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Medtech news over the Christmas period 2015

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Quiet though the last few days of the year usually are, medtech watchers might still have wondered whether a last-minute billion-dollar merger might sneak through before the fireworks went off on New Year's Eve. In the event almost the opposite happened, with news of an investigation into Biomet that could see the terms of its acquisition by Zimmer altered markedly.

Elsewhere, much of the news over the holiday period came courtesy of the FDA. After approving Cerus's blood treatment system two weeks ago, the US regulator has ushered through another device to help in the fight against Ebola, a test marketed by Roche. It had less welcome news for HeartSync, slapping a Class I label on the recall of its defibrillator electrodes. Funding news has been similarly mixed, with a £10m raise on one hand and a twice-cancelled IPO on the other.

Regulatory

December 29

The FDA has granted emergency approval for a diagnostic to detect the strain of Ebola that has infected nearly 20,000 people worldwide. The LightMix Ebola Zaire rRT-PCR Test, developed by Roche and the German company TIB Molbiol, may now be used at CLIA laboratories to test blood from patients with signs and symptoms of Ebola Zaire virus infection and who meet certain other criteria, such as having recently travelled from West Africa.

The LightMix test runs on of Roche's LightCycler 480 or cobas z 480 instruments and produces results in under four hours, allowing treatment to start relatively quickly. The approval only stands for a limited time, Roche said – the test may be used as long as the US government declares that emergency circumstances exist.

December 24

The FDA upgraded its recall of HeartSync's defibrillator electrodes to class I, indicating that use of the devices carries a risk of serious injury or death. Blame might more reasonably be placed on Philips because the electrodes are used with automated external defibrillators made by Philips, and the Dutch company recently tweaked the connector design used in two of these machines. HeartSync's electrodes will no longer work with either the FR3 or FRx models.

HeartSync's electrode pads must be pre-connected to the FRx unit, and until they are this defibrillator will emit an alarm, alerting the user that it is not safe to use. But the FR3 does not require pre-connection and the user might not discover the incompatibility until the defibrillator comes to be used, potentially endangering the patient.

Earlier in December another electrode maker, ConMed, found itself in exactly the same situation. It is to be hoped that next time Philips alters its defibrillator design there is no knock-on damage to the companies that make add-on products.

Deals

December 23

It emerged just before Christmas that the US Department of Justice and Securities and Exchange Commission were looking into allegations of bribery against Biomet, which could delay or alter the ortho company's $13bn acquisition by Zimmer. An article in the New York Times stated that Biomet employees might have been involved in bribing government doctors in Mexico and Brazil, and cited confidential documents leaked by an anonymous whistleblower.

Biomet was already facing these problems when it negotiated the deal with Zimmer, and Zimmer knew about them before signing the papers. Still, Biomet will want to fix the situation as quickly as possible to safeguard the buyout.

But a lot could yet go wrong: the US government could exact stiff financial penalties or even bring criminal

charges against the private group's management. If charges are pressed the company’s participation in federal healthcare programmes could be restricted. These factors could cause Zimmer to restructure the deal or lower the price. One of the marquee deals of 2014 might only happen in a markedly changed form.

Business

December 23

The coronary artery disease diagnostics firm CardioDx has once again shelved its plans to go public. In July 2013 the company said it would raise $75m at a $14-16 per share range; that November it upped its expectation to $92m before abruptly pulling the Nasdaq float citing poor market conditions (*CardioDx yanks float as medtech market fails to pick up, November 18, 2013*).

CardioDx then revived the plan last April, though without setting terms. It has now cancelled again, and for the same reason. It did, however, raise $35m in a private financing in mid-December. Alberta Investment Management participated in the round along with the company's existing investors.

Also on December 23, Cerevast Therapeutics revealed in an SEC filing that it had raised $10m to fund development of a headset to treat stroke patients. The non-invasive Clotbust ER device emits ultrasound energy to help break down blood clots. It is designed to be used in emergency rooms to treat patients presenting with acute ischaemic stroke.

The company has now raised a total of $32.5m, and will have been aided in this latest round by a positive interim safety analysis of the first in 250 patients in a phase III trial of Clotbust ER. The Clotbuster study aims to enrol 800 ischaemic stroke patients on a 1:1 basis to either Clotbust ER in combination with Alteplase, or Alteplase alone. The primary efficacy endpoint of the trial will be 90-day functional recovery as measured by the modified Rankin Scale.

Study	Trial ID
Clotbuster	NCT01098981

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