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Xbrane Reveals Urgency To Find A Partner For One Of Two Biosimilars By October

Initial Discussions Held On Biosimilar Cimzia After Biogen Exited Project

by Dean Rudge

Cash is king for fledgling biosimilar companies. Xbrane Biopharma has revealed just how close it is to the edge after Biogen unexpectedly pulled the plug on a key licensing deal, but the company is maintaining optimism.

In an at times candid update, *Xbrane Biopharma* has disclosed that it must secure an out-licensing deal by this October for one of its two biosimilar candidates that are up for grabs, in order to satisfy the company's working capital requirements from the beginning of November 2024 and onwards.

However, the Swedish player believe this is "feasible," considering the "high level of interest" and uniqueness in its XB003 proposed biosimilar to UCB's Cimzia (certolizumab pegol); and the "revised streamlined clinical development focusing on outside of US markets based on positive European Medicines Agency feedback" for its Xdivane (nivolumab) proposed biosimilar to Opdivo.

"Both out-licensing processes are being led by a highly regarded external biopharma licensing consultant," Xbrane noted, while acknowledging a more difficult atmosphere than anticipated for nivolumab given the potential for high development costs.

"The company's board of directors and senior management are fully committed and working relentlessly to resolve this and are also exploring other possible avenues to preserve shareholder value."

Xbrane And Biogen End Deal For Cimzia Biosimilar

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Xbrane was caught unawares earlier this month when its former partner on certolizumab pegol, Biogen, pulled out of the deal (*see sidebar*).

This was an "unforeseen event," Xbrane admitted, "which significantly impacted the company's expected income during the coming six-to-12 months."

Having previously set a target of reaching positive operational cash-flow in the first quarter of 2025, Xbrane disclosed after Biogen's withdrawal that it now envisioned reaching positive operational cash-flow in the following quarter – and that considering several milestones it must hit.

By David Wallace

05 Aug 2024
Biogen has decided to terminate an alliance with Xbrane Biopharma linked to the firm's proposed biosimilar to Cimzia (certolizumab pegol). The move represents the latest setback for Xbrane, with the firm acknowledging that losing Biogen as a partner will impact its financial goals over the next year.

Read the full article here

Contingent upon US Food and Drug Administration approval for its Ximluci (ranibizumab) proposed biosimilar to Lucentis, Xbrane must also successfully out-license both Xdivane and XB003 "during the coming months" to ensure financing until its envisioned positive operational cash-flow in Q2 2025.

Xbrane is currently working towards resubmitting its ranibizumab biologics license application to the FDA in the final three months of the year, as well as approval and launch of a pre-filled syringe in Europe during 2025. (Also see "*Xbrane Working Towards Q2 2025 US Ranibizumab Approval*" - Generics Bulletin, 9 Jul, 2024.)

"Growth in sales of Ximluci in Europe doubled in Q2 2024 compared to the observed growth in previous quarters. This is much stronger than anticipated and impacts the profit-sharing income positively in Q2 2024," Xbrane noted.

Cimzia Biosimilar Timeline Can Be Accomodated

As recently as last month, Xbrane had trumpeted a milestone for certolizumab pegol that saw the firm produce the first drug substance scale-up batch with the firm's contract manufacturer, ahead of plans to produce good manufacturing practice batches at the end of 2024 and beginning of 2025.

Pitching the value of its project, Xbrane noted in a 12 August update that it had made "significant progress in the program lately," with a readiness to initiate clinical trials during 2025.

With Xbrane working under an accelerated timeline, the firm has revealed that initial discussions have been held with several undisclosed interested parties, "and the company perceives a high level of collaboration interest around the program."

"The out-licensing process runs according to a strict established timeline with an envisioned license agreement to be signed at the latest by the end of October 2024. Given the high level of interest in the product, Xbrane believes that this timeline can be accommodated."

But Opdivo Biosimilar A Trickier Prospect

The other program on the slate, Xbrane's proposed biosimilar to Opdivo, is proving more difficult to out-license than initially anticipated, the firm admitted, "despite the size of the opportunity and the relatively low competition envisioned from other biosimilar candidates."

"Xbrane has had discussions with several potential partners regarding development collaborations for a long time, but the main challenge has been related to the high envisioned clinical budget for both a Phase I and a Phase III trial, as per current biosimilar development guidelines," the firm conceded.

Having received positive feedback from the EMA for a streamlined clinical development plan, on the back of a highly similar analytical profile of Xdivane versus the reference product across an extensive panel of analytical methods, Xbrane has what it termed a "crucial" meeting with the FDA scheduled in mid-September 2024.

"If the FDA requires a clinical development plan including a full Phase III trial, the company will target a development of the biosimilar candidate for outside US markets, since it now stands clear the company will be unable, by itself or via partners, to finance a full phase III program," Xbrane admitted.

"This impacts the out-licensing timeline of the program, and the company will hence refocus out-licensing discussions with companies interested in Europe and other key territories outside of US where current interest is greater than for a global transaction."

Speaking exclusively to *Generics Bulletin* earlier this year, Xbrane's CEO Martin Åmark commented that on project like nivolumab, it would make sense if the company "ended up having to do some kind of regional deals – in the US, in Europe, or even to think about some co-promotion structures, creating a larger consortium that can invest behind the continued development." (Also see "*'Keytruda? We Believe Opdivo Is The Better Choice': Xbrane's CEO Martin Åmark*" - Generics Bulletin, 11 Jun, 2024.)