

Newron Pharmaceuticals

Safinamide ends 2014 on a high note

Safinamide/Xadago has received a positive opinion from the European CHMP regarding its approval for mid-late stage Parkinson's disease (PD). The formal EMA (European Medicines Agency) decision is usually made within two months (67 days) and generally concurs with the CHMP recommendation. This should trigger a milestone payment from partner Zambon and initial EU launch is anticipated in H115. Increasing Xadago's European probability to 100% in addition to a lower discount rate reflecting the recommendation increases our Newron valuation to €321m/CHF401m or CHF30.7/share. Newron has also now re-filed safinamide in the US.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/12	8.9	(2.5)	(0.29)	0.0	N/A	N/A
12/13	3.5	(7.7)	(0.62)	0.0	N/A	N/A
12/14e	1.4	(11.4)	(0.90)	0.0	N/A	N/A
12/15e	6.9	(7.8)	(0.60)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

EU recommends Xadago/safinamide for mid-late PD

The CHMP (Committee for Medicinal Products for Human Use) recommendation marks the first Xadago (safinamide) regulatory decision, with a positive opinion in mid-late stage PD. We estimate this patient group represents 75-80% of the PD market, suggesting ex-US peak sales of €200m (we previously forecast €500m peak sales, split broadly equally between the US and ex-US).

Partner Zambon to launch Xadago/safinamide in H115

Xadago is partnered with Zambon globally excluding Japan and Asia. The formal EU approval should trigger a milestone payment from Zambon in early 2015 (we estimate €6m). Initial launch by partner Zambon is expected in H115, although this will be dependent on securing reimbursement in individual EU countries. We believe Newron is entitled to receive double-digit royalties on Xadago sales, which we now include in our financial forecasts.

Safinamide now re-filed in the US

In the US, safinamide has now been re-filed in both early and mid-late stage PD, which could allow for approval by the end of 2015 assuming a standard review process. Newron and partner Zambon continue to work towards sub-licensing safinamide, particularly in the key US region where Zambon has a limited presence and we believe the EU recommendation could help to secure partner(s).

Valuation: Raising rNPV to €321m/CHF401m

Our updated valuation is €321m/CHF401m or CHF30.7/share (from €260m/CHF325m or CHF24.9/share) based on 100% probability of €200m ex-US Xadago sales and assuming a lower discount rate to reflect the positive EU opinion. We have made no changes to our Xadago US peak sales or probability.

Regulatory updates

Pharma & biotech

9 January 2015

Price CHF25.8

Market cap CHF335m

€0.8/CHF

Net cash (€m) at end June 2014 30

Shares in issue 13.0m

Free float 75%

Code NWRN

Primary exchange SIX

Secondary exchange N/A

Share price performance



Business description

Newron Pharmaceuticals is an Italian CNS focused biotechnology company. Safinamide/Xadago for Parkinson's disease has been recommended for approval in mid-late PD in Europe; the US regulatory process is ongoing. Safinamide is partnered with Zambon and Meiji Seika.

Next events

Formal EMA safinamide approval	Q115
EU safinamide launch by partner Zambon	H115
Safinamide sub-licensing	2015
US safinamide regulatory decision	Q415

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Valuation

Our safinamide valuation has been updated to reflect a number of revised assumptions. These include an increased 100% probability of success in Europe (from 90%) following the positive CHMP opinion. However, our peak ex-US sales are now €200m (from €250m) with the recommendation for mid-late stage PD, which represents around 80% of the entire PD market. We have reduced the discount rate to 10% for safinamide, commensurate with our standard assumptions for approved products. In the US, with the re-filing in both early and mid-late stage PD, we have made no adjustments to our 90% probability of €250m peak sales.

We have made no changes to our underlying assumptions for the earlier stage pipeline, although these have altered slightly with rolling our valuation forward. Our updated valuation is therefore €321m/CHF401m or CHF30.7/share. The breakdown of our rNPV valuation, which uses a 12.5% discount rate for all products in development, is shown in Exhibit 1.

Exhibit 1: Newron rNPV valuation

Product	Indication	Launch	Peak sales (€m)	NPV (€m)	Probability	rNPV (€m)	rNPV (CHFm)	NPV/share (CHF/share)
Safinamide	Parkinson's disease	2015	450	213.3	90-100%	202.7	253.3	19.4
sNN0031	Severe PD	2018	200	97.7	25%	19.7	24.6	1.9
sNN0029	ALS	2018	250	129.6	25%	27.0	33.7	2.6
Sarizotan	Rett syndrome	2017	260	184.2	20%	34.1	42.6	3.3
NW-3509	Schizophrenia	2019	380	60.7	15%	7.1	8.9	0.7
Net cash				30.1	100%	30.1	37.7	2.9
Valuation				715.7		320.7	400.8	30.7

Source: Edison Investment Research

Financials

Following the positive recommendation for safinamide in Europe, we now include safinamide royalties from 2015 within our financial forecasts; we assume Newron is entitled to receive double-digit royalties on safinamide sales from partner Zambon. In addition, in 2015 we also include a €6m milestone payment from partner Zambon for EU approval. We believe a further similar milestone will also become due on US approval, which could be possible by the end of 2015; however, as we generally exclude unknown/uncertain milestones from our forecasts, we do not include this US-related milestone in our financial projections. With the EU approval milestone and initial safinamide royalties, we believe Newron could be sufficiently financed for the foreseeable future. The main changes to our forecasts are shown in Exhibit 2.

Exhibit 2: Key changes to financial forecasts

€m	2014 Old	2014 New	% Change	2015 Old	2015 New	% Change	2016 Old	2016 New	% Change
Revenue	1.401	1.401	+0%	0.000	6.854	N/A	0.000	3.251	N/A
Research and development	(6.000)	(6.000)	+0%	(7.500)	(7.500)	+0%	(7.000)	(7.000)	+0%
EBITDA	(11.771)	(11.771)	+0%	(15.028)	(8.174)	-46%	(14.902)	(11.650)	-22%
Operating profit (reported)	(11.715)	(11.715)	+0%	(14.971)	(8.117)	-46%	(14.844)	(11.593)	-22%
Profit before tax (reported)	(11.419)	(11.412)	-0%	(14.741)	(7.821)	-47%	(14.858)	(11.366)	-24%
Profit after tax (reported)	(11.419)	(11.412)	-0%	(14.741)	(7.821)	-47%	(14.858)	(11.366)	-24%

Source: Edison Investment Research

Newron is based in Italy and reports financial results in euros. It is listed in Switzerland on the SIX, with the share price quoted in Swiss francs (CHF). Our valuation is based on an FX rate of €0.8/CHF.

Exhibit 3: Financial summary

	€000s	2010	2011	2012	2013	2014e	2015e	2016e
Year end December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS								
Revenue		806	4,289	8,924	3,539	1,401	6,854	3,251
Cost of Sales		0	0	0	0	0	0	0
Gross Profit		806	4,289	8,924	3,539	1,401	6,854	3,251
Research and development		(15,922)	(3,822)	(3,534)	(4,537)	(6,000)	(7,500)	(7,000)
EBITDA		(21,789)	(6,570)	(2,760)	(7,815)	(11,771)	(8,174)	(11,650)
Operating Profit (before amort. and except.)		(21,667)	(6,499)	(2,710)	(7,786)	(11,739)	(8,141)	(11,617)
Intangible Amortisation		27	17	13	10	24	24	24
Exceptionals		0	0	0	0	0	0	0
Other		0	0	0	0	0	0	0
Operating Profit		(21,640)	(6,482)	(2,697)	(7,776)	(11,715)	(8,117)	(11,593)
Net Interest		(33)	45	200	63	303	295	227
Profit Before Tax (norm)		(21,700)	(6,454)	(2,510)	(7,723)	(11,436)	(7,845)	(11,390)
Profit Before Tax (FRS 3)		(21,673)	(6,437)	(2,497)	(7,713)	(11,412)	(7,821)	(11,366)
Tax		1,128	(8)	122	615	0	0	0
Profit After Tax (norm)		(20,572)	(6,462)	(2,388)	(7,108)	(11,436)	(7,845)	(11,390)
Profit After Tax (FRS 3)		(20,545)	(6,445)	(2,375)	(7,098)	(11,412)	(7,821)	(11,366)
Average Number of Shares Outstanding (m)		6.6	7.3	8.2	11.5	12.7	13.0	13.0
EPS - normalised (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.90)	(0.60)	(0.87)
EPS - normalised and fully diluted (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.90)	(0.60)	(0.87)
EPS - (IFRS) (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.90)	(0.60)	(0.87)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		100.0	100.0	100.0	100.0	100.0	100.0	100.0
EBITDA Margin (%)		-2703.3	-153.2	-30.9	-220.8	-840.2	-119.2	-358.3
Operating Margin (before GW and except.) (%)		-2688.2	-151.5	-30.4	-220.0	-837.9	-118.8	-357.3
BALANCE SHEET								
Fixed Assets		6,026	5,937	11,900	9,821	9,856	9,890	9,923
Intangible Assets		5,188	5,171	11,199	9,125	9,122	9,119	9,116
Tangible Assets		128	56	72	79	117	154	190
Investments		710	710	629	617	617	617	617
Current Assets		13,106	7,629	32,747	21,797	26,940	20,155	9,174
Stocks		396	246	233	301	301	301	301
Debtors		2,557	1,469	2,811	2,088	2,088	2,088	2,088
Cash		8,087	5,367	29,243	18,426	23,887	17,411	6,671
Other		2,066	547	460	982	665	355	114
Current Liabilities		(4,635)	(2,827)	(11,585)	(6,070)	(4,637)	(5,233)	(5,176)
Creditors		(4,635)	(2,472)	(11,230)	(5,712)	(4,279)	(4,875)	(4,818)
Short term borrowings		0	(355)	(355)	(358)	(358)	(358)	(358)
Long Term Liabilities		(2,306)	(4,154)	(5,454)	(4,458)	(4,100)	(3,742)	(3,384)
Long term borrowings		0	(1,802)	(1,447)	(1,087)	(729)	(371)	(13)
Other long term liabilities		(2,306)	(2,352)	(4,007)	(3,371)	(3,371)	(3,371)	(3,371)
Net Assets		12,191	6,585	27,608	21,090	28,059	21,071	10,538
CASH FLOW								
Operating Cash Flow		(17,973)	(4,884)	6,015	(10,071)	(11,941)	(6,322)	(10,517)
Net Interest		0	0	0	1	303	295	227
Tax		(1,128)	8	(122)	(615)	0	0	0
Capex		(7)	(1)	(11)	(56)	(70)	(70)	(70)
Acquisitions/disposals		0	0	9,971	301	0	0	0
Financing		4,787	0	8,378	(20)	17,527	(21)	(21)
Dividends		0	0	0	0	0	0	0
Net Cash Flow		(14,321)	(4,877)	24,231	(10,460)	5,819	(6,117)	(10,382)
Opening net debt/(cash)		(22,408)	(8,087)	(3,210)	(27,441)	(16,981)	(22,800)	(16,682)
HP finance leases initiated		0	0	0	0	0	0	0
Other		0	0	0	0	0	0	0
Closing net debt/(cash)		(8,087)	(3,210)	(27,441)	(16,981)	(22,800)	(16,682)	(6,300)

Source: Edison Investment Research, Newron Pharmaceuticals accounts.

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