Evaluate Vantage

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Marqibo and Vascepa join Vitaros in biotech purgatory

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When Talon Therapeutics' vinca alkaloid Marqibo received US approval in August for a rare blood cancer it should have given the tiny biotech cause to celebrate. Not so.

Instead, the drug has found itself in a similar situation to Amarin's Vascepa: both are products that, months after getting regulatory clearance, are no closer to being made available commercially. This growing army of the approved but unlaunched has as its leader Apricus Biosciences' Vitaros, which has now spent a staggering two years mired in pharmaceutical purgatory (see table). It seems that, whenever a biotech eschews partnering and touts an in-house launch, investors should be on the alert.

Of course, any company making such a claim might simply be being disingenuous; maybe it has been unable to find a partner, overreached in demanding top-dollar terms, or is hoping that a deal will materialise just as soon as the regulatory risk is eliminated. But the resulting game of who blinks first often has dire consequences.

Out of time

Talon looks like a company that has run out of time, money and ideas. Shortly after Marqibo was approved for Philadelphia-negative acute lymphocytic leukaemia Talon said it planned to launch the drug itself as well as considering strategic partnerships, but this failed to resonate with shareholders.

At yesterday's quarterly update this claim was repeated, but no news of progress was forthcoming. With the company capitalised at $14m, with just $5.6m in third-quarter cash, the prospects are bleak.

While analysts assign no value to Marqibo, Amarin's purified fish-oil drug Vascepa probably faces the opposite problem (*Amarin languishes as Vascepa's NCE non-status takes centre stage, October 11, 2012*). At a massive $1.7bn of consensus 2018 sales, Vascepa expectations have likely run so far ahead of reality that only a knockout deal – impossible without clarity on market potential – will suffice. So instead there is no deal – and no launch.

Meanwhile, the remarkable two years of Canadian non-commercialisation of Vitaros, Apricus's alprostadil cream for erectile dysfunction, is down to the dominance of oral PDE5 inhibitors like Viagra – even though Vitaros targets patients unable or unwilling to take PDE5s.

This small detail has not stopped Apricus stating that the market is worth $4bn; other alprostadil product sales are negligible. With Vitaros stalled in the US and EU, a deal with Abbott Laboratories for Canada was signed early this year.

Roth Capital Partners optimistically predicts an unfortunately termed "soft launch" in Canada for the fourth quarter, but events have moved quickly. The recent revocation of Viagra's Canadian patent is set to shake pricing up further, and investors are still waiting.

A Viagra-based conundrum also faces Vivus's own PDE5 inhibitor, Stendra, approved in the US in April. The drug was Vivus's plan B after the initial failure of its obesity treatment Qsymia but, the latter now having been approved and launched, it is Stendra that has gone to the back burner. Launch now depends on finding a partner.

Dead or alive? Selected approved but unlaunched drugs				
Drug	**Company**	**Approved**	**Consensus 2018 sales**	**NPV**
Vitaros (Canada)	Apricus Biosciences	November 12, 2010	$13m	$26m
Surfaxin	Discovery Lanoratories	March 6, 2012	$85m	$134m
Stendra	Vivus	April 27, 2012	$87m	$174m
Prochymal (Canada)	Osiris Therapeutics	May 17, 2012	$43m	$60m
Belviq	Arena Pharmaceuticals	June 27, 2012	$945m	$2.6bn
Vascepa	Amarin	July 26, 2012	$1.7bn	$6.0bn
Marqibo	Talon Therapeutics	August 9, 2012	none	none

Outlier

For all the criticism that Vivus's rival Arena Pharmaceuticals has faced over its obesity drug Belviq, this is likely an outlier. The drug is partnered with Eisai and its delay – launch is expected in the first quarter – is due to discussions with the US Drug Enforcement Administration over scheduling.

The same cannot be said of Discovery Laboratories' newborn respiratory distress syndrome drug Surfaxin, whose launch the loss-making company recently delayed from late 2012 to the second quarter of 2013 – over a year after US approval – following quality control problems. Still, long-suffering investors might not mind waiting a bit longer; it took eight years and five attempts at filing before Surfaxin was cleared.

Meanwhile, Cell Therapeutics' Pixuvri (pixantrone) was at last introduced in parts of the EU this month, six months after getting conditional approval, although the mysterious withdrawal of the US filing on the eve of a February advisory panel still smarts. And Osiris Therapeutics shareholders can decide for themselves whether Sanofi's handing back of rights to Prochymal, the first ever western-approved stem cell therapy, increases its chances of a commercial launch this year (*Osiris's battles will continue despite landmark approval for Prochymal, May 21, 2012*).

So what can investors learn from the experiences of biotech companies that end up in this delayed launch hall of shame? Very often it comes down to having realistic expectations before things get this far; yes, a late-stage product probably retains more value than an early one, but protracted waiting games over partnering can verge on the ridiculous.

And those who hope that approval will be the deal trigger need to remember that it still takes perhaps six months from an initial approach to the signing of a deal. Ultimately, commercialisation needs to be timely, and is usually best left to the big boys. Anything less should set off alarm bells.

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