

## Cymbalta good cheer spreads to Cypress



[Lisa Urquhart](#)

While there may have been celebrations at Eli Lilly's headquarters following the FDA's approval of Cymbalta in fibromyalgia, 1,700 miles away executives at Cypress Bioscience may have been tempted to have a small party of their own, given that the decision significantly improves the chances of Cypress's milnacipran making it past the regulators without a hitch in October.

Industry observers were also feeling more confident about success as the shares yesterday finished the day 10% higher and continued their rise in early morning trading today, moving up by 5% to \$8.68.

Given milnacipran's importance to Cypress, it is not surprising the effect on the shares that positive news has had. The drug is worth \$506m, according to EvaluatePharma's NPV Analyzer, and represents pretty much all of the company's value and is forecast to pull in royalties of \$96m by 2012.

### One shot on goal

Milnacipran, which has been on the market in Europe for over 10 years, is also Cypress's one and only shot on goal, as it has little else in its pipeline, with the exception of a phase II osteoarthritis drug and a pre-clinical treatment for arthritis.

As such, the group has done as much as it can to smooth milnacipran's passage to approval including conducting an additional and uncalled for ambulatory blood pressure study that is expected to report by the end of next month, following concerns about slightly elevated blood pressure and heart rates. Many believe milnacipran and Cymbalta differ very little in their safety profiles, leading some analysts to suggest that the additional blood pressure data could actually prolong the FDA's review, and cause it to miss the October PDUFA date.

Even with a three-month delay, milnacipran would still be third to market following the approval back in June 2007 for Pfizer's anti-depressant drug Lyrica. And analysts believe that the drug's unique mechanism of action as a norepinephrine serotonin reuptake inhibitor (NSRI) could enable it to take share from the two incumbents.

The more bullish have estimated that if milnacipran only takes a sixth of the market, sales for Cypress and its US partner Forest Laboratories could reach \$1bn.

These ambitious sales figures could go some way to illuminate why some analysts have share price targets on the group of up to \$30. They also could explain the large disparity between Cypress's market capitalisation of \$311m and its total NPV of \$516m.

### Growing competition

Cypress is, however, unlikely to enjoy those kind of sales for too many years. Fibromyalgia is a very attractive-looking market, with an estimated 5 million sufferers in the US alone. Prescriptions for drugs to treat the pain disorder are also expected to increase with better physician education, meaning other companies are bound to turn their attention to the field soon.

There are already a number of candidates nipping at Cypress's heels offering alternative treatments for the disorder that causes pain in muscles and ligaments as well as depression, including UCB and Jazz Pharmaceuticals' JZP-6, which is due to report the first of two phase III trials by the end of this year.

<b>Fibromyalgia: Late Stage Pipeline</b>			
<b>Phase</b>	<b>Product</b>	<b>Company</b>	<b>Pharmacological Class</b>
<b>Phase III</b>	Pfizer	S,S-Reboxetine	SNRI
	Jazz Pharmaceuticals	JZP-6	CNS depressant
	Wyeth	Pristiq	SNRI
	UCB	Xyrem	CNS depressant
	UCB	JZP-6	CNS depressant
	Jazz Pharmaceuticals	Xyrem	CNS depressant
	Biotest	Intratect	Immunoglobulin
<b>Phase II</b>	Merck & Co	MK-0677	Growth hormone secretagogue
	UCB	Neupro	Dopamine D2 & D3 agonist
	UCB	Vimpat	Collapsin-response mediator protein 2 (CRMP-2) modulator
	Taisho Pharmaceutical	S-flurbiprofen Patch	NSAID
	Sanofi-Aventis	Eplivanserin	5HT2A antagonist
	Sosei	AD 337	SNRI

But even with the increasing competition, getting approval will be a seismic shift for Cypress, which will trigger more of the milestones that were part of its original 2004, \$250m deal with Forest and could enable the group to buy more products to shore up its skinny pipeline.

[More from Evaluate Vantage](#)

Evaluate HQ  
[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

Evaluate Americas  
[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC  
[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

© Copyright 2021 Evaluate Ltd.