Lakefront Biotherapeutics

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Judah Frommer: Good afternoon, everyone. Welcome to the final fireside of Day 2 at Morgan Stanley's Global Healthcare Conference. Judah Frommer, one of the SMID biotech analysts here. We're very excited to have Henry, Aaron and Eric representing Lakefront. Let me just get through a quick disclosure before we get started.

For important disclosures, please see the Morgan Stanley Research Disclosure website at www.morganstanley.com/researchdisclosures.

All right, with that, the team's been leading Lakefront through quite a transformation. So before we dive in, maybe give the audience an intro to the company and your focus since taking the helm last summer.

Henry Gosebruch: Great, we're delighted to be here, and thanks for hosting us. We're a clinical stage biopharmaceutical company now with a very exciting portfolio of T-cell engagers with a lead program that is going to start registration studies next year and four programs in total, and it was quite a journey to get here. We started about 18 months ago. The company, at that time named Galapagos, had a portfolio that was built in ex-vivo CAR-T. And we spent a couple months analyzing that portfolio and went through a very thorough process analyzing strategic alternatives and ultimately determined that those programs were not commercially viable.

We then negotiated with works councils and unions in Europe to get clearance to unwind that portfolio, which we did. We had over 650 employees and about $300 million annual spend. And we began winding all that down this January, which was obviously quite a complex process which is now almost complete.

In parallel to that, we pursued business development. So, we had about €3 billion in capital. And we looked at a very long list of opportunities without necessarily honing in on just oncology or just autoimmune programs. But when we saw the initial data from Ouro Medicines just about a year ago, actually sort of September / October last year, we were just blown away with what we saw on the lead program and started doing some serious diligence. And the more work we did, the more we were convinced that this was a very unique opportunity and one that we were a very good party for.

We ultimately renegotiated our historical deal with Gilead to where they contributed to that deal and ended up paying half the deal consideration. And we ultimately prevailed in a competitive process to secure that asset in March. And for the last six months, we've been heads-down executing on that program. It's going quite well. The studies are enrolling well and progressing nicely. And we're quite excited to unveil some data toward

the end of this year and then start registration studies next year.

Judah Frommer: Okay. Great. And we'll spend most of our time on gamgertamig and that acquisition, but maybe just further set the stage on that Gilead relationship. There's obviously, like you said, a history of collaboration between the two companies even before the acquisition. So maybe just a little more context around the relationship, how it stands today.

Henry Gosebruch: So we inherited a relationship with Gilead, who entered into this broad strategic alliance with then-Galapagos in 2019. It was a 10-year agreement. So, we've got another three years running on that agreement. And as part of that agreement, they put about $5 billion into the company, and so that is where a good chunk of the cash comes from. That agreement allowed them to opt into any program we have at the company at POC stage, and to opt in for a pretty small amount, $150 million for commercial rights ex-Europe.

So of course, when we got involved, and frankly, following some discussions even before we took our roles, it was very clear that Gilead was highly motivated to, through us, find a way to deploy that capital very effectively, but to also reimagine that historical deal. And so as part of the negotiation with Ouro, we also in parallel negotiated with our partners at Gilead to where ultimately, again, they put up half the money to do this transaction, and we're splitting operational responsibilities. They will ultimately commercialize the lead program, and we will take a royalty. I think it shows that on a combined basis, we can very effectively pursue business development.

So we're very pleased with the engagement. We're operating at a very senior level at Gilead. They talked about it in their fireside chat today. So this is a program that gets a lot of attention. And we're pleased with how the two companies are collaborating to really broaden and accelerate the program and hopefully bring it to patients in the not too distant future.

Judah Frommer: Okay. Great. And maybe just a bit of background on how that Ouro transaction came together. I know you and Gilead had a focus on certain therapeutic areas, but broader than just Galapagos was focusing on. So maybe a bit about the funnel of opportunities you considered. What interested you specifically about Ouro and gamgertamig and then the terms of the deal?

Henry Gosebruch: So again, we didn't specifically target autoimmune diseases or opportunities. We didn't specifically target one therapeutic area. We really looked very broadly across the biotech landscape. But we specifically wanted opportunities that had very clear clinical proof of concept. Ultimately with Ouro, we saw more than 60 patients' worth of efficacy and safety data. So that was, as I said, quite compelling.

We wanted to be in a place where we are the rightful owner of an asset. I didn't want to be somewhere where I knew every pharma company was focused today and likely reviewing every asset. This is a set of orphan diseases, which we think are quite significant, multi-billion dollars each in terms of commercial potential. But where, I think, many folks in pharma don't have that on their list of strategic priorities at this point. Some of these diseases aren't commercially understood at this point, there haven't been effective medicines, and we have a chance to be first-in-class in many of these indications. So, it was important to find something where we have a real angle in terms of us being first and us having a good competitive position.

So again, at the end of the day, this aligned well with where we were interested strategically and where Gilead was willing to put up half the money to participate, so it's sort of a win-win across all of that. And again, ultimately being first-in-class in a new exciting area was a really compelling component of this. Then we can talk, of course,

about the specific clinical profile and all of that good stuff more at a high level. I'll sort of reframe it.

Judah Frommer: Okay. Great. So maybe let's get a little bit deeper into the data package we have for gamgertamig at this point. What indications has it been studied in? How many patients do we have data for in autoimmune indications specifically?

Eric Hedrick: Yes. So the focus of the program to date has been in a few diseases that are mediated by autoantibodies. The most mature data in terms of studies have been done both in China and outside of China, Australia, U.S., would be the autoimmune cytopenias. So ITP and hemolytic anemia. There was also an initial focus in the clinical trials in China on pemphigus vulgaris, which is an autoimmune skin disease. Those are the three indications where the most data exists.

There's another ongoing trial outside of China investigating some other autoimmune diseases -- Sjogren's disease, myositis, confirmatory experience in pemphigus that's ongoing. And I think ultimately, the list of diseases that are amenable to this type of therapy is actually quite large. And part of our plan over the next year is to expand the number of proof-of-concept studies to start addressing that larger set of diseases.

Judah Frommer: Okay. Great. I think you might have investigated gamgertamig in multiple myeloma, so obviously the focus for you guys is on autoimmune. But any data in that indication that was helpful in framing the profile here?

Eric Hedrick: Yes, I think in terms of the myeloma data, I think you know, a lot of people know this is a class - BCMA-directed T-cell engagers and CAR T-therapies. BCMA is an established target in myeloma, and there are marketed drugs being used. Our partner, Keymed, who has rights to the drug in China, is developing in myeloma.

One of the things that was interesting about that experience is that they were able to show in their myeloma data that the rate of cytokine release syndrome, which is one of the key safety considerations here, seemed appreciably lower than what was observed with teclistamab. And we think that that's due to the fact that this antibody has been engineered, so it has a lower affinity for CD3. So it's less prone to cause T-cell overactivation. And that was one aspect of the myeloma data that interested us, in addition to the fact that it's been studied in well over 100 patients with myeloma. So just the breadth of the experience was important for us to see as well.

Judah Frommer: Okay. Great. And maybe just on the competitive landscape across BCMA T-cell engagers, so not long after you guys announced your acquisition, Candid was acquired by UCB, I believe. You have Cullinan out there. Maybe talk about some of the properties of gamgertamig and how do you think gamgertamig is differentiated versus those other programs? Presumably, you did due diligence across many BCMA T-cell engagers.

Henry Gosebruch: Once we found Ouro, as I said about a year ago, we of course did a pretty thorough assessment of other, not just BCMA-directed T-cell engagers, but we looked at some CD19 programs as well. So, we have a pretty good sense of how everybody stacks up. And what we liked about Ouro, well, of course, the data sort of spoke for itself. But it was an indication, as I said, that Ouro had very smartly picked where to develop this program. And so, we now have a 2-plus year advantage over the next competitor, and so that is quite helpful, of course.

Secondly, the data we saw was already in a subcutaneous format and at a dosing regimen that is one that we think makes sense to use for registration studies. And so again, a lot of this space is really working through finding that optimal dose where you have a benign

safety profile and efficacy, and that's not trivial. So Ouro had already achieved that, which was very, very attractive. So, all of that gives us a really nice timing advantage and a really nice platform to go into other diseases.

And so, yes, it's a competitive space. We're, fully focused on maintaining and hopefully even accelerating our timeline advantage. But these are large enough markets that at the end of the day, if somebody else comes in the market, it's still a very large opportunity. So, it's not necessarily a winner-take-all type market. But as I said, and I keep saying, it's important, it's nice to be first, and we intend to keep that advantage.

Eric Hedrick: And I guess I would add to what Henry said. There were two main targets in this space, CD19 and BCMA. BCMA was previously thought to be largely restricted to plasma cells and plasmablast. We think those cell populations are important. Those are the ones that are producing the autoantibodies. But we also recognize it's important to address the B-cell compartment as well. And I think what is being observed now through gamgertamig studies, through studies that Candid's doing, through studies of teclistamab in these diseases, is you actually get a much broader range of cellular depletion than what you would have originally thought. So BCMA is expressed in sufficient amounts, even in naive B-cells.

And so, to us, you get the sort of depletion pattern you would expect with CD19, which is restricted to B-cells, but you also address the plasma cell component. And we believe in some of these or many of these autoantibody-driven diseases, that's going to be an important thing to address.

Judah Frommer: Okay. Great. That makes sense. And you touched on it a bit earlier specific to the CRS, but I guess, what have we seen clinically that suggests gamgertamig can induce that immune reset with better safety?

Eric Hedrick: What I would say, we haven't commented specifically on the incidence or severity of CRS that we're seeing in the studies. What I would say, Henry mentioned this is a subcutaneously administered drug. In all the trials to date, it's been administered as an outpatient therapy. Obviously, if you were seeing something of concern with CRS, you might rethink whether that would be the right way to administer the drug. We've seen nothing in the studies so far that would make us think that this is not going to be an outpatient administered drug in a subcutaneous formulation. So, we're comfortable with what we're seeing as far as the CRS profile.

Judah Frommer: Okay. Great. And then just touching on the initial indications that you'll be going into, clearly you prioritized registrational development in some rare autoimmune indications. Maybe tell us a bit about those indications, the rationale behind pursuing those first. And if you could, give us an idea for how big those opportunities could be.

Eric Hedrick: I can start and Henry can add in. One of the appealing aspects of starting with diseases like ITP, hemolytic anemia, pemphigus is that the proof of concept is very clear. If your platelet counts go up, your platelet counts go up. If your hemoglobin goes up, it goes up. If your skin lesions go away, they go away. So, there were three diseases where it was very easy to interpret proof of concept and the effect size was very clear. As a way to establish proof of concept in this set of diseases, they picked the right three diseases. Henry also mentioned the aspects of the fact that these are diseases with well-established regulatory precedents, so we think there's a very clear path from proof of concept stage right into Phase 3.

Henry Gosebruch: And from a commercial perspective, while these are orphan and we've obtained orphan designation from the FDA for all three of them, they're pretty sizable populations, and

there really isn't anything effective out there today. These patients are really very sick. It can be deadly. They are basically sidelined. They're on these chronic therapies. They're heavily on steroids and other immunosuppressants. We think, as I said earlier, these are all multi-billion dollar commercial opportunities easily, and I think they would be really elevating the existing standard of care very significantly. So that's what gets us excited.

Judah Frommer: Got it. And you've talked about more data for gamgertamig being shared later this year. Maybe give us a sense of what might come with that update, which indications could it include, how many patients, length of follow-up, anything you can share on.

Henry Gosebruch: The key focus is the cytopenia set of studies that we've talked about. So, we're talking ITP and AIHA. And as I said, we had about 60 patients when we entered into the deal in March. Since then, these studies have been enrolling in the U.S. and Australia very attractively. We have many more patients now. So, we know response rates. We know how many of these patients saw their B cells being depleted. We of course are seeing the safety profile since that generally happens right around dosing, so we know that. So that's all very good.

What we want to demonstrate, though, is whether we're truly achieving immune reset. So that means B cells get depleted, and then after some period of time, they come back and they come back healthy, and patients stay without disease for some meaningful period of time. So essentially, that's just a question of time. We saw a few patients when we did the original deal back on the earlier data set that had already achieved that.

But we want to get it to a meaningful number where we believe it would be interesting to share that with the market and demonstrate that this is an immune reset therapy. So that's the goal. And we think by around year end, we'll have enough patients that have been on therapy long enough to adequately describe that drug profile.

Judah Frommer: Okay. Great. And maybe just a bit more on dosing. What doses have been explored thus far? Do you think we'll have go forward dosing with this update? How should we think about dose selection?

Henry Gosebruch: So we haven't disclosed the exact dose and dose regimen. But what we have said is that even the data we saw back in March, a good chunk of those 60 patients were at doses or close to doses that we think would be what the registration studies would be. So now we of course have much more of that.

What we've also said is that what's very commercially attractive is, and frankly, very important when you think about what this means for patients and quality of life and so forth, that this is a very short initial course of dosing, and then that's it. So, these patients ideally go through that pretty quickly, get monitored for a very short period of time, and then essentially go back to normal life. That's the ambition. And that's the profile we're seeing. Again, it would be an exciting step forward for patients in these diseases, and that's what we hope to demonstrate when we roll out the data by the end of the year.

Eric Hedrick: And I would maybe add to that another aspect of the Ouro program that was attractive to us at the time that we were doing diligence is that the very first experiences with the drug in autoimmune disease in China were conducted at doses that were much higher and longer in duration than what we're using in the clinic now. Even at those doses, you achieve the reset profile. And the safety profile was acceptable. Probably not optimized, but acceptable.

So, we were really in the position where the dose ranging work for us was dose de-escalation to the point where we have this sort of efficacy safety profile that we think will

be attractive to go forward. And that's a much easier proposition than starting from zero and building up. So that was an appealing part of the program.

Judah Frommer: Okay. Great. And you've talked about starting registrational trials next year. So, what can you tell us about potential first indications, maybe high-level thoughts on trial design? Just any details or timing around when you could share details on those trial designs?

Henry Gosebruch: At this point what we can say is that, again, the focus is on the cytopenia. So, ITP and AIHA will be the first two registration studies kicking off next year. We have to have further discussions with the regulators about exactly what the design is and exactly the number of patients we ultimately need for approval. I think there's a good precedent, as Eric talked about, in terms of the regulatory pathway in ITP. And that is really more based on a relatively shorter-term platelet count-type endpoint.

At the end of the day, we want to design a trial that doesn't just achieve that primary endpoint, but again, really demonstrates this immune reset and quality of life for patients. So what exactly does that looks like? We look forward to sharing more on that when we fully align on that with FDA. That's at some point next year. But what's attractive is we don't envision very large studies. We do think they're probably going to be controlled studies. But again, these are orphan diseases, and this is a very profound impact, so you don't need to squint to see the two lines separate. Therefore, we don't think these are going to be very large studies and not super long.

Judah Frommer: Okay. Great. And maybe just last question on gamgertamig. You've talked about proof-of-concept basket studies. Any additional autoimmune indications? Anything you'd share there, or just kind of stay tuned?

Henry Gosebruch: At this point, we have spent some good time with our collaborators at Gilead, and we have pretty developed plans for additional basket studies. So, the plan is to start two basket studies early next year. They will cover clusters of diseases.

Again, for each individual disease, this drug makes such an impact that for each disease, we need a strong handful or low-double digit kind of numbers of patients, we think, to have proof-of-concept in those diseases. So, basket studies are a pretty efficient way, both from a time and a capital perspective, to really very quickly accelerate it. So again, we'll roll it out early next year. We'll share more with the market then as to what the indications are.

But again, just to come back one more time to what we like so much about the opportunity to begin with, given that it's already subcutaneous and the dosing regimen is effectively established, we can run pretty quickly and expand this. We don't have to go through extensive dose finding for other diseases, et cetera.

Judah Frommer: Okay. Great. And maybe just another aspect of the Ouro acquisition. There were three preclinical assets you talked about in-licensing. I'd imagine there's not a ton you can say about it right now. But maybe just level of excitement, anything you can share around timelines for disclosure of those or progress with those.

Henry Gosebruch: We're actually quite excited about these three programs. A little known fact about Ouro is that Ouro actually started with those programs and then gamgertamig came. So, it isn't something that, hey, we have gamgertamig and let's add some pipeline to it. No, no, they actually started with those programs they have, and we now have a really capable team that has proven that when we see an interesting mechanism, we can create what looks to be very effective programs.

So, I'd say they're not too far away from IND, but we're going to share more next year as to exactly where they stand. Some of those will allow us to go into similar diseases as gamgertamig. Some will even further expand the diseases we can address. So those really present additional upside that's quite attractive.

Also from a deal perspective, these are programs that we fully own at this point. Gilead has an opt-in right. But if they choose to opt in and pay us the opt-in fee, it would flip to a 50/50 profit share all the way through. So not 50/50 followed by a royalty structure, but 50/50 all the way through. So again, the focus today should be on gamgertamig, but these represent nice potential that we're quite excited about.

Judah Frommer: Okay. Maybe just spend a minute on the integration of the Ouro team. How has that come along? And could that potentially translate to future pipeline development?

Henry Gosebruch: That's gone extremely well. We think of it less as a traditional integration. We think of it more as, again, even though the old Galapagos had 600-plus people. The core of the new Lakefront prior to Ouro was actually more like 35 people. So it’s really more adding two equal pieces together. And in fact, we're really co-creating what we want the new Lakefront to look like.

It's a phenomenal team. It's a team that is quite excited about what we can build together. And frankly, it's a team that is looking at gamgertamig and saying, wow, this is an opportunity I want to be a part of. At this point, we've barely lost anybody. Having gone through hundreds of M&A deals, that's very, very rare. We even have the prior CEO staying with us for six months. We are very pleased with how that's going.

And to your question, we have that early translation and clinical development capability now that we could deploy in different ways. The focus very much is gamgertamig and the portfolio, so we're in no rush to do anything beyond that. But we do have that capability now, and that's, strategically really valuable for us going forward as well.

Judah Frommer: I wanted to touch on some financial and capital allocation questions. Even after Ouro, clearly, the cash balance is still very healthy, maybe just remind us how much is allotted to the broader collaboration with Gilead versus what can be used for other purposes.

Aaron Cox: Yes, and what we said with our key Q2 Earnings is we expect to end the year at €2 billion in cash. And we also gave a number related to what we expect to have following all related spend to Ouro and our other operations through the first approval of gamgertamig, and that number was €1.6 billion. So, you have basically the €400 million there that we're implying can be fully deployed for gamgertamig and our preclinical portfolio and any milestones associated with that. And we see that €1.6 billion as kind of a minimum. There's upside there depending on interest income, royalties we receive, and things like that.

In terms of Gilead specifically, with the Ouro transaction, we were able to negotiate a $500 million bucket that would be completely independent of anything we may do in the future where Gilead doesn't have to be involved or Gilead doesn't have any opt-in rights. As part of that, we have $150 million sublimit of that $500 million where we can use for a share buyback, which we announced a €50 million share buyback in June that we expect to complete by year end.

In terms of the other capital available, obviously with the €1.6 billion minus the $500 million, there's still that €1.1 billion. But again, as we look at BD opportunities, we see a high bar to do another one with that capital.

Judah Frommer: Okay. Great. And just on the winddown of the legacy cell therapy activities, any color on what's left to be done there?

Henry Gosebruch: So, we're really largely wrapped up. We have the last wave of our team wrapping up the clinical study reports and so forth. So, the spend is pretty modest at this point, and again, well within our estimates. That was actually one of the reasons we were able to keep our €2 billion guidance, despite starting a €50 million share buyback. So that is really largely wrapped up. The team has done a phenomenal job under difficult circumstances to wrap it all up in a good way. And kudos to all of our former colleagues. It's not easy to go through a process like that. So, it's really taking less focus of us today relative to what it did over the past year.

Judah Frommer: Okay. Great. And then maybe just lastly, other potential sources of cash. There's the interest income. Just remind us about expectations for Jyseleca. I think there's still some potential cash inflow from that status of the TYK2 inhibitor.

Aaron Cox: We really have some nice legacy assets here that generate some nice income for us. In terms of royalties related to Jyseleca, we received royalties both from Gilead and Alfasigma. And that ranges in €15 to €20 million a year. And depending on the success of that product going forward, those could go higher.

Interest income, obviously a meaningful balance of cash earning interest. We have made a concerted effort to shift a lot of that. Last year when we came in, we were 80%, 90% euro denominated. We've flipped that to more U.S. denominated to take advantage of the higher interest rate environment. So that could generate meaningful interest income on the €2 billion. You get 3% to 4%; that's pretty meaningful income coming in.

We also have some legacy tax credit receivables. These are actual tax refunds that we get from various governments related to historical R&D activity. And at the end of Q2, we had about €125 million of those still to be received over the next several years. And we estimate that in the €20 to €35 million range a year.

Henry Gosebruch: And then finally, over the years, and again, Galapagos has been around for 27 years now. So, there's actually been some equity investments made and there's been some historical out-licensing, all of which could provide other upside from either downstream considerations or if some of these companies are going public or sold, et cetera. So the legacy is rich, and it provides us with really a nice amount of value that in some ways should be added on top of our cash. And we're happy to have that as an additional stream of value creation for shareholders.

Judah Frommer: Okay. Great. In the last minute, I'm just going to try to tick through a mini survey we're asking all the biotech management teams at the conference. First, I'm very curious to get your take here. With the rise in Chinese biotech innovation, how are you thinking about competitive position? Does it influence R&D, business development, or both?

Henry Gosebruch: It does influence both. Of course, our asset originated in China. And things are moving very quickly. So, I think there's a high premium, and I said probably three or four times during this talk, speed is key. Execution is key. We have an advantage now. We have to keep it. But I think both from a BD and R&D general execution perspective, you have to stay very close and keep an eye on China.

What was very attractive about Ouro was that while the asset originated in China, some of the initial data was China, when we did the deal, we actually saw both Chinese data and global - U.S. data and Australian data. And that gave us additional confidence.

So, we do think it's a theme that's here to stay. Our team is active looking at other things both from a competitive intelligence perspective and from a BD perspective. But as Aaron said, the bar for us to do another deal is extremely high given how busy we are with the current portfolio and given how excited we are about those opportunities.

Judah Frommer: Okay. Great. Next is on AI impacts to your business and potential for it to be disruptive.

Aaron Cox: We obviously use AI. It's table stakes now in today's world. We use it throughout R&D, BD, competitive intelligence, things like that. It's obviously moving quickly, and we'll continue to monitor how that evolves and how we can further use it to generate more efficiency in various areas of the organization.

Judah Frommer: Great. And then just lastly. On the regulatory front, anything in particular that you see being impactful to your business, whether changes at FDA, MFN pricing, tariffs, and anything else on the regulatory front that's most topical for you?

Henry Gosebruch: I would say despite some of the things that are being written about the FDA, we've been very, very pleased with the level of regulatory engagement. It's shown in orphan designation for all three of our indications. So, we've been really, really pleased with their engagement and are confident as we approach discussions on ultimate registration studies. So maybe we're a bit more bullish on that than some of our peers.

I think, of course, some of the other aspects you mentioned, MFN, IRA, et cetera, we're monitoring all that very, very carefully. But we still at this stage, I think the FDA interface is probably the most important theme, and again, that is going extremely well. So, we're not seeing the same clouds that some other companies are talking about.

Judah Frommer: Okay. Great. Well, with that, we're out of time. Thank you again for being here.

Henry Gosebruch: Very good. Thanks again for hosting us.

Judah Frommer: Thank you.