

Newron Pharmaceuticals

Xadago launches in Germany

Xadago has been launched in Germany as expected by commercial partner Zambon, which should lead to Newron's first recurring royalty income. Xadago has been priced at a premium to Azilect in Germany, which if replicated in other countries and regions, could suggest upside potential to our current forecasts and valuation. We continue to expect a Xadago US approval decision by YE15. Our valuation and forecasts have been updated to reflect the CHF24.3m fund-raise, with our valuation CHF526m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/13	3.5	(7.7)	(0.62)	0.0	N/A	N/A
12/14	1.6	(10.7)	(0.80)	0.0	N/A	N/A
12/15e	7.1	(11.1)	(0.82)	0.0	N/A	N/A
12/16e	5.8	(11.1)	(0.80)	0.0	N/A	N/A

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

First Xadago launch in Germany by partner Zambon

As expected, commercial partner Zambon has now launched Xadago in Germany, with pricing 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 launch to continue in additional EU countries as pricing and reimbursement are agreed in the coming months/quarters.

Price premium suggests upside potential

Our current forecasts and valuation assume safinamide is priced broadly in line with Azilect, leading to peak sales of around €450m based on a 10% penetration of the PD patient market. If Xadago can achieve premium pricing to Azilect across Europe and the US, as in Germany, then all else being equal, our peak sales would be closer to around €660m. This would be worth around a further CHF160m to our valuation, or CHF12/share. Until further pricing is agreed, particularly in the US, we make no changes to our forecasts at this stage.

US Xadago decision by YE15; pipeline opportunities

Xadago remains under review in the US with a PDUFA decision date of 29 December 2015; Zambon continues to focus on sub-licensing in this region. A Phase II trial is being planned with NW-3509 as an add-on to antipsychotics prior to potential partnering. A small pilot trial with sarizotan for Rett syndrome is also expected to start this year, with data in early 2016.

Valuation: rNPV updated to CHF526m with fund-raise

Our valuation has been updated to reflect the recent CHF24.3m (gross) fund-raise in addition to rolling our valuation forward in time. We have made no changes to our underlying product assumptions, which include €450m Xadago PD peak sales, and contributions for Xadago in dyskinesia and the earlier-stage orphan pipeline.

Pipeline update and capital increase

Pharma & biotech

20 May 2015

Price **CHF28.60**

Market cap **CHF400m**

€0.94/CHF

Net cash (€m) at end December 2014 24.6

Shares in issue 14.0m

Free float 75%

Code NWRN

Primary exchange SIX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (4.7) 0.4 82.7

Rel (local) (5.2) (3.9) 70.0

52-week high/low CHF35.0 CHF14.3

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 December 2015. Safinamide is partnered with Zambon and Meiji Seika.

Next events

US safinamide regulatory decision Q415

Safinamide sub-licensing 2015

NW-3509 out-licensing 2015/2016

Sarizotan Phase II data 2016

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Valuation

We have made no major changes to our underlying product assumptions, which include €450m of Xadago peak sales in Parkinson's disease (PD), in addition to risk-adjusted contributions for Xadago in dyskinesia and the pipeline of orphan opportunities: (1) sarizotan in Rett syndrome; (2) sNN0031 for severe PD; and (3) sNN0029 in ALS. Our valuation also includes NW-3509, which Newron is planning to partner.

Our valuation has been updated to reflect the recent CHF24.3m gross fund-raise at CHF28.80 (we estimate CHF23.1m/€21.7m net assuming a €0.94/CHF FX rate) in addition to rolling forward in time. Our valuation is therefore CHF526m (from CHF496m), or CHF37.7/share.

Exhibit 1: Newron rNPV valuation

Product	Indication	Launch	Peak sales (€m)	NPV (CHFm)	Probability	rNPV (CHFm)	NPV/share (CHF/share)
Safinamide	Parkinson's Disease	2015	450	315.6	90-100%	300.5	21.5
	Dyskinesia	2018	390	130.9	40%	52.4	3.8
sNN0031	Severe Parkinson's Disease	2018	200	138.3	25%	30.3	2.2
sNN0029	ALS	2018	250	181.1	25%	40.7	2.9
Sarizotan	Rett syndrome	2017	260	237.3	20%	40.3	2.9
NW-3509	Schizophrenia	2019	380	79.1	20%	12.4	0.9
Estimated net cash post CHF24.3m fund-raise				49.3	100%	49.3	3.5
Valuation				1,131.6		526.0	37.7

Source: Edison Investment Research

Key newsflow in the next 12-18 months

Exhibit 2: Anticipated newsflow

News	Period	Comments
NW-3509 start of Phase II trial	Q215	
Sarizotan start of pilot study	mid-2015	Small pilot trial prior to a pivotal trial in 2015.
Safinamide US approval	Q415	PDUFA date is 29 December.
Sarizotan start of potentially pivotal study	Q415	
Safinamide sub-licensing	2015	Zambon is working to sub-license safinamide in regions including the US.
NW-3509 partnering	2015-2016	A partnering deal could come before or after the availability of Phase II data.
Sarizotan data from pilot study	Q116	Will validate preclinical models and provide insights into ability to reduce apnoea.
NW-3509 Phase II data	H116	Will provide first proof of concept.
sNN0029 data from ongoing Phase II trial	2016	Could trigger a decision on the development and commercial strategy (alone or with a partner).
sNN0031 data from ongoing Phase II trial	2016	Could trigger a decision on the development and commercial strategy (alone or with a partner).

Source: Edison Investment Research

Financials

We have made only minor changes to our financial forecasts, incorporating the CHF24.3m capital increase, which leads to increased interest income as a result of the higher cash balance.

We estimate pro forma net cash of CHF49.3/€46.3m, consisting of reported net cash at end December of €24.6m in addition to estimated net proceeds of €21.7m from the recent fund-raise. We estimate that this should be sufficient to fund operations for the foreseeable future, including development of the earlier-stage pipeline, where it is likely that only small trials will be needed to obtain regulatory approvals.

Exhibit 3: Financial summary

	€000s	2010	2011	2012	2013	2014	2015e	2016e
Year end December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS								
Revenue		806	4,289	8,924	3,539	1,557	7,130	5,822
Cost of Sales		0	0	0	0	0	0	0
Gross Profit		806	4,289	8,924	3,539	1,557	7,130	5,822
Research and development		(15,922)	(3,822)	(3,534)	(4,537)	(6,017)	(11,500)	(10,000)
EBITDA		(21,789)	(6,570)	(2,760)	(7,815)	(11,248)	(11,511)	(11,673)
Operating Profit (before amort. and except.)		(21,667)	(6,499)	(2,710)	(7,786)	(11,228)	(11,484)	(11,644)
Intangible Amortisation		27	17	13	10	13	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)	(11,215)	(11,460)	(11,620)
Net Interest		(33)	45	200	63	492	356	497
Profit Before Tax (norm)		(21,700)	(6,454)	(2,510)	(7,723)	(10,736)	(11,128)	(11,147)
Profit Before Tax (FRS 3)		(21,673)	(6,437)	(2,497)	(7,713)	(10,723)	(11,104)	(11,123)
Tax		1,128	(8)	122	615	628	0	0
Profit After Tax (norm)		(20,572)	(6,462)	(2,388)	(7,108)	(10,108)	(11,128)	(11,147)
Profit After Tax (FRS 3)		(20,545)	(6,445)	(2,375)	(7,098)	(10,095)	(11,104)	(11,123)
Average Number of Shares Outstanding (m)		6.6	7.3	8.2	11.5	12.7	13.5	14.0
EPS - normalised (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.80)	(0.82)	(0.80)
EPS - normalised and fully diluted (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.80)	(0.82)	(0.80)
EPS - (IFRS) (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.80)	(0.82)	(0.80)
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	-722.4	-161.5	-200.5
Operating Margin (before GW and except.) (%)		-2688.2	-151.5	-30.4	-220.0	-721.1	-161.1	-200.0
BALANCE SHEET								
Fixed Assets		6,026	5,937	11,900	9,821	7,686	7,741	7,795
Intangible Assets		5,188	5,171	11,199	9,125	6,993	6,975	6,957
Tangible Assets		128	56	72	79	67	140	211
Investments		710	710	629	617	626	626	626
Current Assets		13,106	7,629	32,747	21,797	29,388	40,858	30,287
Stocks		396	246	233	301	102	102	102
Debtors		2,557	1,469	2,811	2,088	3,320	3,320	3,320
Cash		8,087	5,367	29,243	18,426	25,702	37,542	27,482
Other		2,066	547	460	982	264	(106)	(617)
Current Liabilities		(4,635)	(2,827)	(11,585)	(6,070)	(4,489)	(4,564)	(4,298)
Creditors		(4,635)	(2,472)	(11,230)	(5,712)	(4,131)	(4,206)	(3,940)
Short term borrowings		0	(355)	(355)	(358)	(358)	(358)	(358)
Long Term Liabilities		(2,306)	(4,154)	(5,454)	(4,458)	(3,324)	(2,966)	(2,608)
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)	(2,595)	(2,595)	(2,595)
Net Assets		12,191	6,585	27,608	21,090	29,261	41,069	31,176
CASH FLOW								
Operating Cash Flow		(17,973)	(4,884)	6,015	(10,071)	(9,370)	(9,891)	(10,093)
Net Interest		0	0	0	1	7,053	356	497
Tax		(1,128)	8	(122)	(615)	(628)	157	0
Capex		(7)	(1)	(11)	(56)	(22)	(100)	(100)
Acquisitions/disposals		0	0	9,971	301	0	0	0
Financing		3,185	0	8,378	0	17,547	21,682	0
Other		1,602	0	0	(20)	(6,946)	(6)	(6)
Dividends		0	0	0	0	0	0	0
Net Cash Flow		(14,321)	(4,877)	24,231	(10,460)	7,634	12,198	(9,702)
Opening net debt/(cash)		(22,408)	(8,087)	(3,210)	(27,441)	(16,981)	(24,615)	(36,813)
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)	(24,615)	(36,813)	(27,111)

Source: Edison Investment Research, Newron Pharmaceuticals accounts. Note: Newron is based in Italy and reports financials 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 €0.94/CHF.

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