Evaluate Vantage

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Medtech news over the Christmas period

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Anyone hoping for a last-minute medtech Christmas present in the form of a big acquisition, perhaps the long-rumoured Stryker-Smith & Nephew tie-up, would have been disappointed as the festive period proved to be predictably quiet.

However, there was cheer for the likes of aesthetic device developer ThermiGen, which will be taken over by the pharma company Almirall, and DiagnoCure, which settled a spat with Hologic over a prostate cancer biomarker. But Johnson & Johnson received a proverbial lump of coal with another big pay-out relating to its troubled transvaginal mesh products, though it says it will appeal against this.

Legal and regulatory

December 30

Any medtech employees thinking of stealing trade secrets should think again; after an ex-Boston Scientific worker was sentenced to a year in prison.

Aaron Khieu had already pleaded guilty to a single count of stealing trade secrets – specifically, files on the design for Boston's Mustang and Sapphire balloon dilation catheters, as well as the new Mustang Plus. He was also allegedly planning to set up a company in Vietnam called Snowflake Medical, using the stolen trade secrets to create a balloon catheter called Snowcat.

December 22

Meanwhile J&J was also in court, but its strategy of fighting individual pelvic mesh plaintiffs is looking increasingly risky after a second case involving its Prolift device went against the company. A Philadelphia jury awarded $5.5m in compensatory damages and $7m in punitive damages.

J&J’s Ethicon division withdrew Prolift in 2012, citing poor sales, but did not recall the devices, which have been linked with severe side effects including pain and perforation of internal organs. These issues have been known about for some time, and the FDA recently reclassified transvaginal meshes as higher-risk class III devices, meaning they need to pass the more stringent premarket approval process.

With nearly 200 cases still pending against J&J in Phildadelphia, and thousands in other US states, the group might now want to consider a global settlement. However, it could take a few more negative verdicts to swing the decision. The case could also have a knock-on effect on other mesh makers including Boston Scientific and CR Bard.

Deals

January 4

Almirall's outright acquisition of ThermiGen, a developer of temperature-controlled radiofrequency systems for plastic surgery and aesthetic dermatology, marked the Spanish speciality group's move into aesthetics.

Almirall is paying $80m on top of the $5m it spent on a 7.7% minority stake in September, exercising the full buyout option that had been agreed at that time. This now seems a relative bargain, with ThermiGen expected to book sales of $30m and reach profitability in 2015.

The Spanish group hopes to become a leader in aesthetics, building on a dermatology portfolio that includes Actikerall for atinic keratosis – expected to be its second biggest product in 2020. Almirall also bought a minority stake in the dermal filler developer Suneva Medical last year.

December 23

The somewhat fractious relationship between the Canadian diagnostics group DiagnoCure and Gen-Probe, Hologic’s clinical diagnostics and blood screening subsidiary, reached a harmonious conclusion just before Christmas when Gen-Probe agreed to buy DiagnoCure’s PCA3 prostate cancer biomarker.

The $4.7m cash-and-stock transaction also grants Gen-Probe right of first refusal to license DiagnoCure's new multi-marker prostate cancer test.

Gen-Probe already holds worldwide rights to PCA3, which it uses in its Progensa urine test for prostate cancer. But last March DiagnoCure, stung by a 12% fall in revenues from PCA3, urged Hologic to step up sales efforts or return the rights to the biomarker. At the time, DiagnoCure's intention was to develop and manufacture an in-house PCR-based version of the PCA3 test to compete with Progensa.

In effect the opposite has happened, and Gen-Probe has acquired all rights to the biomarker for $4m in cash and DiagnoCure's repurchase of 4.9 million of its series A convertible preferred shares currently held by Gen-Probe, valued at $744,229. The transaction will cancel all the preferred shares issued by DiagnoCure, so the group's outstanding securities will consist solely of common shares.

Development

December 28

The difficulty of detecting breast cancer recurrence before metastases are large enough to be seen via imaging is a barrier to effective treatment. So the start of a pilot trial to evaluate a new way of detecting cancer recurrence in triple-negative breast cancer patients could mean that this test will be available in just a few years.

Cynvenio Biosystems is collaborating with the South Korean group ATGen Global to combine the former's ClearID test with ATGen's NK Vue blood test to detect cancer recurrence in previously treated triple-negative breast cancer patients who have no radiographic signs of metastases. Around 250 people will be recruited into the study.

Some women who have been treated for this cancer will experience recurrence, and in these women there will be a point at which, though their metastases are too small to be observed radiographically or to cause detectable biomarker changes, individual tumour cells circulating in the blood may be found.

The companies believe that using ClearID, based on Cynvenio's liquid biopsy technology, with NK Vue, which measures the activity of natural killer cells, will be able to identify women whose cancer is at this stage. They will also seek to analyse the tumour cells to identify targeted therapies in the hope of improving outcomes.

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