Evaluate Vantage

January 02, 2013

Medtech news over the Christmas period

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The medical device arena has been understandably quiet over the past few weeks, but it has not frozen up completely. The new year often prompts resolutions to slim down, and Quest Diagnostics has shed a few pounds – and gained a few dollars – by selling off its saliva diagnostics wing, OralDNA Labs.

And, perhaps appropriately for the party season, the two significant US device approvals both concerned diagnostics for sexually transmitted infections, one developed by Cepheid and the other from Chembio.

Deals

December 31

Quest Diagnostics's divestiture of OralDNA Labs is intended to permit the Madison, New Jersey company to focus on core diagnostic information services for physicians and hospitals, and follows initiatives to save money it put in place in November. Quest controls around 9% of the $72bn US diagnostic lab market, according to AJ Rice, an analyst at UBS.

The buyer is Access Genetics, a clinical laboratory that has provided OralDNA-based testing services since 2008. OralDNA's tests are currently run from labs in Brentwood, Tennessee, but will be moved Access's CLIA-certified lab in Eden Prairie, Minnesota. Terms of the deal were not disclosed.

December 28

AorTech is also looking to cut the flab, and is in talks to sell its medical polymers business. The unit initially went on sale earlier this year but failed to drum up interest as it was low on cash. This has been remedied through the resolution of a legal tussle with St Jude Medical that saw a $3.4m payout come AorTech's way on Christmas Eve.

The two companies had had a dispute over the supply and manufacture of Elast-Eon, a biomaterial used in the manufacture of heart valves. St Jude now has an exclusive, perpetual, non-royalty-bearing licence to Elast-Eon for use in pacemaker leads. AorTech will gain a further $500,000 at the end of March 2013, and St Jude will buy AorTech's factory for $250,000.

Regulatory

December 27

Sunnyvale, California-based Cepheid gained 510(k) clearance for Xpert CT/NG, a molecular diagnostic for the detection and differentiation of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). The test enables same-day patient consultation and treatment for the first time, and should find a ready market: chlamydia and gonorrhoea are the two most common sexually transmitted bacterial infections in the US. Cepheid's share price jumped 6% on the news, reaching $34.60, but settled down to close at $33.04.

December 21

Even more important is the premarket approval of a point-of-care HIV test developed by Chembio Diagnostics. The Dual Path Platform HIV 1/2 assay can be used with oral fluid or blood samples, and beats current lateral flow HIV test technologies on accuracy, Chembio says. The test gives results in just 15 minutes.

The market is expected to grow significantly after the US Preventive Services Task Force recommended insurance reimbursement for routine HIV testing. Chembio, whose share price increased by 25% on the approval, is now seeking CLIA-waived status for the test, and intends to launch it during the second half of 2013.

December 21

The recall of Medtronic's SynchroMed II stall-prone drug pump was designated Class I – the most serious kind – by the FDA. The pumps were recalled in November after worrying failure rates were seen when they were used to deliver certain drugs. The overall failure rate of SynchroMed II at 78 months post-implant is 2.4% when used

to dispense approved drugs, and 7.0% when used to dispense unapproved drugs, the FDA said.

The pumps had already been the subject of a Class I recall in January 2011, as they had been found to inject drugs into the patient's subcutaneous tissue.

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