

Newron Pharmaceuticals

Evenamide Phase II completes recruitment

Newron has completed the recruitment of 138 patients into the Phase II study of its novel schizophrenia drug, Evenamide. As expected, the read out is due in March 2021. Newron notes that Evenamide Phase III trials could start in H221 and it is progressing possible partnering and co-development deals. Newron had €39m cash at end-June 2020, with enough cash to fund development well into 2022. Our indicative value remains CHF121m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/18	4.03	(15.01)	(0.84)	0.0	N/A	N/A
12/19	7.04	(20.16)	(1.13)	0.0	N/A	N/A
12/20e	5.59	(14.47)	(0.81)	0.0	N/A	N/A
12/21e	6.67	(20.19)	(1.13)	0.0	N/A	N/A

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

Evenamide on track to enter pivotal trials in H221

Newron has finished recruiting for the four-week exploratory safety trial (Study 008) in 138 patients with chronic schizophrenia who are taking an established therapy (NCT04461119). Doses tested were 7.5mg and 15mg given twice a day versus a placebo arm. The data report should be available in March 2021, after which Newron aims to start two pivotal studies in H221. These comprise Study 003 in patients with inadequate, worsening response to antipsychotic agents plus Study 004 in patients who are resistant to clozapine. Clozapine is currently the most effective antipsychotic agent but about 30–50% of patients become resistant, giving no further options. Newron is seeking a partner for the more general indication of inadequate response to current atypical antipsychotic agents and plans direct marketing of Evenamide for the focused indication of clozapine-resistant adjuvant treatment. Alternatively, co-development could also yield a higher return than a standard royalty deal.

Xadago's further trial plus potential novel therapies

Xadago is a marketed product that faces competition from established generic products such as rasagiline. Extending its indications into relief of levodopa-induced dyskinesia in Parkinson's disease would add value. Newron wishes to run the study and will provide 50% of the funding (up to €10m) with the licensee, Zambon, funding the remainder. If agreement is reached soon, a trial could start in 2021, with possible approval from 2023. Newron is also seeking to in-license novel products targeting the central and peripheral nervous systems.

Valuation: Funding to 2022

Newron had €39.4m cash in June 2020. There is cash and available funding to support development well into 2022, partly from an unused €15m EIB loan facility, and partnering would extend this. Our model indicates an unchanged value of about CHF121m (CHF6.8/share). A partnering or co-development decision would potentially trigger a valuation rebasing depending on the terms.

Clinical trial update

Pharma & biotech

25 January 2021

Price CHF2.72

Market cap CHF49m

€1.05/CHF; \$1.03/CHF; \$1.08/€

Cash and investments (€m) at 30 June 2020 39.4

Shares in issue 17.85m

Free float 99.6%

Code NWRN

Primary exchange SIX

Secondary exchange XETRA

Share price performance



% 1m 3m 12m

Abs 29.5 47 (60.5)

Rel (local) 23.3 34.5 (60.6)

52-week high/low CHF6.90 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 trials from Q221.

Next events

FY20 report March 2021

Evenamide Phase II outcome March 2021

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Exhibit 1: Financial summary

	€000s	2018	2019	2020e	2021e
Year-end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		4,025	7,038	5,590	6,669
Cost of Sales		0	0	0	0
Gross Profit		4,025	7,038	5,590	6,669
EBITDA		(14,931)	(20,707)	(13,757)	(19,593)
Operating Profit (before amort. and except.)		(14,967)	(20,899)	(13,963)	(19,616)
Intangible Amortisation		(11)	0	0	0
Exceptionals		0	0	0	0
Other		0	0	0	0
Operating Profit		(14,978)	(20,899)	(13,963)	(19,616)
Net Interest		(41)	737	(507)	(572)
Profit Before Tax (norm)		(15,008)	(20,162)	(14,470)	(20,189)
Profit Before Tax (reported)		(15,019)	(20,162)	(14,470)	(20,189)
Tax		(16)	(45)	0	0
Profit After Tax (norm)		(15,024)	(20,207)	(14,470)	(20,188)
Profit After Tax (reported)		(15,035)	(20,207)	(14,470)	(20,189)
Average Number of Shares Outstanding (m)		17.8	17.8	17.8	17.8
EPS - normalised (c)		(84.20)	(113.24)	(81.09)	(113.13)
EPS - (reported) (€)		(0.84)	(1.13)	(0.81)	(1.13)
Dividend per share		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		487	342	342	332
Intangible Assets		30	20	20	10
Tangible Assets		106	116	116	116
Investments		351	206	206	206
Current Assets		59,512	59,946	49,912	40,674
Stocks		0	0	0	0
Debtors		15,659	20,783	19,783	19,783
Cash		43,853	39,163	30,129	20,891
Other		0	0	0	0
Current Liabilities		(4,432)	(5,595)	(7,081)	(8,081)
Creditors		(4,432)	(5,595)	(7,081)	(8,081)
Short term borrowings		0	0	0	0
Long Term Liabilities		(731)	(17,895)	(25,395)	(40,395)
Long term borrowings		0	(16,749)	(24,249)	(39,249)
Other long-term liabilities		(731)	(1,146)	(1,146)	(1,146)
Net Assets		54,836	36,798	17,778	(7,470)
CASH FLOW					
Operating Cash Flow		(15,954)	(22,210)	(16,484)	(24,189)
Net Interest		(78)	71	0	0
Tax		0	0	0	0
Capex		(40)	(51)	(50)	(50)
Acquisitions/disposals		0	0	0	0
Financing		51	0	7,500	15,000
Other		3,002	16,619	0	0
Dividends		0	0	0	0
Net Cash Flow		(13,019)	(5,571)	(9,034)	(9,239)
Opening net debt/(cash)		(60,081)	(43,853)	(22,414)	(5,880)
HP finance leases initiated		0	0	0	0
Other		(3,209)	(15,868)	(7,500)	(15,000)
Closing net debt/(cash)		(43,853)	(22,414)	(5,880)	18,358

Source: Company accounts, Edison Investment Research

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