

FDA nod for first sensor-drug would be a milestone for Proteus



[Elizabeth Cairns](#)

Having raised a phenomenal amount of venture cash over the past couple of years, the time has come for Proteus Digital Health to make good on its promise. The FDA has accepted an approval submission for the first product combining a drug – Otsuka’s Abilify – with one of Proteus’s ingestible sensors, and the compliance-tracking technology must win approval if Proteus is to justify its investors’ confidence.

Promisingly, those investors include pharma and medtech companies which see value in this technology for improving sales of their own products. Should the new drug-device gain approval, one of these companies, quite possibly perhaps Otsuka itself, could decide to obtain the sensor tech by buying its developer.

On the face of it approval should not be too difficult to achieve, as both drug and device are approved separately ([Proteus aims to change the shape of healthcare delivery, August 18, 2014](#)). The approval submission for the combination product is an NDA, possibly suggesting the FDA views it more as a drug than as a device. NDAs take around a year for approval, but this technology is a world-first, so nothing is guaranteed.

Digital drugs

The sensor, the size of a grain of sand, is embedded within the Abilify pills and monitors the drug’s metabolism by the patients and the effects it has on their body. The patient wears a patch on the skin which measures physiologic parameters including heart rate, body angle and activity.

In the case of Otsuka’s schizophrenia medicine, the main intention is to assess patients’ compliance with their prescribed regimen. For the Japanese company, meanwhile, this will be an important reinforcement of its efforts to extend the blockbuster’s patent life. The companies have been collaborating on sensor-drug combos since 2012.

And Otsuka has pumped some funding into Proteus, participating in its series F round in 2013. Another participant in the same round, Novartis, also has a partnership with Proteus to develop digital drugs. Medtronic and St. Jude Medical took part in Proteus’s \$32m series D round in 2008.

Under other circumstances the involvement of corporate VCs might suggest a lack of interest from traditional funds, but this has clearly not been the case with Proteus. The company has raised a very impressive \$235m over a little more than two years, a period during which venture funds have been very reluctant to invest in medtech.

Future

And with great endowment comes great responsibility. Proteus will need approval of this first project to show that the technology is viable from a regulatory perspective and therefore spur interest among other potential partners.

It may also prompt interest from acquirers. Between financings and collaboration deals, Proteus certainly has the wherewithal to continue independently, but should this technology live up to its promise, a sufficiently generous takeover offer may well materialise.

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