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Roche seeks Harmony with Ariosa buy

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Ariosa Diagnostics is living the medtech dream: develop a single product, get it on the market via the cheapest route possible, and sell up. Its purchase by Roche has come in the nick of time, with its last venture funding more than two years ago and the shelving of a planned IPO back in April.

Roche's decision-making is less scrutable. Ariosa's sole product, a maternal blood test for foetal chromosomal abnormalities, is neither CE marked nor FDA approved, though it is sold in the US. It is also expensive, and payers are still assessing whether to offer it and to whom. And finally, while it won a patent case last year, it is the subject of an appeal that could see it pulled from sale.

Ariosa had revenues of $53.3m in 2013, and Harmony was its only product. But with its last fund-raising, a $52.7m B round, completed in February 2012, and the yanked $60m Nasdaq IPO, Ariosa was in need of rescue in some form, and a buyout is almost always the dream scenario in medtech. Terms of the purchase were not disclosed.

The acquisition is fortuitous for Ariosa for another reason: it means the California company can dodge dealing with the forthcoming rule change that is likely to see the FDA take over the regulation of *in vitro* diagnostics. The Harmony product, which tests for trisomy 21 – Down's syndrome – and trisomies 18 and 13, is sold in the US as a lab-developed or homebrew test.

Loophole

This regulatory loophole ought soon to be closed, meaning that if Roche wants to continue selling the test in the US it will have to take it through the premarket approval process (*FDA takes aim at unapproved cancer drug tests, August 4, 2014*).

This might not be too onerous: Roche is one of the companies that is punctilious about obtaining full US approval of its diagnostics, even though this is not strictly necessary and is a lengthier and more expensive route to market (*Interview – Qiagen set to benefit from increased test regulation by the FDA, November 10, 2014*).

Harmony is one of four maternal blood tests for trisomy 21 available in the US – the others are sold by Illumina, Sequenom and Natera – but these are also homebrews. This means that there is no FDA-approved test that could be used as a 510(k) predicate for Harmony, condemning it to the more stringent PMA path.

But it also means that if Roche gains approval, and the new regulations come into force, sale of the three competitors will become illegal, and Roche will corner the market.

Transplant

The size of this market is an open question. The US list price for Harmony is around $800, and while this is cheaper than amniocentesis it is not so cheap that health systems and insurance companies will fund its indiscriminate use. Programmes are under way in the UK, for instance, to assess which groups will benefit from the test, which as it is less invasive than amniocentesis also poses less of a risk to the pregnancy.

Perhaps a marketing push by Roche will prompt customers to pay out of pocket for the test.

Analysts from Leerink, however, point to another arena in which Ariosa's technology could be made to pay. Instead of detecting foetal DNA in a mother, a test could be created to detect donor DNA in the blood of a transplant recipient.

Ariosa presented proof-of-concept data last year on the use of donor cell free DNA (cfDNA) as a marker for evidence of organ rejection. Leerink analysts believe that pursuit of a this programme would have been a low priority for the independent Ariosa, but wrote that "this area has historically been of greater interest to Roche".

Here it would compete with CareDx, though this company is already well down the path of developing cfDNA tests for both heart and kidney transplant, and should be first to market.

Chances

The final piece of the puzzle is the patent litigation in which Ariosa is engaged. The victory it won against Sequenom a year ago still stands, though Sequenom is appealing. A decision is expected in the next few months.

But battling Roche is a very different prospect for Sequenom than fighting Ariosa. If the decision does go Sequenom's way it could well be that Roche reaches a deal under which it licenses rights to the disputed patent.

After all, Roche has taken on a company whose product is unapproved, tricky to sell and may or may not benefit from a change to the FDA's working practices: it seems pretty happy to take chances.

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