

## Medtech news over the Christmas period



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### **Vantage's roundup of medtech news you might have missed includes Boston Scientific hitting its 11th biz dev deal of the year.**

Boston Scientific closed 2018 the same way it opened it: with a deal with the mitral valve repair specialist Millipede. Having taken a small stake in the group last January, Boston has now acquired the company outright.

Elsewhere, Edwards Lifesciences scored approval of the latest form of its Sapien catheter-based aortic valve, and two gastric balloon companies, Obalon and Reshape, had very different financial developments.

#### *December 28*

The current US governmental shutdown means that [the FDA is not accepting any new regulatory submissions](#). It is, however, still working through those already filed, and Edwards Lifesciences' Sapien 3 Ultra, the newest iteration of the Sapien transcatheter aortic valve franchise, won the agency's approval. This may be used in patients for whom open-heart surgery is considered an intermediate or greater risk.

The device was CE marked in November, but Edwards has been unable to launch it in Germany, the largest medtech market in Europe, owing to a patent dispute. In October the District Court of Düsseldorf found that Edwards had infringed a patent Boston Scientific obtained when it bought the Swiss valve maker Symetis for \$435m in May 2017, and granted Boston an injunction barring the valve from the German market.

The court is to hold a full hearing on the dispute in mid-2019.

#### *December 27*

With Abbott's MitraClip mitral valve repair device the subject of [great controversy and excitement](#) over the summer, and with the product probably set for a further US approval in a broader mitral regurgitation population in the coming year, Boston Scientific has not surprisingly decided to get in on the action. The company has pulled the trigger on its option to acquire Millipede, maker of the Iris transcatheter annuloplasty ring, a device intended for patients with severe mitral regurgitation who cannot tolerate open-heart surgery.

In January 2018 Boston obtained the option to buy Millipede, at the same time buying \$90m of newly issued shares in the group. The successful completion of the first human trial of the Iris device appears to have been the cue for Boston to make its move. The group will buy the remaining Millipede shares for \$325m, with a further \$125m due when the device hits an unspecified commercial milestone.

Boston is still way behind its competitors here. MitraClip has been on the market for years, and other devices, including Edwards' Cardioband and Cardiac Dimensions' Carillon, are already in pivotal US trials. Iris might also have application in tricuspid valve repair, where MitraClip is used off label.

<b>Boston Scientific's 2018 M&amp;A</b>				
<b>Date</b>	<b>Deal type</b>	<b>Target</b>	<b>Value (\$m)</b>	<b>Focus</b>
Dec 27	Acquisition	Millipede	450	Cardiology
Nov 20	Option	BTG	4,200	Cardiology; general & plastic surgery; neurology; radiology
Oct 16	Acquisition	Augmenix	600	General & plastic surgery; radiology
Aug 31	Acquisition	Veniti	160	Cardiology
Aug 2	Acquisition	Claret Medical	270	Drug delivery
Jul 5	Acquisition	Cryterion Medical	202	Cardiology
Apl 30	Acquisition	Nxthera	325	Endoscopy; urology
Apr 16	Acquisition	Nvision Medical	275	Endoscopy; obstetrics & gynaecology
Apr 3	Acquisition	Securus Medical Group	50	Cardiology
Mar 5	Acquisition	Emcision	-	Endoscopy; general & plastic surgery
Jan 24	Minority stake	Millipede	90	Cardiology

*Source: EvaluateMedTech.*

#### *December 27*

While two gastric balloon companies, Apollo Endosurgery and Reshape Lifesciences, recently swapped assets in a bid to wring some value from these devices after patients implanted with them [suffered adverse events](#), another group has managed to raise cash.

Obalon, the maker of the only swallowed intragastric balloon, has closed two financing deals that between them are worth up to \$30m. It has signed a deal with Lincoln Park Capital Fund under which Obalon will have the right to sell up to \$20m of shares to Lincoln over 36 months. Lincoln will be obliged to buy at a price based on the market value of Obalon's shares at the time of each sale, with no upper limit on the price.

The group also signed up Canaccord Genuity in an at-the-market equity offering that could be worth up to \$10m. Any money Obalon gets from these deals will go towards funding clinical trials, other R&D costs or the repayment of debt. At the end of September Obalon had long-term debt of \$9.4m and total liabilities of \$16.7m.

#### *December 27*

As Obalon gets richer, the aforementioned Reshape Lifesciences is in trouble. In an SEC filing Reshape disclosed that it had received written notice that Nasdaq is to delist its stock after this failed to maintain a minimum bid price. The exchange suspended trading in Reshape from December 31.

The company can appeal against the delisting within 15 days, and says it is considering its options. In the meantime Reshape stock will be eligible to trade over the counter.

#### *December 27*

Illumina has lost out in the patent suit it brought against Roche, alleging infringement of intellectual property covering non-invasive prenatal testing (NIPT). The US District Court for the Northern District of California threw

the case out, stating that Illumina's patents were directed towards natural phenomena that are not patentable in the first place.

The suit concerned the Harmony NIPT, which detects foetal chromosomal abnormalities in a mother's blood and was developed by Ariosa, a group acquired by Roche four years ago ([Roche seeks Harmony with Ariosa buy, December 2, 2014](#)). The court's decision in favour of Roche is a reversal of one a year ago; last January the same court awarded Illumina \$26.7m in damages, having determined that Ariosa's technology did infringe two other Illumina patents.