

# Newron Pharmaceuticals

Product news

## Xadago US approval slips out further

Newron has received a complete response letter from the FDA for its Parkinson's disease drug Xadago (safinamide). Specifically, the FDA has requested clinical data on the potential effect of Xadago relating to abuse liability and dependence/withdrawal effects. No further efficacy or safety data for Xadago in patients with Parkinson's disease has been requested. In next steps Newron will meet with Controlled Substance Staff (CSS) of the FDA to discuss exact requirements to address the issue. We anticipate that Newron will need to provide data relating to abuse liability and dependence in healthy subjects, and thus additional trials may be required. As such, we place our financial forecasts and valuation under review until we receive clarity on next steps and the potential impact on regulatory approval and market launch in the US.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14**	1.6	(8.6)	(0.63)	0.0	N/A	N/A
12/15	2.4	(18.3)	(1.17)	0.0	N/A	N/A
12/16e	N/A	N/A	N/A	N/A	N/A	N/A
12/17e	N/A	N/A	N/A	N/A	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items. \*\*FY14 PBT is restated.

We place our valuation under review while we await further clarity from the company post discussions with CSS on the revised approval timelines for Xadago in the US, to understand the magnitude of the slippage.

Our previous valuation of CHF504m (see our [update note](#) of 15 March) was predicated on a US launch in H216 and peak global sales for Xadago of approximately €450m, with the US representing c 65% of this estimate. Overall, Xadago represents CHF23.7 of our previous CHF35.5 per share Newron valuation. In Europe the Xadago roll-out is ongoing, with commercial partner Zambon having launched the product in Germany, Italy, Switzerland and Spain.

Pharma &amp; biotech

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**Price** **CHF16.05**  
**Market cap** **CHF228m**

Net cash (€m) at 31 December 2015	40.2
Shares in issue	14.2m
Free float	77%
Code	NWRN
Primary exchange	SIX
Secondary exchange	N/A

### Share price performance



### Business description

Newron Pharmaceuticals is an Italian CNS-focused biotechnology company. Xadago (safinamide) for Parkinson's disease has been launched in Europe. Xadago is partnered with Zambon (EU), Meiji Seika (Japan) and US WorldMeds (US).

### Analysts

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