of 65 because most of the OA patients we want to test in Phase II, will be around that age. So those data as well that study is fully recruited, and that study will read out early next year and will allow us to move them in Phase II. That will be a Phase II proof-of-concept study we will do together on a global scale with Servier, kicking off early next year. So it's a compound blocking ADAMTS-5, which is as well, one of the novel targets we have discovered in our platform; and we as well believe, we are the first oral compound now moving into the clinic in Phase II against ADAMTS-5. And we've decided on the overview of the clinical studies. And I hand over to Bart for the operational highlights.

Bart Filius - *Galapagos NV - COO & CFO*

Thank you, Piet, and good afternoon, everyone in Europe. Good morning in the U.S. I'll take you through a couple of slides on the financials. For those of you who've been tracking the company, they will look familiar to you in terms of setup and format.

First, let's talk about the cash position and the cash burn. At the end of September, we were in a comfortable position of EUR 1.2 billion of cash; coming from end of December, EUR 980 million as you see on this slide. As a reminder, we did an follow-on offering of EUR 350 million in April of this year, which is the big driver for the increase, obviously, in the first 9 months. There is a currency translation effect. I've shown this also at the end of June, dollar to euros as we keep parts of our cash position, roughly 20% in dollars for future dollar expenses. But those are translated in euros. So these unrealized, those are translated in euros in our balance sheet and flow through our P&L to the tune of EUR 25 million in the first 9 months. And then we get to the actual cash burn, which is almost EUR 90 million. This is increasing quarter-on-quarter. We're reflecting the money programs that we are running that have just been described by Walid and by Piet, and reflecting also the increase in expenses that will continue for a little while longer as these trials get broader and the patient inclusion, especially on filgotinib is also increasing. So EUR 89 million for the first 9 months. Anticipating for the full year to be at the lower end of our previous guidance. The guidance was EUR 135 million to EUR 155 million, so we anticipate to be at the lower end of that range. Then to the P&L. Revenues, healthy increase of 64% to EUR 106 million over the first 9 months. Really 2 drivers. On one hand, there is milestones in blue. Here, on the slide, that is cash income that is been generated over the first 9 months. But the main increase is the recognition of deferred revenues. So these are revenues that have been, from a cash point of view, generated when we signed up with Gilead in 2016, early '16, but the recognition are of -- in proportion of the cost that we are making is going over the entire development period. So this is something that you've seen before, but is driving a big chunk of the increase compared to the first 9 months of last year. Then in operating expenses, as a result, we see the same evolution. Saw an increase there as well, mainly on the development fronts as there's more and more programs in late-stage developments, and the programs around filgotinib get more and more mature. So we're almost at EUR 100 million over the first 9 months in development and total expenses on the company are closing to EUR 170 million over 9 months. Net results are a combination of the 2 above. So increase in revenues, but also an increase in expenses. The operational evolution on the slide here is EUR 14 million negative. So that's the combination of those 2 drivers that I was referring to before. There are 2 other comparators that are important in our numbers if you compare this to the first 9 months of 2016. One is the noncash financial asset adjustment that we had as a result of the Gilead deal. I've explained it quite a few times on the phone, but this is in the numbers as a positive in 2016; and obviously, nonrecurring in 2017 for EUR 57.5 million. And then there is the FX fluctuation, the translation effect that I was describing previously for EUR 22 million that is also negatively affecting our net results, bringing the total net results to $85 million negative. So all in all, financials, in line with expectations on our perspective. And with that, I hand it over back to Onno.

Onno van de Stolpe - *Galapagos NV - Founder & CEO*

Thank you, Bart. If we go to the outlook, it's clear that our programs are on track and are delivering filgotinib in a number of different inflammatory diseases. The CF triple combo going into patients, 1690 going in a late-stage program in idiopathic pulmonary fibrosis. MorphoSys and atopic dermatitis, MOR106, very interesting program as well. And of course, our osteoarthritis program, 1972, which will go in a Phase II, of which Galapagos will run the full Phase II study in the U.S. More clever proprietary clinical programs moving forward. And we will announce more data on that at a later stage. And at the meantime, we have initiated building the commercial organization. So all in all, I'm very pleased with how things are going in the company, both on the science side as well as on the development side. And this is all backed by a solid balance sheet. So we can actually finance the programs to what they need and make the best choices to get the most value for the shareholders long term. With that, I'll turn it back to Elizabeth for the Q&A. Thank you.

Elizabeth Goodwin - *Galapagos NV - VP of IR & Corporate Communications*

All right. Thank you, gentlemen. That concludes the presentation portion of our audio conference call. I'd now like to ask the operator, Celia, to connect us to any callers who may have questions for our team.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We'll go first to Brian Abrahams with RBC Capital Markets.

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

First question is on MOR106. I was wondering if you could maybe expand on any new learnings that you have on the IL-17C mechanism. And really, where you see the most potential for differentiation there, given turn of the competitive bar and where this could be novel? And also, curious if you could talk a little bit more about the status of the subcu form. Any estimates for frequency volume, viscosity, your needle size for administration there. And then I have a follow-up after on CF.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay. Thank you, Brian, for the question. MOR106. So we're investigating MOR106 broadly in a number of animal models of inflammatory conditions. Really continuously pops up only in those disease model, where local epithelial process is ongoing. So that is in the different skin models then, skin diseases pops up as very promising option for a therapy. We've done psoriasis to these animal models. Scored excellently, but there, the bar is quite high. So we'll not move there immediately. Atopic dermatitis, second, as well in different models shows very nice results. Haven't gone yet or didn't see a model yet, where we can fairly compare it to the -- pretty much of today. So we haven't done a comparison. But this is completely novel, and in fact, it works independently of the pathway so -- and that's where we think its -- to have a broad application. Asthma is on our agenda, of course. But we will announce further studies the moment we engage on them, with a small effect that local amplifier. So we expect and we don't see any systemic side effects, in fact. So it should be a very safe way of inhibiting inflammatory responses in the skin broadly. And so atopic dermatitis is the first of what we tackled on. And then, the status on the subcu, so we are currently running the tox with -- and the subcu formulation we have developed. And that will move into Phase I next year. And then as soon as we have the data from that, we will inform you. But we are confident that we'll have a patient-friendly system to administer locally as a subcu this drug in the future.

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

Got it. That's very helpful. And then just one other question on the CF program. Sounds like you have clearance in regulatory buy-in and to proceed with the triple combo. Wonder if you could talk a little bit more about sort of the nature of the discussions. The -- I guess, regulatory comfort and testing multiple new drugs together, and how this might apply kind of going forward, best ways to assess the safety PK, and follow-up of the long-acting metabolite that you've seen with 2451. And how you guys are thinking about the design of that study, how we should think about what the next specific steps would be for that initial trial.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

On CF, indeed, as you point, our bringing 3 new compounds together is not an easy task. It is a complex task. And so we spent most of the time explaining them the data we had, the tox coverage we had. The way you calculate safety margins, the similarities between the single component tox and the combo tox stated in the package. And as such, they felt comfortable that we now move into a patient study. They did not give any comment on the long-acting nature of the metabolite that was discussed extensively, but that did not seem for them, I think, an issue at the moment. So no, it was a very constructive meeting, focusing on what patients really need and these are novel triple treatments. And we are one of the promising there. And they were very supportive of us moving forward into a combo study, which will be triple agent study high dose in patients. And we'll disclose the full nature as soon as that is coming online.

Operator

We'll go next to Dane Leone with BTIG.

Dane Vincent Leone - *BTIG, LLC, Research Division - Director and Diagnostics and Life Sciences Analyst*

So could I follow-up actually on the last question? From here to get the triple study started, what are the remaining steps to get the trial up and running? And can you just remind us of the different trial sites and the general logistics of the study?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay. Thank you. So it will be a multi-country study. So we are not finalizing based on the input from the meeting, the protocol, addressing what they really thought was the most important, making that clear in the text. So it's a clinical trial application, which we then expect, we will get approval quickly. That's our experience, in general, if you discuss those complex trials upfront with the authorities. If they see major issues in the package, then they make it clear. It doesn't make sense neither for them, neither for us that we submit a trial application for them to turn it down. Because according to them, some major things are missing. So we discussed then everything what's needed is there. And so we are finalizing the text we submitted. And then that will get approved, we hope, somewhere in November so that we can start the study this year. These are the steps. And so we'll have 2 -- 3 countries in Europe involved in these studies, probably.

Dane Vincent Leone - *BTIG, LLC, Research Division - Director and Diagnostics and Life Sciences Analyst*

And how do you think about -- I guess, 2 follow-ups on that. How do you think about the study design and the data generation that will come from the study? And how that would be applicable to a potential U.S. study? And then, after this first triplet study that you're planning to run, is AbbVie then, in charge of the next steps, the next clinical steps in the program?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

So okay. So what we'll do is a proof-of-concept study, and will be separate cohorts for the homozygous and the het/min patients. And then as soon as we have done proof of concept because then that's the proof of concept of our in-house triple, we will do a Phase II dose range of study. And at that moment, probably, we'll need to decide whether it's 3067 base or a 2451 base study, but that will then be based on the data. And we will do that study. And then it depends a little bit on how the regulatory landscape pans out. If it's the classic way, if it's a Phase III, then normally, AbbVie will perform the Phase III. So second question relates to the latest part of the program. We have an open IND for 2222. And we will open the other INDs next year. So we will offer this proof-of-concept open studies in U.S. as well.

Dane Vincent Leone - *BTIG, LLC, Research Division - Director and Diagnostics and Life Sciences Analyst*

Okay. Great. And if I can squeeze in one last one, actually, on filgotinib. That program is expanding quite rapidly after some great data competitively and some developments that seem to work in your favor quite recently. I was curious, as the indications keep building for what you're looking out with filgotinib, do all these new indications that you're starting to lay out still fall in the master agreement with Gilead? Or are there potentially different economics as you continue to build out different indications of interest under that program?

Onno van de Stolpe - *Galapagos NV - Founder & CEO*

Thank you. I'll take that question. Yes. This was all in the master agreement that we agreed with Gilead. We agreed to pay 20% of all further development costs, actually, kept to a max. And if we get above that max, then further contribution of the 20% will be taken out of a future, late-stage milestone that we expect from Gilead at some point.

Operator

We'll go next to Phil Nadeau with Cowen and Company.

Philip M. Nadeau - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Just one follow-up on the cystic fibrosis trials. I know you mentioned that there'll be separate cohorts for homozygous and het/min patients in the studies. Can you give us some sense of -- some more sense of the design, so how long will the patients be dosed for? How many dose levels will be tested? And will all patients will be given the triple, or will there some patients in trial B given some subset of the candidates?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

It's a proof of concept. Thank you for the question. It's a proof of concept. So all patients will get access to the triple therapy, but in separate cohorts. And we will include typically 2-dose levels so that we have an idea, an early view on whether we quickly pick up on the dose response. So normally, we expect to see quite solid Cl brought on sweat and on FEV, so that will be the endpoints. And patients will be dosed for 4 weeks in this proof-of-concept study.

Philip M. Nadeau - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Great. And in the past, you've guided to data from the study around midyear 2018. Is that still your expectation, now that you've been through consultation with the regulators?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Yes, that's correct. That's still the plan.

Philip M. Nadeau - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Great. And then one last question for me on filgotinib. We've seen great data from other JAKs in atopic dermatitis. It doesn't seem like that's an area that Gilead is planning to do proof-of-concept studies. Is that correct? Is filgotinib not going to be investigated in atopic dermatitis, and if so, why is that?

Walid Abi-Saab - *Galapagos NV - Chief Medical Officer*

Thanks for the question, Phil. So yes, I mean, I think, we always look at these data and evaluate and react to what's happening out there. I think there is good reason to believe that filgotinib, like other JAKs should work on this. And this will be part of our evaluation as to whether we want to test it going forward. So that's where we are today.

Philip M. Nadeau - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. So no decision has formerly been made, yes or no on atopic dermatitis?

Walid Abi-Saab - *Galapagos NV - Chief Medical Officer*

There is no decision now to start the study now. But it's on the radar screen, as you can imagine.

Operator

We'll go next to Christopher Marai with Nomura Instinet.

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

I was wondering with -- you quickly touched upon 1690 and IPF. I guess, you studied it over 12 weeks if I recall earlier in the FLORA study. I was wondering if you had further follow-up or a long-term extension study for -- from FLORA and when you might share the data? And then, secondarily, if you can maybe comment on any potential toxicities you've been looking at with longer-term dosing of autotoxin inhibitors. And some of the checks have suggested that there is some CNS side effects that might crop later in dosing for longer-term dosing of the immunotoxins. So would love to hear your commentary on that. And can you remind us on the path forward there?

Walid Abi-Saab - *Galapagos NV - Chief Medical Officer*

Thanks, Chris. This is Walid. I'll take this call -- this question. So at the time when we conducted FLORA, we had the tox package that would allow us to dose for 3 months. So as a result, we did not have a longer-term extension for that trial. In the trial, we have seen no signs of any CNS side effects that would be of concern to us. Now since then, we have conducted the preclinical package that would allow us to dose chronically. And again, I can confirm in those studies we see, again, nothing that would make us concerned about CNS toxicity.

Operator

We'll go next to Matthew Harrison with Morgan Stanley.

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

I have 2. So first, on MOR106, can you just talk about what the path forward there is? What kind of studies we should expect next, and what sort of time line we can think about? And then can you just confirm in terms of when you went for scientific advice on the CF program, are there any monitoring or longer follow-up or any conditions that they placed related to the long-lived metabolite?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Thank you, Matthew, for the questions. I'll take them. So first, on MOR106. So we've no longer tox coverage and so the next study will be a dose range Phase II study. IV dosing, that we'll dose every other week, not weekly, every other week or with bigger intervals. And that study will start quickly so we are finalizing protocols there. We will submit and then kick that off early next year. So that will keep us busy full of 2018. Will be more than 100 patients as well, so will be quite large study. And in the meanwhile, as I said before, so we have a subcu formulation ready that's in preclinical tox right now, and that will move into Phase I. First as a PK and eventually, we'll do some multiple dose in patients as well. So the dose data come together with the outcome of the dose range. And then see whether we can move to Phase III immediately. On CF scientific advice, no, they have not implied any long-term monitoring that was -- we do what is required to do in the field, of course, CF. We follow the patients, as we have done before in the Phase I. And there was no question to add any extra measures there.

Operator

We'll go next to Adam Walsh with Stifel.

Neil Eric Carnahan - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

This is Neil on for Adam. On MOR106, could you guys just -- given the differentiate in safety profile, could you guys just share some color on how you think it fits within the current treatment paradigm?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Well, in view of the mechanism of action, there is no reason why we think there should be any restriction currently on patients we can include. So we don't see any restrictions there. How clinically this will pan out and compare to DUPI that's a bit early. But from what we've seen or by the fact that we haven't seen anything and straight line that, we feel comfortable that safety will not be a limiting factor for MOR106 as well. If you look to how and where IL-17C works, it's -- if you do the paperwork, it's one of the safest targets we have ever seen. So we are quite comfortable that if efficacy pans out as well in the first study, we will have a high rate of efficacy combined with an excellent safety and hope that, that will be a competitive profile. Whether we can be combined with DUPI or not, that still needs to be worked out.

Operator

We'll go next to Anastasia Karpova with Kempen.

Anastasia Karpova - *Kempen & Co. N.V., Research Division - Research Analyst*

Three, if I may. Initially, on IPF program, can you all update where you are in the discussions with the regulators concerning Phase II -- Phase III trials. And would you consider to the combination or monotherapy as well? And do you need to do any breathing studies to open up the IND in the U.S. given that the trial -- the FLORA was conducted in Europe. The second question is regarding ALBATROSS. Given that Vertex Phase III in a similar population did not demonstrate improvement in Saphira 1 in contrast to Phase II trial, have your expectations for efficacy signal in the ALBATROSS changed? And what do you expect to learn from there? And finally, what magnitude of biomarker movement would you consider compelling in the OA trial that is reporting early next year?

Walid Abi-Saab - *Galapagos NV - Chief Medical Officer*

So this is Walid. I'm going to take the IPF question first and then turn it over to Piet. So regarding the IPF, we will initiate a placebo-controlled study on top of the standard of care in the first quarter of 2018. As this study design has already been discussed previously, with both the FDA and EMA. In addition, we will be discussing additional studies with both agencies in order to complete our registrational programs. And specifically, whether we need to do any bridging before we go to U.S., the answer is no, we can go straight in the U.S. with the package that we have now. Piet?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay. Thank you, Anastasia, for the question on CF. So we designed the Phase II study on top of Kalydeco hoping to see sweat chloride signal and an FEV signal. Clearly, that was based on the Phase II results of projects, which were positive. In the meanwhile, their Phase III is negative. I think anything we can show there in terms of efficacy illustrates that at least, we will have a very active 2222 compound. But we should not hope for extreme high activity because it's the largest phase of the window to see clinical efficacy, is probably limited there. But we are still hopeful that both sweat and FEV will read out in a positive way there. That's for ALBATROSS. Then OA. So what is new there? I said is, for the first time, includes female patients in the study. We've extended age range and as well we've dosed not 2 weeks but 4 weeks. The biomarker signal in the healthy volunteers was still in an ascending phase, while we were stopping study. So we hope that we now as well see where the maximal effect is in terms of the biomarker and hope that within 1 month, in fact, we should see the maximal efficacy in plasma. So it will be the same biomarker, but over a dose range and for longer and then both in males and females. So that should give us nice complementary data to then move further into Phase II.

Operator

We'll go next to Nick Nieland with Citi.

Nick Peter Russell Nieland - *Citigroup Inc, Research Division - VP and Analyst*

I've got 3, please. The first one is, how does the development of 1690 impact your planned cash burn for next year? And has it changed the scale of the commercial organization that you're building? And the second one is, are we still expecting a futility analysis and milestones for the SELECTION study in Q4 this year? And thirdly, what do the milestone payments look like with regards to the CF program with the initiation of the triple combination over the next few months?

Bart Filius - *Galapagos NV - COO & CFO*

Bart speaking. Let me take a couple of those questions. Maybe first on 1690. So indeed, if we are expanding the program into registrational trials, next year, we will anticipate that the cash burn next year will go up. I said that previously, I think, on other calls as well already. We'll give precise guidance by the time we get to the full year results in February. But once you'd expect, indeed, a meaningful increase in cash burn compared to this year, driven by on one hand, filgotinib is accelerating; and on the other hand, 1690 is adding to that as well and CF is continuing. And in terms of commercial, indeed, we have decided and stipulate that we want to be the sole owner of this drug, including the commercial opportunity. So Michele Manto has joined us to build out the commercial organization in our company. He's also looking at the opportunity in IPF and evaluating our options there for commercialization of the drug as well. Then secondly, your question was on the UC transition. We anticipate that in the first half of 2018. And indeed, there should be some financial compensation associated with that as well. And then, thirdly, on CF, your milestone question on CF. I think you've seen several announcements of milestones all to the tune of, let's say, $10 million of the past 12 months for different trial initiations. And as this program continues with additional Phase Is, but also with some more advanced patient studies, you'll see a couple of more announcements coming up to that same level. So no major, major increases suddenly, but there will be some smaller amounts from AbbVie associated to development in the CF program.

Operator

We'll go next to Peter Welford with Jefferies.

Peter Welford - *Jefferies LLC, Research Division - Senior Equity Analyst*

I think I got 3 little ones left. Firstly, on 1972, I wonder if you can just confirm, are the dose levels the same as those in the prior Phase I, or are you investigating different doses? Then a similar vein question in CF. You mentioned there were 2 dose levels that were going to be studied over 4 weeks. Given the dosing work that's been done, perhaps is more extensive with the corrector one, G2222, and I guess, a little bit more is knowing about 2451. Is the plan just to collect the dose of one of the correctors, or is the plan to have a low and a high dose of all 3 components as part of that triple? And then, finally, on 1690. You mentioned a little bit about the fact you were going to do a Phase III combo trial or Phase II/III combo trial, I guess, first, in the early part of '18. Perhaps could you just discuss when you've had the discussion with the regulator authorities about that, what duration of dosing the regulator looking for in an IPF pivotal study? And also what endpoint they'd like to look at in that combo study.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay, Peter. Thank you. I'll go first on 1972. So those levels in data are the ones we have tested before in -- as part of the Phase I. So we'll have now 100-, 200- and 300-milligram doses evaluated for 1 month. And as we did choose to go low because we did not have the dose. We have a suboptimal biomarker response so that -- that's why we decided to explore as part of the study, the lower end here to really see where we pick up a dose response on the biomarker. But it is within the safety exploration as what we've done before. Then more on dosages for CF. So we will escalate one -- we will keep fixed 2 out of the 3 components in the combo and have one component, which will have a lower and high dose included there. But it's not going to be the triple high dose and then for each of the 3, a lower dose. No, we will keep 2 of them constant and only vary one. Thank you. Over to Walid.

Walid Abi-Saab - *Galapagos NV - Chief Medical Officer*

And I'll take the question on 1690. This is Walid. So regarding the study in the double-blind placebo-controlled study that we -- that I discussed, the duration of dosing will be 1 year long. And this will be -- there will be also a long-term open label extension that the patients can enroll into and be followed for longer term for safety as well as we can monitor efficacy as well. With regards to endpoints, we will be looking at the usual primary endpoint of change in FVC annualized rate, but also we will be looking at other major event hospitalization. That's the usual and the functional endpoint of 6-minute walk test, but the primary will be the foresight of capacity change.

Operator

And we have no further questions at this time.

Elizabeth Goodwin - *Galapagos NV - VP of IR & Corporate Communications*

Okay. I think that we had a great question-and-answer session this morning. And so we'll wrap it up with that. I look forward to seeing many of you at our IR event at NACFC. See you in Indianapolis on the 2nd of November. And also, at ACR, the week after. You can reach out to me directly for more details on that. Our next financial results webcast will be on the 23rd of February 2018, when we present our full year 2018 results. So we thank all callers today for their support and participation. And thank you very much. Bye-bye.
