

Newron Pharmaceuticals

Safinamide filed in the US

Safinamide has now been filed in the US, which should allow for approval in Q215. First safinamide launch could still be in early 2015 with European approval potentially by end 2014. The CHF18.6m capital raise extends the cash runway to end '16 and should allow Newron to advance development of the pipeline of orphan drugs, which it could commercialise alone. Our updated valuation including the capital increase is €267m/CHF333m.

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	0.8	(12.0)	(0.98)	0.0	N/A	N/A
12/15e	0.0	(14.8)	(1.13)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments. We exclude safinamide royalties until formal approval.

US filing should allow for approval in Q215

Newron and partner Zambon have filed safinamide with the US FDA for both early-stage PD as an add-on to dopamine agonists, and in mid- to late-stage PD as an add-on to levodopa. A standard 12-month review process would allow for approval in Q215. The filing should trigger a small milestone payment to Newron. Safinamide was also filed in Switzerland in March. European approval could be by the end of this year following MAA filing in December. Sub-licensing safinamide remains key.

Plans to progress NW-3509 to Phase II confirmed

NW-3509 preliminary data from the ongoing Phase I trial were recently presented at the SIRS (Schizophrenia International Research Society) conference. NW-3509 was well tolerated in healthy volunteers and Newron plans to start a Phase II trial later and is exploring partnering options. NW-3509 is a potential treatment for schizophrenia as an add-on treatment to antipsychotics.

Cash allows execution of orphan drug strategy

Newron raised CHF18.6m gross proceeds in April from the issue of 1.2m new shares at a price of CHF15.75. These funds extend the cash runway to at least end 2016 and should allow Newron to advance the pipeline of orphan drugs. Milestones and royalties related to safinamide could potentially extend the cash reach beyond first launch of one of these candidates in 2017. The orphan pipeline includes sNN0031 for severe PD, sNN0029 for ALS and sarizotan for Rett syndrome.

Valuation: Risk-adjusted NPV of €267m/CHF333m

We value Newron at €267m/CHF333m or CHF25.6/share based on a risk-adjusted NPV analysis, including current net cash, safinamide in PD, the portfolio of orphan drugs and NW-3509. Current net cash of €34m including proceeds from the recent private placement and commitments from third parties should now be sufficient to fund operations to at least end 2016 beyond key value inflexion points, including safinamide regulatory approval decisions and potential sub-licensing.

Regulatory update and capital increase

Pharma & biotech

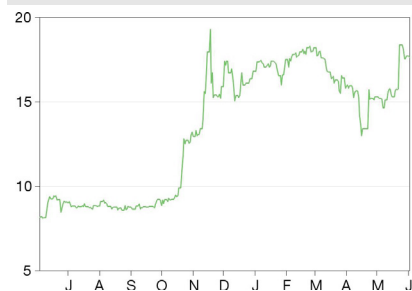
3 June 2014

Price CHF17.7
Market cap CHF230m

€0.8/CHF

Net cash (€m) at end December 2013	17
Shares in issue	13.0m
Free float	75%
Code	NWRN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	15.4	(0.3)	116.6
Rel (local)	12.1	(5.0)	93.9
52-week high/low	CHF19.3	CHF8.1	

Business description

Newron Pharmaceuticals is an Italian biotechnology company focused on CNS diseases. Its most advanced drug, safinamide, has been filed in Europe, the US and Switzerland for Parkinson's disease. Safinamide is partnered with Zambon and Meiji Seika.

Next events

Safinamide sub-licensing	2014
NW-3509 start of Phase II	Q414
Safinamide EU approval	Q414
Safinamide US approval	Q215

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Valuation

Our underlying product valuation assumptions are unchanged, although these have altered slightly with rolling our valuation forward. We now include the CHF18.6m/€14.9m proceeds from the recent capital raise in our net cash, which together raise our rNPV to €267m/CHF333m. This is diluted to CHF25.6/share given the increased number of shares. The breakdown of our rNPV valuation, which uses a 12.5% discount rate, 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	500	173.7	90%	157.0	196.2	15.1
sNN0031	Severe PD	2018	200	88.7	25%	16.4	20.5	1.6
sNN0029	ALS	2018	250	119.2	25%	24.1	30.1	2.3
Sarizotan	Rett syndrome	2017	260	168.9	20%	29.8	37.2	2.9
NW-3509	Schizophrenia	2019	380	55.3	15%	5.6	7.0	0.5
Net cash				34.0	100%	34.0	42.5	3.3
Valuation				639.8		266.8	333.5	25.6

Source: Edison Investment Research

Financials

Following the capital increase, we estimate current net cash of €34m (including €17m net cash at end December, €2.9m from issuing 211k shares as part of a private placement to JPMorgan at CHF17/share and c €2m of cash commitments from third parties). We estimate cash should be sufficient to fund operations to at least end 2016. We do not include any royalty income for safinamide in our revenue forecasts until formal approval. In addition, our estimates only include a milestone payment (<€1m) from partner Zambon for US filing. We do not include any milestone payments for regulatory approvals in the US or Europe, which we estimate could together be around €11m. We do not include any potential milestone income from safinamide sub-licensing. In addition, our R&D spend assumes NW-3509 is partnered at the end of Phase II development, with Newron paying all Phase II-related costs. If these milestones are achieved or R&D spend is lower than we anticipate, the cash runway could potentially be extended.

We have made only very minor changes to our financial forecasts, with the increased cash position leading to higher interest income in the next few years and hence a slightly narrower net loss. These changes to our P&L forecasts are shown in Exhibit 2 and our financial model is shown in Exhibit 3. With the lengthened cash runway, we no longer include illustrative financing in 2015, but do still show €5m in 2016, which we class as long-term debt for the purposes of our model.

Exhibit 2: Key changes to financial forecasts

EUR millions	2014e Old	2014e New	% Change	2015e Old	2015e New	% Change	2016e Old	2016e New	% Change
Revenue	0.800	0.800	+0%	0.000	0.000	n/a	0.000	0.000	n/a
Research and development	(6.000)	(6.000)	+0%	(7.500)	(7.500)	+0%	(7.000)	(7.000)	+0%
EBITDA	(12.372)	(12.372)	+0%	(15.028)	(15.028)	+0%	(14.901)	(14.901)	+0%
Operating Profit	(12.316)	(12.316)	+0%	(14.971)	(14.971)	+0%	(14.844)	(14.844)	+0%
Profit Before Tax (reported)	(12.126)	(12.020)	-1%	(14.986)	(14.741)	-2%	(14.858)	(14.858)	+0%
Profit After Tax (reported)	(12.126)	(12.020)	-1%	(14.986)	(14.741)	-2%	(14.858)	(14.858)	+0%

Source: Edison Investment Research

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 €0.8/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	800	0	0
Cost of Sales		0	0	0	0	0	0	0
Gross Profit		806	4,289	8,924	3,539	800	0	0
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)	(12,372)	(15,028)	(14,901)
Operating Profit (before amort. and except.)		(21,667)	(6,499)	(2,710)	(7,786)	(12,340)	(14,995)	(14,868)
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)	(12,316)	(14,971)	(14,844)
Net Interest		(33)	45	200	63	296	230	(14)
Profit Before Tax (norm)		(21,700)	(6,454)	(2,510)	(7,723)	(12,044)	(14,765)	(14,882)
Profit Before Tax (FRS 3)		(21,673)	(6,437)	(2,497)	(7,713)	(12,020)	(14,741)	(14,858)
Tax		1,128	(8)	122	615	0	0	0
Profit After Tax (norm)		(20,572)	(6,462)	(2,388)	(7,108)	(12,044)	(14,765)	(14,882)
Profit After Tax (FRS 3)		(20,545)	(6,445)	(2,375)	(7,098)	(12,020)	(14,741)	(14,858)
Average Number of Shares Outstanding (m)		6.6	7.3	8.2	11.5	12.3	13.0	13.0
EPS - normalised (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.98)	(1.13)	(1.14)
EPS - normalised and fully diluted (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.98)	(1.13)	(1.14)
EPS - (IFRS) (€)		(3.11)	(0.89)	(0.29)	(0.62)	(0.98)	(1.13)	(1.14)
Dividend per share (EUR)		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	n/a	n/a
EBITDA Margin (%)		-2703.3	-153.2	-30.9	-220.8	-1546.5	n/a	n/a
Operating Margin (before GW and except.) (%)		-2688.2	-151.5	-30.4	-220.0	-1542.5	n/a	n/a
BALANCE SHEET								
Fixed Assets		6,026	5,937	11,900	9,821	9,826	9,831	9,835
Intangible Assets		5,188	5,171	11,199	9,125	9,122	9,119	9,116
Tangible Assets		128	56	72	79	87	95	102
Investments		710	710	629	617	617	617	617
Current Assets		13,106	7,629	32,747	21,797	26,058	12,382	3,316
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	22,997	9,566	500
Other		2,066	547	460	982	671	427	427
Current Liabilities		(4,635)	(2,827)	(11,585)	(6,070)	(4,791)	(5,387)	(5,330)
Creditors		(4,635)	(2,472)	(11,230)	(5,712)	(4,433)	(5,029)	(4,972)
Short term borrowings		0	(355)	(355)	(358)	(358)	(358)	(358)
Long Term Liabilities		(2,306)	(4,154)	(5,454)	(4,458)	(4,400)	(4,042)	(9,062)
Long term borrowings		0	(1,802)	(1,447)	(1,087)	(729)	(371)	(5,391)
Other long term liabilities		(2,306)	(2,352)	(4,007)	(3,371)	(3,671)	(3,671)	(3,671)
Net Assets		12,191	6,585	27,608	21,090	26,693	12,784	(1,241)
CASH FLOW								
Operating Cash Flow		(17,973)	(4,884)	6,015	(10,071)	(12,249)	(13,242)	(14,010)
Net Interest		0	0	0	1	296	230	(14)
Tax		(1,128)	8	(122)	(615)	154	0	0
Capex		(7)	(1)	(11)	(56)	(40)	(40)	(40)
Acquisitions/disposals		0	0	9,971	301	0	0	0
Financing		4,787	0	8,378	(20)	16,768	(21)	(21)
Dividends		0	0	0	0	0	0	0
Net Cash Flow		(14,321)	(4,877)	24,231	(10,460)	4,929	(13,073)	(14,086)
Opening net debt/(cash)		(22,408)	(8,087)	(3,210)	(27,441)	(16,981)	(21,910)	(8,837)
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)	(21,910)	(8,837)	5,249

Source: Edison Investment Research, Newron Pharmaceuticals accounts. Note: We include €5m illustrative financing in 2016 as long-term debt.

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