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PRESENTATION

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Okay. I assume I'm ready to start now. Are we? Okay, great. Thanks. Well welcome, everybody, to the Hutchison China MediTech Interim Results Presentation for 2019 -- First Half of 2019. This is the first of 2 analyst meetings today we will do here for, obviously, the U.K. and Hong Kong people calling in, and then later today at 9:00 a.m. Eastern Time, we'll do another call with U.S. analysts.

So what I like to do is take you through primarily the financial highlights for the first 6 months as well as the operating highlights. A lot has happened during the first half of the year for the company, and we have a lot of positive things to talk about. Then at the end, we will talk about the pipeline, and the upcoming events and cash and guidance.

This is very detailed presentation as always with Chi-Med. So I will do my best to cover each slide on a relatively high-level, but for the most part, this is a presentation that is drafted for people to spend a lot of time, really understanding each of the slides and the data in them.

So on a high level, just as we always do, just to explain what we're trying to do as a company broadly, really looking to establish ourselves as a global science-based or science-focused biopharmaceutical company from our established base in China. The global innovation, all of it signified or shown throughout the presentation with the red globe there, is the work that we are doing to bring our most advanced assets out into the global market in first of all in the U.S. and Europe and beyond. We currently have 5 assets, 5 drug candidates that are in clinical trials outside of China, and I will update you on the progress of those programs as we go through the presentation.

China oncology, obviously, is our bedrock, our foundation in our operation in China. Last year, as you all know, we became the first company to bring an innovative therapy from discovery all the way through to unconditional approval and launch. The news today is that we have 2 more that are coming soon behind fruquintinib, but obviously depending on clinical data. But the pipeline really has reached this point of a flow of these assets now is starting come through to NDA submission and approval, and we'll go through that in a moment.

But we have 8 clinical drug candidates in China that are progressing and Elunate, fruquintinib, I'll give you a full detailed update on the progress of Elunate, and how we should be thinking about how it's progressing. And then, obviously, our existing China business continues to be a cash generating tool for us to help fund our research and development.

So on a high level, the organization, really, there is one new addition to the organization chart senior management chart. We just recruited Senior Vice President of Human Resources from Merck. His name is Andrew Shih. He had been with Merck for 16 years, running their Global -- sorry their Asia oncology organization. So what we are trying to do with Andrew and building out, as we all know the battle for talent in Asia is particularly strong. There is a lot of investment going into China biotech these days, and there's a great demand for talented people in this field. So what we are trying to build out is a best practice compensation and benchmarking structure underneath Paul Carter, who is the head of our Remuneration Committee. Paul Carter is the Former Head of Commercial for Gilead, who's one of our -- well he's our Senior Independent Director. So as we build

out our organization, and we talk about that through the presentation, we're able to bring in really high-quality people into the team. And you can see the organization on the innovation side is now up to over 440 people, and the commercial side is many thousands of people across China today.

Financial highlights. No surprises, aside from the RMB depreciating 6% relative to last year so because of all the global trade wars, et cetera. But so we now are showing our results at constant exchange rate, just to give perspective there, but everything was on track. The revenues were a little bit over $100 million, up 5% on a CER basis. Innovation Platform continues to invest deeper into our pipeline. So we put a further 29% over last year into the R&D. Commercial Platform was up 9% on a net income basis on a constant exchange rate basis. So that is on track with what we expected, driven by strong performance in the prescription drug business as usual. Relatively high costs on the group level, primarily around the preparation for listing in Hong Kong, which we can talk about more later. And overall group net loss of USD 45 million. So ahead of last year, but very much on track, and I'll talk about our guidance later.

On the Innovation side, we are now starting to see -- revenues were down a little bit to $12 million, but now we're starting to see a transformation from historically our revenues on the innovation side were driven by milestone payments and were driven by fee-for-service as we provided service to our partners in managing development of our collaboration product. Now we're transitioning more towards royalty and manufacturing revenue structure. So most of our revenues is now starting to come from sources that are going to continue into next year, going to be less lumpy basically, which is a good thing.

R&D expenses for the period USD 74.5 million, very much driven by the development of those 5 programs outside of China as well as the 8 inside China, building out our GMP manufacturing facilities that we are now expanding, establishing the U.S. clinical regulatory team and now also expanding into the commercial side on oncology. We built up a team now of about 60-or-so people on the commercial side in oncology in China that are doing the prep work for surufatinib , as we start to get ready to consider launching surufatinib next year. The work -- the preparation work needs to start happening now. So that team is growing rapidly and is very functional.

On the Commercial Platform, revenue's up 7% on constant exchange rate, those are the consolidated revenues. The JVs were up also around 8% to almost USD 277 million. Our main cardiovascular drug, She Xiang Bao Xin pill, did very well, sales up 15% on constant exchange rates. So that was really good performance in the period. And then net income, $27.7 million, which was 11-or-so percent up versus last year on constant exchange rate basis for the prescription drug side.

The overall charts, I won't go into this in a lot of detail, but these -- this Commercial Platform has generated a lot of cash for us through the years. You can see net income to Chi-Med here on this chart Page 11, almost USD 300 million has come to Chi-Med from our Commercial Platform over the last 10, 12 years. And now it's been very helpful in helping fund a sustained investment on the R&D side.

So operating highlights. I think probably the biggest operating highlight in the first half has been the early unblinding of our Phase III SANET-ep study in nonpancreatic NET. That independent data monitoring committee analysis in June led to unblinding basically a year ahead of schedule for this indication. So I will go into that in more detail as we go through the presentation.

But surufatinib, we also started a biliary tract Phase IIb/III in China and have set off multiple combination studies with PD-1 antibodies. Elunate, fruquintinib, off to a reasonable start in China, and I'll talk about that later. One of the biggest things that's going to now take our focus is looking to get on the National Drug Reimbursement List in China and will -- I'll give you an update on that in a moment.

Savolitinib, I'd say the big news on savolitinib is the completion of enrollment of our registration study in Exon 14 deletion non-small cell lung cancer. So we've now reached the enrollment target for the registration study that data will mature over the next few months. Objective response rate is the primary endpoint. Subject to that data being positive, we will be targeting to submit the NDA early next year on savolitinib in China. So that's a big step for us. Also great data was presented in EGFR mutation-positive non-small cell lung cancer, the combo with Tagrisso, the SAVANNAH study was started up, and we saw good data in renal cell carcinoma.

So I'll take you through now in a bit more detail, all of those things. So surufatinib, just so that everybody understands what surufatinib is. It's a multi-kinase inhibitor, but it really focuses on 2 key areas; VEGFR inhibition, so cutting off the blood flow to the tumor, but unique to surufatinib is

its inhibition of CSF-1R. CSF-1R is a receptor or a target that's involved in the production of tumor associated microphages that sort of defend the tumor cell from T-cell attack. So inhibiting CSF-1R reduces that shroud of tumor-associated macrophages, allowing the T cells to do their job and to kill those cancer cells. So we have seen this sort of angio-immuno response in patients where cutting off the blood flow, but also activating the host's immune system to really go after those cancer cells.

Our focus area has been on development in neuroendocrine tumors. We've never really talked too much about the scale of the opportunity on NET. In the U.S., you've got about 140,000 patients, NET patients. Neuroendocrine tumors are -- it's cancer that essentially emerges from the endocrine cells and the sort of nerve cells in patients across all of the body's organs. You get functional NET, you get nonfunctional NET. Functional NET have hormone-related symptoms like flushing and heavy diarrhea. About 40% of patients have functional NET, about 60% have nonfunctional, where there are no symptoms. They're very difficult to grade, quite a broad range and this makes it quite difficult when you actually come to assessing the CT scans of patients to really understand where those patients are, but you have well-differentiated patients and those are the patients where the cells look very similar to the normal cells. And those are generally earlier patients you have poorly differentiated patients that where the cells look very different from healthy cells, and those are generally later-stage patients. You also have the ability to use biomarkers to evaluate the grading, the mitotic count and the Ki-67 antigen index. These are both biomarkers you can track to gauge the grading of the tumors.

But in general, on the right-hand side of this chart, you can see there are really 3 kind of key groups of neuroendocrine tumors. There's a gastroentero-pancreatic, which is 55% to 75%. There is Lung Bronchus, which is 25% to 30%, and there's another 10% to 20% of unknown primary origin. The GEP, gastroentero-pancreatic NET is split into 2 groups. Pancreatic gets a lot of attention because there are approved drugs in pancreatic NET, but it's actually a very small portion of overall NET. You can see on this chart. In the U.S., pancreatic NET represents about 6% of patients. It's quite small. Other gastrointestinal NET is another 50-plus percent. You can see the treatments that are available today are also quite fragmented. The Somatostatin analogues are used generally for earlier-stage NET, the sort of 40%, 50% of patients that are earlier stage. What the somatostatin analogues do is they alleviate the -- particularly in functional NETs, they alleviate the symptoms. And what they tend to do is they tend to allow those NET tumors to stabilize and not grow, but they are not going to shrink the tumors. So somatostatin analogues are used earlier in the treatment setting, but they are not going to really lead to major levels of response. As patients go later, you start to see targeted therapies emerging into the treatment of advanced neuroendocrine tumors.

As I said earlier, in pancreatic NET, you have both Sutent and Afinitor. You now have Lutathera, which is a somatostatin receptor radiotherapy, it's not a targeted therapy, it's a radiotherapy that targets the receptors of somatostatin receptors. But -- So you have some targeted therapies for the -- for later advanced treatment in pancreatic. Afinitor is approved in certain other gastrointestinal and lung indications, but it's fragmented. So what we tried to do with surufatinib with the SANET-ep study is study everything. So surufatinib across all neuroendocrine tumors. We have 2 Phase III studies, one is in pancreatic NET, so it's a NET niche indication. The other, the SANET-ep study that read out positive covers everything. And that's probably the most exciting aspect of surufatinib is its broadness of spectrum of activity and efficacy.

This is a chart on Page 16, I'm not going to take you through in a lot of detail. It's enormous detail, but I think it's important. It lays out the scale of the therapies today. You can see the somatostatin analogues, our Sandostatin LAR and Somatuline Depot from -- who does Somatuline? It's Ipsen. Yes, sorry. Ipsen, yes. Anyway, look -- Ipsen, yes. So you've got basically $1 billion worth of sales now on the somatostatin analogues. You can see on Lutathera, still less than a couple of $100 million. One of the reasons for it being less than a couple of $100 million is that it's quite a difficult drug to administer because of the radiotherapy aspect of it, 72-hour half-life and that so makes it basically pretty impractical for China given the logistics implications there.

But then Afinitor, Sutent and surufatinib are all oral doses, and -- but you can see Afinitor and Sutent primarily, they're relatively large businesses, but they are obviously approved in many other indications.

So this chart, I won't go through any more detail other than to say, again, the treatments today are very fragmented. The epidemiology of NET is fragmented, the treatment environment is fragmented and for surufatinib the big opportunity is to address as broad a spectrum of NET as possible.

You can see the Phase II data that we've presented previously has, obviously, pretty impressive response rate in the sort of 15% to 17% rate in the Phase II. Obviously, as you go into Phase IIIs, you would expect those to be slightly lower, but still response rate and progression-free survival in Phase II was very positive, and that's what led us into the Phase III programs.

As far as China NET is concerned, we talked a little bit about the U.S. NET patient population being 140,000. NET is a very slow-growing disease. So what you tend to find is relatively low incidence. So the incidence in the United States is 19,000 new NET patients per year, but you've got 140,000 prevalence. So you've got 7 times the prevalence as you do the incidence. That's quite rare in the field of cancer. So it is a slow-growing solid tumor. And in China, there is less data available, but we do know the incidence of NET in China is roughly 67,000 patients a year. If you use the same prevalence incidence ratio as in the United States that would lead to you assuming that there might be prevalence of up to 490,000 NET patients in China. That's a big patient population. Our hunch though, as a company and also working with investigators in China, is that, that prevalence number in China is probably lower just because patients are less, there is less diagnosis of NET, there are less treatment options and more likely these patients are today at least before their treatment option's available, they are progressing and dying faster, meaning a lower level of prevalence.

So we estimate that overall in NET, there is probably around 300,000 NET patients in China living with neuroendocrine tumors. The split between pancreatic and extrapancreatic in China, we think it's about 80-20, whereas, in the west, it's probably 90-10. Again, that's probably because you've got Sutent and Afinitor approved in pancreatic NET in China. So they are looking for it, they are diagnosing it. It's more evident. I think we'll have to see as we go along what the actual split is, and what the actual prevalence is. You can also see here for surufatinib as far as the potential. You see the biliary tract cancer, patient population of about 64,000 patients that we are also targeting.

So this is a chart that shows the sales of some of the products in China, Sutent and Afinitor. Obviously, Sutent and Afinitor are approved in beyond pancreatic NET. So Sutent in renal cell carcinoma and GIST, and Afinitor in renal cell carcinoma as well. You can see in 2018, the sales of Sutent in China, it was $24 million. The sales of Afinitor was about $13 million. So they are not that big products in China. Sandostatin LAR, just purely in GEP-NETs (sic) [GEP-NENS] was about $15 million. Now they have all gone on the reimbursement list recently. You can see Sandostatin LAR went on in October last year, Sutent went in October last year, Afinitor one year earlier. So the growth of those sales is now going to start increasing as those patients are getting their drugs reimbursed. But from this, we can take away assuming that the split in China is about 80-20. We can take away that maybe pancreatic NET today is about 20 million and extra pancreatic is probably 100 million to -- maybe 100 million, give or take. So total NET as of today could be something in the order of 100 million to 120 million. We would hope that as surufatinib comes into the market, that there will be better diagnosis of the much broader scale usage of the product, and patients would live longer, thereby creating a larger market potential.

So just summarizing now on Page 20. So the 2 Phase IIIs, obviously, the first one at the top, SANET-ep has read out positive, at least met its primary endpoints with PFS. The study has been stopped. We intend to present the data in full at a conference later on in 2019. And we expect to submit the NDA in China sometime in the next few months, maybe September or October of this year. So that will be our second NDA as a company.

The SANET-p study, which is the pancreatic NET study, obviously, the smaller patient population is expected to hit its interim analysis probably early next year now and would follow -- if positive, obviously, would follow the same path that SANET-ep is following. You can see the chart there on the bottom left of Page 20, Q4 2019 potential NDA submission based on this.

Now in red here on Page 20, you see what we are doing globally. We have been running a Phase II study in the U.S. in patients that -- in pancreatic NET that have failed on Afinitor and failed on Sutent. We are very excited about this as our potential indication. We are now looking at expanding it to potentially ep-NET globally, and we will engage in a end-of-Phase II meeting with the U.S. FDA, probably around the end of this year, hoping to start our global registration study in neuroendocrine tumors on surufatinib early next year.

Okay, Fruquintinib, Elunate. This is a chart many of you have seen before on Page 22. The epidemiology, there is about 55,000, 60,000 patients a year third-line colorectal cancer. You can see the launch pricing, it was launched relatively high at little bit over USD 3,000. A strong patient access program that required patients to pay for 3 months, and then beyond that the drug was free. That patient access program today represents about 35%, 40% of our unit sales. We've been working hard to broaden drug reimbursement. So just last month in June, the Shanghai regional reimbursement drug list added fruquintinib and essentially is providing a 60% discount to patients. So that's a good step. But it doesn't show up in the first half results.

So actual sales on fruquintinib in the first half, USD 11.4 million, a little bit over RMB 77 million, 6,800 plus cycles of treatment, and you can see our revenue came from manufacturing and royalties, a little about USD 4.7 million. So the question is, how is that? Is that good performance? Is that bad performance? How do we judge how fruquintinib is doing in China to this point?

This next chart is very important chart. On Page 26 -- sorry 24, what this shows is the 5 small-molecule VEGFR inhibitors that have been launched in China by multinationals over the last 10 years. So you've got Stivarga and Nexavar from Bayer. You've got Sutent and Inlyta from Pfizer, and you've got pazopanib, which originally was Glaxo but is now Novartis. So these 5 small-molecule VEGFRs have been launched into a number of different indications in China. And you can see here the U.S. dollar sales for each of these products through the years since they have been launched.

And if you look at it what you see is that, the first 6 months of sales for fruquintinib is actually well ahead of all of those 5 multinational VEGFR inhibitor launches in China. Regorafenib, Stivarga in its first 6 months did less than USD 5 million, USD 4.7 million I believe it was. Sorafenib did $80.6 million in its first full 12-month period. So that -- But that was launched some time ago. Sutent in its first full year did $7 million, $7.4 million. You can see that Inlyta and Votrient, so axitinib and pazopanib, in their second year of first full year of sales were around $12 million. So fruquintinib is relative to those multinational launches, it's actually in pretty good shape.

Now the question is, in those first 6 months what happens? In China, when you launch a novel drug candidate into the system, you launch it through the retail pharmacy channel. Getting your drug in distribution into hospital pharmacies takes anywhere between 6 months and 12 months. It's a big process to run across all of China, and it's a lot of effort. So what companies do when they come out of the gate, when they launch a drug is they put it into the retail pharmacies as the first point. Those retail pharmacies are generally surrounding the hospitals in which the physicians are prescribed -- diagnosing and prescribing the drug. Medical reps go detail the drug to those physicians in the hospitals, the patients then go outside of the hospitals to procure the drug at the retail pharmacies. No reimbursement, all out of pocket. So it's quite labor-intensive, and essentially it's a stopgap. Now when you get on the reimbursement list, as you can see on this chart, in the blue areas, all of these drugs are now on the reimbursement list. When you get on the reimbursement list, you are automatically granted access and distribution to all hospital -- state-owned hospital pharmacies across China. So it still takes a bit of time, it takes a few months. But you go from having no hospital distribution to covering everywhere. The patient that is diagnosed and is prescribed for fruquintinib in a hospital in China, who is on the medical insurance scheme, they will get that drug reimbursed if they procure fruquintinib from the hospital pharmacy, if they procure it from a retail pharmacy, they get no reimbursement. So it's complicated. The point is coming out of the gate for the first 6 months, you make do. You have a stopgap structure of putting your drug into retail pharmacies and directing patients to procure that -- doctors to prescribe and patients to procure that drug in a local retail pharmacy. As soon as you are on the reimbursement list, it goes mainstream. And that's where you see the big step up.

So if you look at regorafenib as an example, Stivarga, the first 6 months, $5 million, 2018 was a full year, $21 million in sales, got on the reimbursement list in October 2018. First quarter 2019, $20 million. So on track maybe this year for $80 million or $100 million in sales.

Now regorafenib, and I'll talk through it in a moment, is in our view, not the best option for patients in colorectal cancer, given its LiverTox profile, but still that's what you can do. You look at even sorafenib, a drug that's been on the market for many years in China, finally getting on the reimbursement list in 2017. So a little uptick in 2018 up to $130 million, first quarter 2019, $50 million. So it's essentially doubled in the 2-year period from going on to the reimbursement list. And the same goes for all of the other assets. So for us, for fruquintinib, I think, we are in a good place right now. I think Lilly is doing a reasonable job, certainly doing as well as any other big multinational could do in China. But getting on the reimbursement list is going to be really important for us, and it's going to be really what propels fruquintinib or Elunate to another level.

Now interestingly, you can see on the last 2 lines, the local VEGFR inhibitors that have been launched in recent years. One is called apatinib from Hengrui, and one is called anlotinib from Sino Biopharm. And you see here the numbers are far greater than the numbers reported by the multinationals. You see Hengrui growing in its first year to $45 million and after 3 years up to over $250 million. And more markedly, anlotinib from Sino Biopharma, $190 million in its first 6 months, just an enormous amount of business. Now these are first-generation multi-kinase VEGFR inhibitors with a fair amount of toxicity approved in very narrow indications, although third-line lung is not that narrow.

The reason these numbers are so high is very high levels of off-label marketing by the local competitors in China, which is noncompliant, which, obviously, major multinationals would not undertake that kind of marketing approach. So you can see from that, the market potential for these VEGFR inhibitors is enormous in China. And one of the reasons that we are now, and we renegotiated the deal with Lilly last year is that we could now go and get into a whole bunch of life cycle indications to expand the label for fruquintinib into many different areas. Why? Because the market potential is there. The local competitors, because they are noncompliant, are pushing very hard in this space today. But if we are able to go and expand our label legitimately, that patient population is going to be a patient population that we can address.

So today, the VEGFR space in China is about USD 1 billion in sales. I think this year, it'll be over $1 billion. I think that from our view, fruquintinib is -- has the potential to be the best in its class, and I think once we are able to expand life cycle indications and get on the reimbursement list, I think we'll see the benefit of that. This chart on page 25, you can see the NRDL reimbursement status. So end of July, a list will be published. It's actually very -- either this week or next week, although you never know, and that list will be all the drugs that a panel of key opinion leaders over China over the last 6 months have decided these are the drugs that we want on the reimbursement list. Once that list is published, the government will engage with all manufacturers, including ourselves and Lilly, to determine or negotiate what would the price discount be that we would provide fruquintinib to the government for to go on the reimbursement. So that goes over the next couple of months and then the full reimbursement list and the discounts will be published in October -- September/October some time. At that point, that would then trigger the distribution of fruquintinib across all the hospital retail pharmacies -- sorry, the hospital pharmacies in China.

Just on a very high level, I won't go into this in detail. These are charts we've shown before, but 26, in the context of colorectal cancer, these data show, again, you've got to be careful comparing cross trials, but regorafenib, which is approved in third-line colorectal cancer relative to fruquintinib approved in third-line colorectal cancer. You see a solid advantage in efficacy for fruquintinib. You also see 2 areas of, in our view, differentiation. First is the use post-VEGFR antibody. So post-Avastin, where you are seeing fruquintinib doing well with a low hazard ratio in patients that have already been exposed to Avastin. Avastin is coming off, or the biosimilars are starting to get reintroduced into China over the next year or so. So having fruquintinib delivering a benefit to patient's post-Avastin is a really positive thing. Regorafenib doesn't show much of an advantage after Avastin run.

And the second area is, obviously, in toxicity. Regorafenib has a black box warning in the U.S. for hepatotoxicity. Obviously, fruquintinib, in our view, has an attractive LiverTox safety profile. That will be a big advantage with 70-or-so percent of third-line colorectal cancer patients already with liver metastases. So you do not want to be treating those patients with a drug that has high levels of liver toxicity. And that's a big advantage for Elunate. So I think once Elunate gets onto the reimbursement list, once we are able to broaden our distribution in hospital pharmacies, our medical sales team, or actually Lilly's medical sales team, will be out there pushing the differentiation around post-Avastin usage benefits and around better applicability for patients with liver metastases. On top of that, better overall efficacy in the FRESCO study relative to what we've seen in the CONCUR study from regorafenib.

Okay, so that's fruquintinib. I think everything is basically on track there. Savolitinib, I won't go through it in a lot of detail. This chart, you have all seen many times before on Page 29. Just the only update here is Tagrisso first half 2019 results, USD 1.414 billion. I think for the first time when Astra presented the results the other day, we were asked a question, maybe some of you were there, around the resistance pathways to Tagrisso and c-MET and savolitinib were both mentioned as areas that ASCO is looking into to solve resistance on Tagrisso.

The big step, this first half driven really by Wei-Guo and the team is the MET Exon 14 deletion program in China. You can see here on Page 30, there are 3-or-so competitors in this space globally, capmatinib from Novartis, tepotinib from Merck Serono. The response rate in these Exon 14 patients in global studies is somewhere end range of sort of 40% to 50% to 60% depending on the line of treatment. We presented data at the American -- sorry, at AACR, in late March that showed savolitinib in Chinese MET Exon 14 deletion patients, efficacy was give or take, not a lot different than what's being seen on capmatinib and tepotinib, is of the same range, difficult obviously to compare cross trials, but certainly we are not at a disadvantage. So we are way ahead of everybody in China. We've now completed enrollment of the registration study and now waiting the 2 or 3 months for that data, that ORR data to mature and subject to that being positive we'll be submitting the NDA next year. That's laid out in the chart here on the bottom of page 31, bottom left to page 31.

As far as the patient population is concerned, the China market opportunity for Exon 14 deletion patients is roughly 2%, maybe 3% of the over 700,000 non-small cell lung cancer patients a year. There is an adjacent population of patients in early non-small cell lung cancer that are c-MET gene amplified, maybe doubles the size of the patient population. But I think for us getting savolitinib approved as the first selective c-MET inhibitor in China, while we, obviously, will be compliant in our marketing activities. We won't be promoting off-label like some of these local players do. But getting a selective c-MET inhibitor into the market in China will give physicians the alternative to prescribe that drug to MET-driven patients, across many solid tumor types, so gastric cancer, et cetera. So we obviously won't be pushing it, but that if the drug is available, it is -- it will be used in China across many MET-driven patient population. So we are very excited about savolitinib and moving rapidly on this.

This data, you have seen in the past. You have seen response data for the savolitinib/Tagrisso combination but for the first time, this, at AACR, we presented the duration of response data for the savolitinib/Tagrisso combo. So here you can see in the second-line setting. For patients of the T790M MET positive, the duration of response was somewhere around 7 months and response rate of over 50%, close to 56%, so very encouraging data. Post-Tagrisso, in later-line patients, second- and third-line patients, you are seeing a lower level of response, because generally those patients are sicker and maybe have more genetic drivers of disease in play, but you are seeing a really good response -- duration of response in the patients that do respond, so 9.7 months there, so pretty encouraging. This data is what led to the start of the SAVANNAH study, which is the global Phase II registration intent study of savolitinib and Tagrisso. It's being enrolled in 11 countries around the world. They are not all started yet but by the middle of this year they should -- well, in the third quarter, they should --they should be started up in all 11 countries. You are seeing a 50-50 split between patients coming off Tagrisso in the first-line setting, and the other 50% is patients coming off Tagrisso in the second-line setting. We've been working on the dose. We'd been looking at a weight-base dosing algorithm for the combination. We've now been running a Phase Ib expansion called the TATTON D study at a slightly lower dose, and we are very close to concluding that work. And we believe it's a very positive outcome.

So SAVANNAH, next year, we'll see, hopefully an interim analysis on SAVANNAH some time middle of the year maybe, maybe this time next year. At that point, we will go subject to the data we will go and talk to the regulatory authorities in the U.S. The savo-Imfinzi combination, I won't go into a lot of detail, but basically the combination of savolitinib and Imfinzi looks like it's delivering some synergistic efficacy. There are multiple theories around the interplay between MET and the immune system. And this early data that was presented in February of this year, I believe, starts to show how a MET inhibitor and a PD-L1 can really benefit patients that are not even MET-driven patients, because you are affecting the body's immune system, and reducing an amount of neutrophils that are protecting the cancer cells.

So other operating highlights. On the B-cell malignancy programs 523, we've now dosed over 150 patients in China and Australia, got a good data set, and we're working on thinking about how to start potential registration studies late this year or early next year. 689 or PI3K Delta is now through our Phase I dose escalation study and is now entering into expansion. And importantly, our teams in the U.S. and Europe are now screening patients to start global Phase Is on 523 and 689. The organization's expanded, clinical regulatory as well as the commercial team in China and discovery, Wei-Guo and the team have now just taken our ninth drug candidate into an IND. Hopefully we'll be able to start development of our HMPL-306, which is an IDH 1/2 dual inhibitor, sometime early next year hopefully. And here you can see the various targets we are working on, both large molecule lines and small molecule, ERK inhibitor idea, RIP1 kinase, IDO, et cetera.

So just on a high level Page 40, the pipeline chart we tried to simplify this a bit, but I think the most important boxes to look at are with the yellow arrows. These are studies that are now transitioning to the next stage, so you can see MET Exon 14 hopefully transitioning to an NDA early next year, and Surufatinib SANET-ep transition to an NDA late this year. You've got AstraZeneca is aligned now to expand our Exon 14 deletion development global. So that will transition. Fruquintinib and surufatinib there coming out of proof of concept and into global registration studies run by Chi-Med. So unpartnered fruquintinib, we own the rights outside of China. Surufatinib, obviously, also. So our team in New Jersey will be launching those registration studies for fruquintinib and surufatinib over this next 12-month period. Savolitinib and Iressa transitioning as well, and obviously 523, the Syk inhibitor transitioning. So there's good movement across our broader pipeline.

Page 41 just lays out the upcoming events. You can see there's a lot going on in the second half of this year, in the first half of next year with 2 NDA submissions targeted. The surufatinib in extrapancreatic NET, an Exon 14 for savo. We have a second fruquintinib interim analysis on the FRUTIGA study in gastric cancer. We conducted an interim analysis earlier this year in March, April, I believe it was. The independent data monitoring committee. It was a very early interim analysis on the first 100 patients for 6 month trending overall survival in PFS.

The independent data monitoring committee were happy with the progress of this study, and the study continues untouched or unchanged. So we'll have a second interim on that FRUTIGA study either late this year or early next year sometime.

I think the -- aside from the 2 NDA submissions, probably the reimbursement on Elunate inclusion in NRDL is probably one of the biggest factors as well.

Okay. So finally and will leave us for 10 minutes with questions -- for questions. But looking at cash and guidance for 2019. We have got cash and resources of around USD 380 million, that's cash of $230 million, $240 million and unutilized banking facilities with over -- of almost $150 million. In the first half, we paid down a credit facility with Scotiabank of Canada and have consolidated that over to HSBC. So we will actually draw down

that same $27 million we paid down in the first half in the second half. So our debt by the end of the year will be about $27 million, and our cash position will be, obviously, $27 million higher. You can see that we've shaved our losses for the year. So we -- our previous guidance was about $120 million to $150 million net cash outflow. This year, we've shaved that down to $90 million to $120 million, taking off about $30 million. Two reasons drove that. #1, the weakening of the RMB actually helps us on the R&D side. When the RMB depreciates by 6%, our cost of running clinical trials, in U.S. dollar terms in China, is significantly lower. So while it hurts us on the earnings side, on the commercial side, it helps us on the R&D expense side. Also we've now scheduled or planned our end-of-Phase II meetings with the U.S. FDA on surufatinib and fruquintinib for the end of this year, early next year. That means that the start of those registration studies will be -- will more likely be in early next year versus this year. In the original plan, we had them starting up late this year. So pushing that out a little bit around those regulatory interactions is what drives down, allows us to shave the losses. So essentially, $90 million to $120 million cash burn this year. Resources we have are in great shape, and it allows us to really take our pipeline through multiple value and inflection points like the NDA submissions for surufatinib , savolitinib, the Elunate NDRL or NRDL inclusion, and the readout on savolitinib in gastric cancer, which will come later Phase II. And so we feel it's -- we are in good shape from a cash standpoint.

So that's it. In summary, that's where we are today on the business, and maybe since we've got 10 minutes left, I'll open it up for some questions. Yes, Richard.

QUESTIONS AND ANSWERS

Richard J. Parkes - *Deutsche Bank AG, Research Division - Director*

Yes, I have got a couple of questions. Firstly, on surufatinib, it's obviously the first compound that you have retained full rights and profits and as you go into the filing, can you talk about what you might need to add in terms of commercial infrastructure when that product launches in China, and what you can and can't leverage from the current commercial operations? And the second question was just a simple one on the Commercial Platform. I wonder if there was -- if you are expecting any impact from the 4+7 tender process during the remainder of the year that we should take into consideration.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Great. Thanks, Richard. So on surufatinib commercial, actually this 60-person team that we've built up on the oncology side, just over the last 6 months in China is very focused on surufatinib, even already. They are involved today in, what I would not classify as medical affairs activities, but it's kind of supportive work going out to all the clinical sites, engaging with all the clinicians that have been running the surufatinib studies, and they are getting to know the NET landscape. So the -- when surufatinib subject to obviously, approval is launched then all of those -- that infrastructure in NET is already established. I think that commercial team for the launch of surufatinib will be a multiple of its size today. I think we'll see probably closer to 200 people by the end of next year, maybe slightly higher than that. So the work we are doing on the commercial organization today is actually preparing for surufatinib coming maybe late next year, if all goes well.

The second question on the 4+7? Did I answer your first part?

Richard J. Parkes - *Deutsche Bank AG, Research Division - Director*

Yes.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Yes, the second question on the 4+7, obviously, the 4+7 policy is a great policy in our view in China. It's really driving down the price of generic drugs in China. What that's doing is opening massive headroom in the medical insurance scheme for urban employees and residence in China to open up headroom to fund reimbursement of innovative drugs. That's why you see all those oncology drugs now going on to the reimbursement

list because the price of generic drugs is being squeezed. So the question is, does that squeezing of generic drug prices affect Chi-Med? And if you look at our portfolio on the Commercial Platform, we basically don't have any generic drugs. We got out of that business a long time ago, because it's a difficult business to be compliant in, it's a low margin, historically a low margin and has been proven the case to be very volatile from a pricing pressure standpoint. So we got out of the generic drug business a long, long time ago. Most of our business, 95%-plus of our Commercial Platform business are -- is proprietary therapies. Now obviously we have OTC business, an OTC cough, cold business, et cetera, that is not affected by 4+7. That's long since been affected by pricing pressures. 7 years ago, they took the prices down there, and we suffered then, but it's been quite stable ever since. But in the prescription drug space, 95% of our business is proprietary, where we are the only people making what we make. So the 4+7 doesn't affect us. But I think overall, the kind of the 4+7 policy and the Chinese government's philosophy of driving down the prices of more mundane products to open up reimbursement on more innovative products, we're helped massively in that, because our whole innovative drug pipeline will benefit from that strategic activity by the government.

Richard J. Parkes - *Deutsche Bank AG, Research Division - Director*

And if I could just squeeze in a third and Merck has made a -- making a big investment behind Keytruda and the TKI combinations, and I know it's early days for your -- for Elunate in combination with PD-1. Could you talk about how your thoughts are evolving in what tumor types you might target where you think there might be an opportunity despite kind of Merck's kind of...

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

I'll ask Wei-Guo to answer that question.

Wei-Guo Su - *Hutchison China MediTech Limited - Chief Scientific Officer, Executive VP & Executive Director*

Actually, it's obviously a very competitive area. Merck is in there, BMS as well. So but -- we think we are in a reasonably good shape in China. At least there is a wind of opportunity for us to take up some indications. So in terms of specific tumor types with Innovent on their PD-1 combination with our fruquintinib, we are just going through a dose escalation and hope to complete dose escalation in a few months, maybe clearly it's only been for end of the year, and we're going to dose expansion over the multiple cohorts, including renal cell, including HCC as well as you know that Merck's Keytruda and Lenvima just got breakthrough therapy designation in the U.S. So it's clearly a validate in our approach, but we think in China, we can still get in to the game actually, probably more than 50% of patients are in China globally. So in HCC so I think it's a big opportunity there.

Aside from there, we are also interested in endometrial cancer as well as, perhaps, gastric. I'm not sure if you noticed that BMS and Bayer, they just announced a collaboration maybe 2 weeks ago post-ASCO. So they are working together to develop the rego/nivo combo in GI, in particular, gastric. So we are interested in it as well and you know China has got more than 50% of global gastric patients. So basically, relatively similar combination is targeting similar tumor types but we are doing more in China with these major patient populations basically. The combination with surufatinib with changes PD-1, we are interested, really trying to maximize or take advantage of the kinase profile of surufatinib being particular CSF-1R and FGFR targeting hopefully to further activating the T-cells in a tumor micro environment.

And so we are looking perhaps clearly neuroendocrine malignancies, including the neck, so NET and neck. We are also interested in breast cancer as well as small-cell lung cancer, for instance. So basically tumors are not as hot. Actually perhaps quite -- be quite interesting in OB/GYN types, including ovarian and cervical as well. So anyway, this is wide open at this point in time to both combinations are going through dose escalation. We think surufatinib is a bit maybe 3 months ahead. So we probably will wrap up with the dose escalation portion sometime in August or September time frame, and we will kick off multiple cohort dose expansion.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Mike, could you pass the microphone for Julie? Thanks.

Michael Clive Mitchell - *Panmure Gordon (UK) Limited, Research Division - Healthcare Analyst*

Michael Mitchell, Panmure Gordon. The national reimbursement pathway, the process is actually pretty short in sort of the players have a history of 4 months. What are the key variables or [mms] that you think you have to deal with, and how sensitive are you on pricing?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Well, actually, Eli Lilly gets to determine the price. So they will judge at the end of the day what the price discount will be with the government. Obviously, Eli Lilly knows this, and they know that it's very important for fruquintinib to get on the reimbursement list. That said, a negotiation is a negotiation. So I think we -- if you look at the -- actually very deep in this presentation, I think, in the last couple of pages as you can see the 32 cancer drugs that have been added to the reimbursement list over the last couple of years, you can see the discounts that have been agreed vary from 30% to 60%. Some of them are as high as 70%. But generally those are all discounts of very high global prices. Fruquintinib is not a very high, global price. It's at a reasonable price for China, 3 -- little bit over 3,000. Somewhere in that range is where it's probably going to end up I would imagine, but it's a bit pretty premature to guess.

Can we pass it over to Steve? Actually, Julie, give it to me.

Stephen McGarry - *HSBC, Research Division - Analyst*

Steve McGarry from HSBC. Obviously you have given us R&D cadence and cost cadence for last year, but as you begin global drug development, that's when things start to get significantly more expensive. So what we think about R&D costs over the next 2, 3 years without giving us quantitative data, maybe us a qualitative idea that where the R&D spend could go? And how you might consider funding that, given obviously we've had the proposed Hong Kong listing discussed over the past few months?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Thanks, Steve. Yes. It's a good question. I think that with fruquintinib, you can see what we hope is going to happen on for fruquintinib. If you get on the reimbursement list, we hope that that's going to take off significantly. If that takes off significantly, the cash that we are generating off fruquintinib is going to be material to us. I think surufatinib, the fact that we own it, outright, if we are able to launch it effectivity next year and start generating cash from surufatinib that will be terrific. Our royalty on savolitinib in China is a fixed royalty of 30%. So as soon as savolitinib hits the market in China, we are going to start generating some pretty material income. So I think to answer your question, we are in this sort of transition period, maybe the next couple of years you are going to see the R&D expense increase as we start to take certain of our assets out into the global market. So you would expect the trend that we have seen in the last couple of years of rising R&D expenses to continue. But I think over the next year -- 2, 3 years, you are going to see an offsetting amount of income coming in from our approved and our launched drugs that is going to help offset some of it, maybe not all of that increase, but some of it. So I would imagine, we've got a long history of kind of eating what we kill and managing our R&D expenses in the context of the income we get from our commercial business, the income we get from our partners and trying to balance it without ever finding ourselves as sort of into this very vulnerable, binary biotech type environment, and we'll continue to do that. But to answer your question directly, I imagine you'll see a gradual increase in the R&D expenses. But I think you'll start to see incoming offset through the royalties and the revenues that we are going to generate from our approved assets.

I think the other thing that we are totally open minded to is to the divestiture of noncore commercial businesses. I think you look at our OTC business is a good example. In the next 5, 10 years, Chi-Med having an OTC business is probably not necessary. Our focus is very much on the prescription drug side, is very much on oncology in China, and while our OTC business been very helpful through the years generating cash for us, it's not really strategically that core for us anymore. So there are these aspects so sort of non-dilutive financing pools that we can go to through that time to help out basically.

Cinney. One for Cinney.

Chenye Zhang - *Bloomberg Intelligence - Equity Research Analyst*

Cinney Zhang from Bloomberg Intelligence. First one, can you just give some comments on your postponed Hong Kong IPO? And second on surufatinib, you mentioned that Astra's leading the effort for the global development in Exon -- MET Exon 14 patients? Are they going to initiate a global pivotal Phase III trial and also what's the royalty rate for Ex-China sales?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Okay. Thanks, Cinney. So postponed Hong Kong listing is probably not the way to sort of describe it. We've obviously done a lot of work in preparation for a potential listing, Roche's on the Hong Kong Stock Exchange. We have done it for the right reasons, we are a Hong Kong based company. We are well known in the region, the region with regards to biotech is really developing quickly. There is a lot of investor interest in that part of the world on biotech, as we've mentioned around the battle for talent and all of this sort of stuff. But right now the Hong Kong market is a little bit shaky with all the protests that are going on, and it's, in our view, it's not the right end of the market. Market conditions are very important for a successful transaction. And so as we've taken you through the financial picture on the company from a cash standpoint, we don't need to be moving forward into difficult markets. We can take our time to reach various valuation inflection points around delivery of our pipeline and our programs, and then when the time is right, we are a biotech company.

So you are always going to need to raise finance at one point or another. But the key is to do it when the markets are right, and when your assets are really showing that they are worth further investment. And we are confident that we will do that in due course. So on the second question on savolitinib Exon 14, the study -- the SAVANNAH study is registration intent. So it's a Phase II study, but it's designed to be used for registration. That would be for conditional approval, if all goes well. It's a single-arm study with objective response rate as the outcome. The interim next year will determine if that Phase II can be used for registration. In other words, we'll do an interim analysis, we will look at the strength of the data, then we'll go with AstraZeneca, talk to the regulatory authorities in the U.S. and the FDA, and at that point, if we are at a level of efficacy and confidence that the SAVANNAH study itself will be sufficient for submission for conditional approval, then we will continue to enroll and submit SAVANNAH...

Wei-Guo Su - *Hutchison China MediTech Limited - Chief Scientific Officer, Executive VP & Executive Director*

Actually Exon 14.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Sorry, you were talking Exon 14. Sorry, sorry I misunderstood your question. So say again?

Wei-Guo Su - *Hutchison China MediTech Limited - Chief Scientific Officer, Executive VP & Executive Director*

Global Exon 14.

Chenye Zhang - *Bloomberg Intelligence - Equity Research Analyst*

So you have mentioned that AstraZeneca is looking at taking savolitinib in MET Exon 14 deletion patients in the U.S., Ex-China. So are they going to initiate a separate pivotal trial...

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Sorry, I misunderstood. So what we are doing is because we've got a very large dataset in China, in Exon 14 and continuing to enroll patients in China. We are now opening up sites hopefully around the world in the United States and Europe to be able to aggregate, potentially to be able to

aggregate all of that data. These are very specific patients with a very specific molecular profile. So the intention is to try to aggregate all of the data, and if the aggregated data is sufficiently strong, potentially, then go and have interactions and engagement with the regulatory authorities in the U.S. around submission of the aggregated data for approval outside of China. That's the idea today. Ultimately, it's -- we find ourselves behind capmatinib and tepotinib. So what we have got to do is try and find a way to catch up, and that would be our approach.

Chenye Zhang - *Bloomberg Intelligence - Equity Research Analyst*

What's the royalty rate for Ex-China sales?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

So it's quite broad range, and it's complicated but, in a nutshell, it's between 9% and 18% subject to a couple of things happening. So it's a tiered royalty, actually its -- tiered royalty of 9% to 13%, but if we are able to get an approval in kidney cancer and papillary renal cell carcinoma, you add another 5 percentage points to the royalty. So it's 9% to 13%, plus potentially an additional 5 if kidney cancer works out.

Great. Okay. Thanks very much for coming. And yes, thank you very much. Goodbye.
