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FDA approval for Onsolis anticipated during summer 2009

Since August 2008, Meda and BioDelivery Sciences International (BDSI) have worked in close collaboration with the U.S. Food and Drug Administration (FDA) to complete the final requirement of a Risk Evaluation and Mitigation Strategy (REMS) program for Onsolis (*fentanyl* - treatment of breakthrough cancer pain).

Last Friday, FDA's review Division informed Meda and BDSI that they had reached agreement with the REMS for Onsolis, but that the FDA needed some additional time to complete the final senior level sign off. Meda therefore expects Onsolis to be approved by the FDA during summer, which could enable a fourth quarter 2009 launch, as previously anticipated.

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