



MEMORANDUM

First pilot of Tandem hybrid closed loop system with TypeZero + Dexcom G6 complete, two-week, at-home study to begin in 1Q18 - January 8, 2018

Tandem [announced](#) this morning that the first pilot study of its integrated hybrid closed loop system (t:slim X2 pump + Dexcom G6 CGM + TypeZero algorithm embedded in the pump) in the NIH-funded IDCL trial has completed. No results from the [supervised, 36-48-hour pilot](#) (n=5 subjects) at UVA were shared, but the second trial - a two-week, at-home study at seven sites - is moving forward with enrollment and will begin in 1Q18, a clear indication that the first in-human experience was positive.

The release reiterates that the pivotal trial for this system will occur in 2018 (1H18, per [October's call](#)), after successful completion and review of the second study. A US launch is still expected in 1H19, leaving tight timing to finish the second and pivotal studies this year, submit to FDA, and secure approval.

At this point, the TypeZero algorithm has been used in >450 patients in >30 clinical studies. Similar TypeZero algorithms are being tested in [Protocols #1 and #2](#) of the IDCL. In a major advantage over other systems, the TypeZero algorithm will include automatic correction boluses for high blood sugars - a key competitive feature relative to the more conservative, basal-only-modulation 670G.

Though not mentioned in the press release, [Clinicaltrials.gov](#) now denotes that the pivotal study of Tandem's PLGS system (PROLOG) with Dexcom G5 is set to conclude on January 15th. It was [previously expected](#) to wrap up "by the end of" 2017, implying a two-week delay. Launch is slated for "summer 2018," meaning an FDA submission needs to happen in the coming few months.

The PLGS system will be very key for Tandem to get out this year, given Medtronic's optimism [today for the 670G](#) ("incredibly strong demand"). Insulet's Omnipod Dash PDM is also likely to launch this year in the US, and its just-announced [positive Medicare announcement](#) might also compete for patients with Tandem.

Notably, Dexcom EVP Steve Pacelli is enthusiastically quoted in Tandem's press release: "...we are excited to have the first integration of Dexcom's next-generation G6 CGM technology in this hybrid closed loop system. We are proud to partner with Tandem in the IDCL trial and are thrilled to see this integrated product moving forward into multi-center studies."

-- by Brian Levine, Adam Brown, and Kelly Close