EDISON

Newron Pharmaceuticals S.p.A

Pharma & biotech

First Xadago sales; US decision by end Q116

Xadago for the treatment of Parkinson's disease is now generating initial sales in Europe following first launch in Germany, leading to royalty income to Newron from partner Zambon. The US regulatory review was recently extended by three months to end March 2016. Beyond Xadago, Newron has prioritised development of orphan drug sarizotan for Rett syndrome (a rare genetic condition) with a pivotal trial planned to start in Q415. Partnering candidate NW-3509 for schizophrenia is also advancing.

First Xadago royalties on initial sales in Germany

Newron has received first royalties from commercial partner Zambon on initial sales of Xadago in Parkinson's disease (PD) in Germany following launch in mid-May. Xadago is priced at around a 40-60% premium to closest comparable Azilect. This is suggestive that health authorities in Germany recognise that Xadago can offer advantages over Azilect (including long-term benefits), which should also aid with physician and patient uptake. We expect further launches across Europe as pricing and reimbursement are agreed by partner Zambon in coming months.

US regulatory decision now in March 2016

The FDA review process was recently extended by three months to process additional submissions (not data-related). The new PDUFA decision date is 29 March 2016. Zambon continues to focus on sub-licensing in this key region.

Pivotal sarizotan trial planned

Newron has a pipeline of three Phase II orphan drugs, which include sarizotan for Rett syndrome (RS), sNN0031 for severe PD and sNN0029 for ALS/Lou Gehrig's disease. These could all be commercialised alone. Newron has prioritised sarizotan and a placebo-controlled Phase II/III trial to investigate breathing disorders associated with RS is being planned, which could potentially support filings. In addition, Newron is advancing NW-3509 as a potential treatment for schizophrenia patients who are poor responders to antipsychotics ahead of potential partnering.

Valuation: Risk-adjusted NPV of CHF526m

We value Newron at CHF526m or CHF37.7/share based on a risk-adjusted NPV analysis, which includes Xadago, the portfolio of orphan drugs and NW-3509. Our valuation includes €450m of peak Xadago PD sales (in the US and Europe) in addition to a contribution in dyskinesia.

Edison estimates

Year end	Revenue (€m)	PBT (€m)	EPS (c)	DPS (c)	P/E (x)	Yield (%)
12/13	3.5	(7.7)	(61.8)	0.0	N/A	N/A
12/14	1.6	(10.7)	(79.7)	0.0	N/A	N/A
12/15e	7.1	(11.1)	(82.4)	0.0	N/A	N/A
12/16e	5.8	(11.1)	(79.9)	0.0	N/A	N/A

Source: Newron, Edison Investment Research

Price	CHF29.35
Market cap	CHF411m

Share price graph

Share details

Code	NWRN
Shares in issue	14.0m
Net cash (€m) at end June 2015	43.1

Business description

Newron Pharmaceuticals is an Italian CNS-focused biotechnology company. Safinamide/Xadago for Parkinson's disease has been approved in mid-late PD in Europe and launched in Germany; the US PDUFA date is 29 March 2016. Safinamide is partnered with Zambon and Meiji Seika.

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.

Analysts

Dr Philippa Gardner +44 (0)20 3681 2521

Christian Glennie +44 (0)20 3077 5727

healthcare@edisongroup.com

Newron Pharmaceuticals is a research client of Edison Investment Research Limited

EDISON

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand