

## BioDelivery thrives in difficult environment for pain drugs



[Jonathan Gardner](#)

Two pain products on the market and a third partnered project that has just passed an important phase III test make BioDelivery Sciences International the subject of buyout rumours. The fact that the partner for its clinical-stage project is the acquisitive Endo International can do nothing to quell that talk.

Shares in the company have doubled this year and, though that is not necessarily remarkable in the frothy biotech market of today, consider that they are now 16 times the price of their end-2011 close. Patient investors who kept the faith after an initial clinical failure of BEMA buprenorphine have been well rewarded, though many might hold on longer in the hopes that Endo will want to absorb its partner.

### Try, try, and try again

On its second and third pivotal trials, BEMA buprenorphine, an adhesive polymer film that delivers the opiate across mucosal tissue inside the cheek, was able to significantly reduce chronic lower back pain in both opioid-naïve and experienced patients over 12 weeks, versus placebo.

In January, the North Carolina-based group announced successful results from a trial in opioid-naïve patients, a group that had been particularly troublesome in an earlier failed trial of the project.

This earlier trial, announced in 2011, showed that BEMA buprenorphine had failed to significantly reduce chronic lower back pain in a population that included both the naïve and experienced patients. Reinforcing the findings of the latest study in opioid-experienced patients announced yesterday, those 2011 analyses indicated that the experienced group missed statistical significance by less than two points ( $p=0.067$ ).

Likewise, the analyses claimed to have identified placebo effect in the naïve population as the difference in pain score between active treatment and placebo groups once again “approached significance” once patients titrated beyond the lowest dose in the trial ( $p=0.066$ ).

It was surprising that Endo agreed to license BEMA buprenorphine for \$30m up front in January 2012 following that trial, but the Pennsylvania-based group apparently agreed that those analyses had revealed some hidden data gems. The redesigned pivotal programme, therefore, tested the experienced and naïve populations separately and, in addition, forced titration beyond the first dose. Both of those redesigns have yielded a desired result.

With shares rising 9% to \$13.06 yesterday, investors were clearly viewing it as a positive – the expected \$10m milestone from Endo for locking the database is greater than William Blair’s \$9m forecast in 2014 for BioDelivery’s Bunavail, a buccal film of buprenorphine and naloxone that the FDA approved for opioid dependence in June.

BEMA buprenorphine is potentially more important for Endo, however. With sales forecast at \$192m in 2020, according to *EvaluatePharma’s* consensus, it represents Endo’s biggest growth driver and would rank as its biggest product – and all this at a time when so many of its other products are shrinking.

### Strike point

Indeed, it is the flatlining revenue picture that has driven Endo’s M&A strategy since Rajiv De Silva came over as chief executive from Valeant Pharmaceuticals International in February 2013. Four acquisitions have occurred since then, including the shrewd buy of Paladin Labs for its low-tax Irish domicile ([Endo engineers Paladin into a return for all, November 6, 2013](#)).

With an estimated \$70m in milestones due to BioDelivery at FDA approval, along with sales royalties and milestones, Endo has many reasons to acquire the smaller firm. Such a transaction would also bring with it Bunavail, which the William Blair analysts forecast to be selling \$73.2m in 2016 – in the hands of Endo, it might do much better than with the much smaller BioDelivery.

The only thing that might hold Endo back is the pricetag, a common complaint in the current environment. The

ideal time to strike might have been in January, when the first of the two trials in the redesigned programme read out – or better yet, two years before that, when BioDelivery was worth just \$25m.

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