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31 October 2014

FDA Pre-Submission Meeting

Calzada ("Company") advised on 23 October 2014 that senior representatives were meeting on 30 October 2014 with the US Food and Drug Administration ("FDA") as part of its regulatory strategy for its Biodegradable Temporising Matrix ("BTM") product in 3rd degree burns.

The purpose of the meeting was to seek the FDA's feedback on questions necessary to guide product development efforts and regulatory submission preparation.

The meeting included a review of preclinical and clinical studies completed to date, and the required scope and design of a proposed pivotal clinical trial to support a future Premarket Approval submission.

This meeting has provided the Company with clarity around the FDA's expectations on what is required to achieve regulatory approval. We expect a constructive and positive dialogue with the FDA to continue as we progress the BTM towards commercialisation.

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