EDISON

Newron Pharmaceuticals

Pharma & biotech

Back on track

Xadago (safinamide) for Parkinson's disease (PD) is back on track in the US as the FDA has informed the company and its partners, Zambon and US WorldMeds, that no further clinical studies will be required following the 29 March complete response letter. Newron resubmitted Xadago's NDA in September; US PDUFA date is set for 21 March 2017. In Europe the Xadago roll-out is ongoing, with commercial partner Zambon having launched the product in multiple European countries. We value Newron at CHF494m or CHF34.7/share.

Xadago US NDA resubmitted

Newron has resubmitted the Xadago NDA (PDUFA date set for 21 March 2017); the FDA no longer requires any extra clinical studies on Xadago's potential abuse liability or dependence/withdrawal effect. This removes uncertainty surrounding Xadago's US future filing. We have reinstated our forecasts and now anticipate US launch in H217. Importantly, partner Zambon continues its roll-out of the drug across Europe; it is now available in 11 European countries.

Evenamide schizophrenia Phase II data due in Q416

The US Phase II proof-of-concept trial is ongoing, assessing the novel mechanism of action drug, evenamide (NW-3509), as an add-on to antipsychotics in patients with positive symptoms of schizophrenia. Phase II data are expected in Q416. NW-3509 is a partnering candidate, given the potential size of the indication and its differentiating mode of action. Partnering activities could provide upside.

Sarizotan potentially written in the STARS

Sarizotan remains a priority given the potentially rapid clinical development path, in addition to the size of the Rett syndrome (RS) market (c 36,000 patients in the US and EU). STARS, the potentially pivotal clinical trial evaluating breathing disorders associated with RS, has now begun. We forecast potential first approval and launch in 2018 and peak sales of €260m; given the size of the indication, Newron could commercialise in RS alone with a small salesforce.

Valuation: Risk-adjusted NPV of €376m/CHF494m

Our updated Newron valuation is CHF494m (from CHF504m) or CHF34.7/share, reflecting primarily a push back to US Xadago launch by six months. Our valuation includes risk-adjusted contributions for Xadago in PD and dyskinesia indications, sarizotan in RS and evenamide in schizophrenia, and reflects 2015 year-end net cash of CHF44.1m. We have not yet adjusted our valuation following the H116 results and the recent CHF26m new share placement (October 2016).

Edison estimates

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	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	2.1	(23.3)	(1.48)	0.0	N/A	N/A
12/17e	6.4	(11.3)	(0.72)	0.0	N/A	N/A

Source: Company data, Edison Investment Research

Price	CHF20.75
Market cap	CHF327m

Share price graph

Share details

Code	NWRN
Shares in issue	15.8m
Net cash (€m) at June 2016	34.3

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).

Bull

- Xadago approved in Europe and launched in Germany by partner Zambon.
- Xadago could have a unique profile (once a day, clean safety) in the growing PD market.
- Pipeline of orphan drugs, which could be commercialised alone.

Bear

- Xadago US regulatory setbacks or delays.
- Zambon does not have a presence in certain markets, including the US.
- Clinical trial failures with the orphan drug pipeline.

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