

Newron Pharmaceuticals

Interim results

Next up - R&D day

Newron continued to make steady progress in H118. A fuller debrief of pipeline assets including sarizotan (Rett syndrome) and Evenamide (schizophrenia) will take place at the R&D day in NYC, scheduled for 31 October. Royalty income from sales of Xadago (Parkinson's disease, PD) rose by 54% to €2m, driven mainly by increased sales in the EU and Switzerland. However, the US sales contribution remained small (launched by partner US WorldMeds in H217). In H118 Newron reported an operating loss of €7.6m (vs a profit of €2.3m in H117 due to a €10.3m one-time milestone payment in the period), and revised cash and financial investments of €50.6m at July 2018 should enable funding to key value inflection points in 2020. We value Newron at CHF788m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	6.7	(15.2)	(1.04)	0.0	N/A	N/A
12/17	13.4	(5.3)	(0.32)	0.0	N/A	N/A
12/18e	5.6	(24.6)	(1.38)	0.0	N/A	N/A
12/19e	10.7	(28.2)	(1.58)	0.0	N/A	N/A

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

Xadago sales uplift needed

Newron has reported €2.0m in Xadago (safinamide) royalties in H118 (vs €2.8m in FY17 and €1.3m in H117). Xadago is now available in 14 European countries as an add-on therapy to levodopa in mid- to late-stage PD. The drug was also launched in H217 into the US market for PD patients (as add-on therapy), and regional partner US WorldMeds expects an uplift in sales in 2019 once its Medicare negotiations come to fruition. Xadago is making slow and steady progress, but a ramp-up in sales is required if it is to reach our global peak sales of €653m (in PD alone). Partner Meiji Seika plans to file for marketing approval in Japan in H218 (following positive Phase II/III data in Japanese patients).

Pipeline progressing; R&D day 31 October 2018

R&D highlights for the period include: 1) progress with patient enrolment into the Sarizotan Treatment of Apneas in Rett Syndrome (STARS) potentially pivotal Phase II/III clinical trial, study now expected to in report in H119 (previously late 2018); 2) Evenamide for schizophrenia – two Phase II/III pivotal efficacy studies to initiate in H119, one in patients with worsening psychosis despite atypical antipsychotic treatment and the other in clozapine-resistant schizophrenia; and 3) US partner Zambon is in advanced discussions with the FDA on the design of a potentially pivotal efficacy study to support Xadago's use in levodopa-induced dyskinesia (PD LID).

Valuation: CHF788m or CHF44.3 per share

Our increased valuation of CHF788m (vs CHF758m) reflects end-June 2018 net cash and short-term investments of €50.6m and rolling forward our model. Our forecasts remain unchanged and include Xadago in PD and risk-adjusted contributions for the dyskinesia indication, sarizotan in Rett syndrome and Evenamide in schizophrenia.

Pharma & biotech

11 October 2018

Price **CHF8.73**
Market cap **CHF155m**

€0.85/CHF

Net cash and short-term investments (€m) at 30 June 2018 50.6

Shares in issue 17.8m

Free float 95%

Code NWRN

Primary exchange SIX

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(14.3)	(34.9)	(38.8)
Rel (local)	(15.5)	(36.3)	(36.8)

52-week high/low CHF14.2 CHF8.2

Business description

Newron Pharmaceuticals is an Italian CNS-focused biotechnology company. Xadago (safinamide) for Parkinson's disease has been launched in Europe and the US. Xadago is partnered with Zambon (EU), Meiji Seika (Japan), US WorldMeds (US), Seqirus (Australia/New Zealand) and Medison Pharma (Israel).

Next events

Sarizotan Phase III STARS data H119

Evenamide Phase II/III start 2019

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Exhibit 1: Financial summary

	€000s	2015	2016	2017	2018e	2019e
Year end December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		2,380	6,726	13,428	5,625	10,671
Cost of Sales		0	0	0	0	0
Gross Profit		2,380	6,726	13,428	5,625	10,671
Research and development (net)		(11,724)	(12,398)	(8,596)	(20,800)	(29,160)
EBITDA		(17,604)	(15,290)	(4,298)	(24,731)	(28,281)
Operating Profit (before amort. and except.)		(17,668)	(15,318)	(4,332)	(24,753)	(28,303)
Intangible Amortisation		(7)	(7)	(14)	(24)	(24)
Exceptionals		(6,725)	0	0	0	0
Other		0	0	0	0	0
Operating Profit		(24,400)	(15,325)	(4,346)	(24,777)	(28,327)
Net Interest		(583)	121	(955)	206	131
Profit Before Tax (norm)		(18,251)	(15,197)	(5,287)	(24,547)	(28,172)
Profit Before Tax (reported)		(24,983)	(15,204)	(5,301)	(24,571)	(28,196)
Tax		2,167	(33)	19	0	0
Profit After Tax (norm)		(16,084)	(15,230)	(5,268)	(24,547)	(28,172)
Profit After Tax (reported)		(22,816)	(15,237)	(5,282)	(24,571)	(28,196)
Average Number of Shares Outstanding (m)		13.7	14.7	16.3	17.8	17.8
EPS - normalised (c)		(117.21)	(103.69)	(32.32)	(137.90)	(158.27)
EPS - (reported) (€)		(1.66)	(1.04)	(0.32)	(1.38)	(1.58)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		100.0	100.0	100.0	100.0	100.0
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		406	451	224	240	256
Intangible Assets		265	261	35	49	63
Tangible Assets		79	120	107	109	111
Investments		62	70	82	82	82
Current Assets		43,974	56,140	72,800	51,900	27,311
Stocks		38	5	5	98	98
Debtors		3,005	9,667	12,714	3,883	3,883
Cash		40,931	46,468	60,081	47,919	23,330
Other		0	0	0	0	0
Current Liabilities		(6,513)	(6,645)	(4,727)	(6,653)	(8,537)
Creditors		(6,151)	(6,281)	(4,727)	(6,653)	(8,537)
Short term borrowings		(362)	(364)	0	0	0
Long Term Liabilities		(755)	(199)	(576)	(576)	(576)
Long term borrowings		(364)	0	0	0	0
Other long term liabilities		(391)	(199)	(576)	(576)	(576)
Net Assets		37,112	49,747	67,721	44,911	18,454
CASH FLOW						
Operating Cash Flow		(10,695)	(19,616)	(8,404)	(12,328)	(24,658)
Net Interest		121	102	388	241	131
Tax		(2,167)	33	0	0	0
Capex		(60)	(69)	(24)	(24)	(24)
Acquisitions/disposals		0	0	0	0	0
Financing		28,392	25,448	22,324	0	0
Other		(4)	(3)	(300)	(51)	(38)
Dividends		0	0	0	0	0
Net Cash Flow		15,587	5,895	13,984	(12,162)	(24,589)
Opening net debt/(cash)		(24,615)	(40,205)	(46,104)	(60,081)	(47,919)
HP finance leases initiated		0	0	0	0	0
Other		3	4	(7)	0	0
Closing net debt/(cash)		(40,205)	(46,104)	(60,081)	(47,919)	(23,330)

Source: Company accounts, Edison Investment Research

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