

Newron Pharmaceuticals

Evenamide update

Gate not yet open to Phase III

Newron is developing evenamide as an add-on to existing anti-psychotic therapies to treat poorly managed and refractory schizophrenia. Two recently completed safety studies, one in patients and the other in healthy volunteers respectively showed no brain or heart safety issues. The patient Phase II study did not show efficacy at the 7.5mg or 15mg *bid* doses requested by the FDA. Newron will now complete the requested safety work using the intended therapeutic dose of 30mg *bid*. This continuation study (008A) will take until H221 to complete. Our indicative value of CHF121m has been retained until Study 008A completes.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	7.04	(18.04)	(1.01)	0.0	N/A	N/A
12/20	5.26	(18.16)	(1.09)	0.0	N/A	N/A
12/21e	6.67	(18.10)	(1.01)	0.0	N/A	N/A
12/22e	7.68	(27.24)	(1.53)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. 2019 accounts were restated.

Confirmatory expansion study at 30mg dose

Evenamide reduces the firing rate of neurons, preventing rapid bursts of the nerve depolarisation that carries electric signals. As neuronal signalling is how the brain and heart function, the FDA required key safety evidence. Newron [reported](#) on 1 April that evenamide was safe. This was based on data from [Study 008](#) with 138 patients studying brain wave activity. A further 58-volunteer heart study (010) showed no effects on heart electrical activity, indicating no risk of arrhythmias.

In study 008 in chronic schizophrenia, patients were assessed on the widely used Positive and Negative Syndrome Scale ([PANSS](#)) for efficacy. There was no statistical difference compared to placebo at the 15mg twice per day (*bid*) dose; 7.5mg *bid* was sub-therapeutic. As a result, an extension, Study 008A, will be run at a 30mg *bid* dose. If Study 008A is positive, the 30mg *bid* intended therapeutic dose could progress into Phase III. A 25mg *bid* dose was evaluated, including PANSS, in a 90-patient, four-week dose escalation [study](#) from 15mg to 25mg with efficacy [reported](#); a single 30mg dose has also been [tested](#).

Effect on cash flow and partnering

Study 008A could complete by late 2021 with pivotal studies now possible from Q222, in our view. Phase III data may not be available before H223 with full year marketing possible from 2025. This also implies that an evenamide deal is unlikely before H222. There is funding and anticipated cash flows to support development until at least late 2022; this may be extended as Phase III costs are delayed.

Valuation: Held at CHF121m until more data available

Our current valuation uses an evenamide probability of 30% and indicates a value of about CHF121m (CHF6.8/share). We have retained this until study 008A reports. If evenamide cannot show sufficient indication of efficacy at the 30mg *bid* dose or if significant safety issues arise, the project might not progress. In that case, the remaining value would rest on Xadago with current annual royalties of €5.3m.

Pharma & biotech

7 April 2021

Price **CHF2.45**

Market cap **CHF44m**

€1.05/CHF; \$1.03/CHF; \$1.08/€

Cash and investments (€m) at 31 Dec 2020 31.25

Shares in issue 17.845m

Free float 99.6%

Code NWRN

Primary exchange SIX

Secondary exchange XETRA

Share price performance



% 1m 3m 12m

Abs (13.7) 15.8 (52.1)

Rel (local) (18.2) 11.3 (59.4)

52-week high/low CHF6.47 CHF1.34

Business description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease is sold in Europe, Japan and the US. Evenamide, a novel schizophrenia therapy, may start Phase III in 2022 if the 30mg *bid* dose has positive results.

Next events

H121 report September 2021

Evenamide Phase II outcome Late 2021

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Exhibit 1: Financial summary

	€000s	2019	2020	2021e	2022e
Year end December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		7,038	5,258	6,669	7,678
Cost of Sales		0	0	0	0
Gross Profit		7,038	5,258	6,669	7,678
EBITDA		(18,567)	(16,386)	(16,681)	(25,822)
Depreciation		(206)	(219)	(219)	(219)
Share option adjustments		(2,126)	(1,461)	0	0
Operating Profit		(20,899)	(18,066)	(16,900)	(26,041)
Net Interest		737	(1,552)	(1,200)	(1,200)
Profit Before Tax (norm)		(18,036)	(18,157)	(18,100)	(27,241)
Profit Before Tax (reported)		(20,162)	(19,618)	(18,100)	(27,241)
Tax		(45)	(1,380)	0	0
Profit After Tax (norm)		(18,081)	(19,537)	(18,100)	(27,241)
Profit After Tax (reported)		(20,207)	(20,998)	(18,100)	(27,241)
Average Number of Shares Outstanding (m)		17.8	17.8	17.8	17.8
EPS - normalised (€)		(1.01)	(1.09)	(1.01)	(1.53)
EPS - (reported) (€)		(1.13)	(1.18)	(1.01)	(1.53)
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross Margin (%)		100.0	100.0	100.0	100.0
EBITDA Margin (%)		N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets		14,797	13,324	13,309	13,294
Intangible Assets		20	11	11	11
Tangible Assets		252	734	719	704
Investments		14,525	12,579	12,579	12,579
Current Assets		45,491	37,874	20,048	8,323
Stocks		0	0	0	0
Debtors		6,328	6,624	6,324	6,324
Cash		39,163	31,250	13,724	1,999
Current Liabilities		(5,595)	(6,892)	(7,151)	(7,651)
Creditors		(5,595)	(6,892)	(7,151)	(7,651)
Short term borrowings		0	0	0	0
Long Term Liabilities		(17,895)	(27,060)	(27,060)	(42,060)
Long term borrowings		(16,749)	(25,674)	(25,674)	(40,674)
Other long-term liabilities		(1,146)	(1,386)	(1,386)	(1,386)
Net Assets		36,798	17,246	(854)	(28,094)
CASH FLOW					
Operating Cash Flow		(22,668)	(12,656)	(16,141)	(25,341)
Net Interest		737	(1,552)	(1,200)	(1,200)
Tax		(45)	(1,380)	0	0
Capex		(51)	(34)	(50)	(50)
Acquisitions/disposals		0	0	0	0
Financing		0	0	0	0
Other		17,337	7,365	(135)	14,865
Dividends		0	0	0	0
Net Cash Flow		(4,690)	(8,257)	(17,526)	(11,726)
Opening net debt/(cash)		(42,972)	(22,414)	(5,576)	11,950
HP finance leases initiated		0	0	0	0
Other		(15,868)	(8,581)	0	(15,000)
Closing net debt/(cash)		(22,414)	(5,576)	11,950	38,675

Source: Company accounts, Edison Investment Research

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