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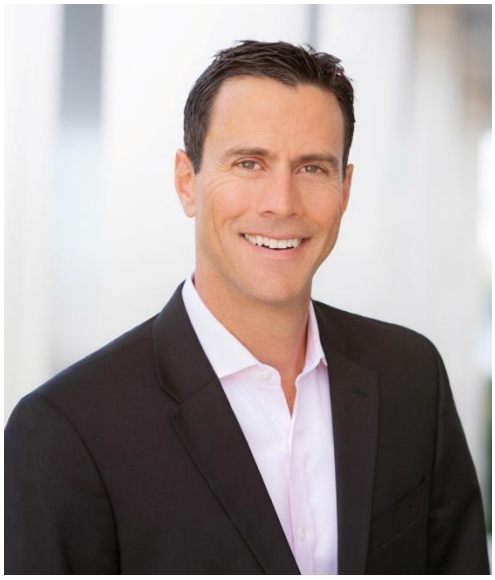
Equillium's Selective T-cell Modulating Agent Itolizumab Showing Favorable Interim Data Analysis as a Treatment for acute Graft-versus-Host Disease (aGVHD)



Bruce Steel
CEO

Equillium, Inc.
(Nasdaq: EQ)

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: ***Mr. Steel, it has been about two years since we talked; what is Equillium like today?***
Mr. Steel: We're excited about where Equillium is today. Equillium's lead asset, our foundational therapeutic drug itolizumab, has advanced considerably since our last call two years ago. We have reported on two essential data sets for itolizumab over the last six to eight months, most notably, the interim data from our ongoing pivotal study in our lead indication, acute Graft-versus-Host Disease (aGVHD), which is a life-threatening complication that can occur after an allogeneic hematopoietic cell transplant (HSCT).The interim analysis was favorable, and we received a "study should proceed" letter from our data monitoring committee in August.

It is worth mentioning that this is an indication where there are no drugs approved currently. The unmet medical need is very high, as these patients are extremely sick with high morbidity and mortality rates for patients that do not respond to the only existing treatment which is high dose Corticosteroids. We are pursuing a label for First-Line Treatment in this indication, which currently would be the only new therapy approved for these patients and we think has potential for significant benefit.

CEOCFO: ***Would you explain what this drug does?***
Mr. Steel: Itolizumab is an antibody therapeutic that targets CD-6, which is a T-cell receptor that modulates T-cell activity, differentiation, and proliferation. T-cells are an important component of the overall immune system and response to antigens and disease.

Itolizumab is a selective T-cell modulating agent. This means we have the ability to selectively modulate the effector T-cells that are involved in the highly inflammatory and pathogenic response, while leaving the regulatory T-cell component intact.

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CEOCFO: *What happens in the body that makes this work?*
Mr. Steel: In many disease states, such as Graft-Versus-Host Disease, ulcerative colitis, and other therapeutic areas that we are evaluating, T-cells are primary drivers of the inflammatory response and over-reactive state or autoimmune state these patients suffer from. We are basically dialing back the body's aggressive immune response selectively in a way that can dampen the disease, but not completely inhibit overall immune capability. It is a selective immune modulating agent designed to be more specific as it relates to certain therapies based on the underlying disease.

CEOCFO: *What else is happening at Equillium?*
Mr. Steel: We completed a lupus nephritis study in April 2024 and from which we reported favorable top line data, but GVHD is the focus right now for Equillium, specifically acute GVHD where we are running a Phase 3, registrational study.

Immediately in front of us are the two most important data events for the company in our history and probably the drug itself. We have the top line data from the acute Graft-versus-Host Disease program. We are expecting to accelerate that data to the first quarter of next year. Keep in mind that this is an indication of high unmet medical need, is concentrated at the top transplant centers in the United States, and is an indication for which we could launch and commercialize on our own, assuming our ongoing study is successful and supports a drug approval process.

Our partner, Biocon Limited, also recently completed a study in patients with moderate to severe ulcerative colitis. We have updated guidance and expect the top line data from that study also in the first quarter of 2025. Therefore, we have two seminal data events for the company and the drug itolizumab coming up in the first quarter of next year.

CEOCFO: *How are you able to move so quickly in this industry that often moves slowly?*
Mr. Steel: Like most of our peers, small biotech companies are focused on the programs we are working with. In this case, itolizumab was our foundational program and is at an advanced stage of development, so we have a high degree of focus and effort applied against this program.

"The takeaway is that the two most important data events in Equillium's history are immediately in front of us: topline Phase 3 data from the acute Graft-versus-Host Disease program and Phase 2 data from our study in partnership with Biocon. These events will set the stage for the company going forward." Bruce Steel

CEOCFO: *How has the medical community that are aware reacted to what you are doing?*
Mr. Steel: The interest in the acute Graft-versus-Host Disease program is very high. We have in our ongoing pivotal study over 100 sites worldwide enrolling patients. In the US we have 9 of the top 10 transplant centers recruiting patients. The reason why there is high interest is that these patients are severely ill when they present with acute Graft-versus-Host Disease, and there are no drugs approved to treat these patients in the first-line setting. If these patients do not respond to the current standard of care – high dose steroids – their outcomes are very poor with high mortality rates.

Itolizumab looks like a promising therapeutic agent that if successful could provide an important benefit clinically to these patients who otherwise typically have poor outcomes. I think the medical community is excited about the potential of this drug for these patients where the unmet need is high.

CEOCFO: *What have you learned through the recent trials and what if anything surprised you?*
Mr. Steel: I would not say we have had any major surprises. What we did experience and learn was that the COVID-19 pandemic, which looks like is more or less in the rearview mirror, presented a lot of challenges for the industry from an overall patient recruitment standpoint. Major delays were not expected when we initiated programs that started before COVID-19. Other than that, I would not say we encountered too many surprises in our course with itolizumab. We are pleased to be at the point we are now with these two data events in the immediate future for the company, which will set the course for our future depending on these outcomes.

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CEOCFO: *Has the investment community evolved in understanding and paying more attention?*
Mr. Steel: There are two sides to the equation. The biotech sector has come off of a difficult period going back from late 2021 to today. The investment environment has been challenging. With that said, institutional investors have the cash to invest and deploy and as it relates to Equillium, we think there is and will be a lot of interest in the upcoming data events. The market today is more one of "show us the data" versus in more frothy biotech times when there is more speculation and investors are more willing to invest in front of data. It is a little bit more of the "show me the data" market.

We are pleased with the overall level of investor engagement we are experiencing right now with significant institutional interest. I think it is driven both in part by the stage of the program now with a pivotal study expected to come to completion shortly, as well as the prospect that this is a drug that we can commercialize on our own and would not necessarily have to partner. These are two things that drive investor interest. With that said, I think that if the data is positive, we have the likelihood that it will drive significant partnering interest and that also could be a benefit.

CEOCFO: *Do you have the funding you need now?*
Mr. Steel: We have funding into Q4 2025, sufficient to get through these upcoming data outcomes. So we are well capitalized to get to these near term milestones.

CEOCFO: *As CEO, what is your typical day?*
Mr. Steel: I spend a good amount of my time making sure that we in the company know our options for capitalizing the business, whether that is from the investment community or the strategic partnering community. I also spend a good bit of my time focused on the operational aspects of the company, particularly as we were coming up to the conclusion of a pivotal study and that is a heavy lift operationally. Cross functionally there is a lot going on, and it is an intense time, as we have significant data events to be announced shortly.

CEOCFO: *Is it more challenging as a global company, or are most of your people in one place?*
Mr. Steel: Most of our team are actually in San Diego, although we have a few exceptions. The clinical studies that we conduct certainly have complexity as they become larger and involve multiple countries such as the equator study in aGVHD as mentioned, I think we are in over a dozen countries and over a hundred clinical sites across those countries. That adds complexity for sure, but we have a capable team that has delivered on our operational execution so far.

CEOCFO: *What is the takeaway for readers? Why look at Equillium right now?*
Mr. Steel: The takeaway is that the two most important data events in Equillium's history are immediately in front of us: topline Phase 3 data from the acute Graft-versus-Host Disease program and Phase 2 data from our UC study in partnership with Biocon. These events will set the stage for the company going forward.