EDISON

Newron Pharmaceuticals

FY16 results

Marching into 2017

Pharma & biotech

We anticipate that the sales and pipeline progression made by Newron in 2016 will be cemented further in 2017/18. A critical catalyst remains the US Xadago (Parkinson's disease (PD) therapy) approval which is imminent (revised PDUFA date is 21 March); this will materially impact the share price performance. We anticipate US launch in H217 by sub licensee, US WorldMeds. Data from pipeline assets sarizotan (Rett's syndrome, RS) and evenamide (schizophrenia) in the upcoming 18 months will highlight Newron's diverse, innovative CNS-based R&D portfolio. We value the company at CHF530m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	2.4	(18.3)	(1.17)	0.0	N/A	N/A
12/16	6.7	(15.2)	(1.04)	0.0	N/A	N/A
12/17e	15.3	(7.2)	(0.46)	0.0	N/A	N/A
12/18e	15.6	(3.9)	(0.24)	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 building; US PDUFA date, 21 March

Newron reported €1.7m in Xadago royalties from commercial partner, Zambon in FY16 and Xadago is now available in 11 European countries. We anticipate US FDA approval on 21 March to trigger a €9m milestone payment to Newron. Zambon has sub-licensed US commercialisation rights to US WorldMeds and we anticipate US launch in H217. We therefore expect FY17 sales to benefit from the ongoing European market rollout by Zambon and the US launch by US WorldMeds.

Evenamide POC schizophrenia data, 24-28 March

Newron has reported encouraging preliminary phase IIa POC evenamide data (good tolerability, safety and preliminary evidence of efficacy) as an add-on to antipsychotics in patients with positive symptoms of schizophrenia. Detailed results from the Phase IIa trial of this novel mechanism of action drug will be presented at the ICOSR on 24-28 March. Newron is planning a potentially pivotal study as next steps; the study could be carried out by Newron or with/by a partner. The announcement of a partnering deal would represent upside to our numbers.

Sarizotan potentially written in the STARS

The pivotal Phase III STARS trial evaluating sarizotan for breathing disorders in Rett syndrome (RS) is underway and top line data are now expected mid-2018. Sarizotan is the first drug for RS granted both in the US and Europe and could become the first drug approved for treatment of patients with Rett syndrome. We forecast potential first approval and launch in late 2018; given the size of the indication, Newron will commercialise in RS alone with a small salesforce.

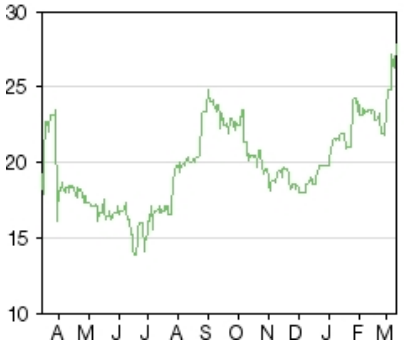
Valuation: Increased to CHF530m or CHF33.6/share

Our updated Newron valuation is CHF530m (from CHF494m) or CHF33.6/share, reflecting a push back to the Xadago launch timeframe in Japan, phasing in R&D costs, and rolling forward our DCF. Our valuation includes risk-adjusted contributions for Xadago in PD and dyskinesia indications, sarizotan in RS and evenamide in schizophrenia and reflects 2016 year-end net cash of CHF46.2m.

13 March 2017

Price	**CHF27.80**
Market cap	**CHF439m**
	€/CHF 1.1
Net cash (€m) at 31 December 2016	46.2
Shares in issue	15.8m
Free float	77%
Code	NWRN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	18.3	49.9	49.1
Rel (local)	15.4	40.0	35.7
52-week high/low	CHF27.8		CHF13.9

Business description

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

Next events

Xadago US PDUFA date	21 March 2017
Evenamide PIIa detailed data	24-28 March 2017
Sarizotan Phase III STARS data	Mid 2018

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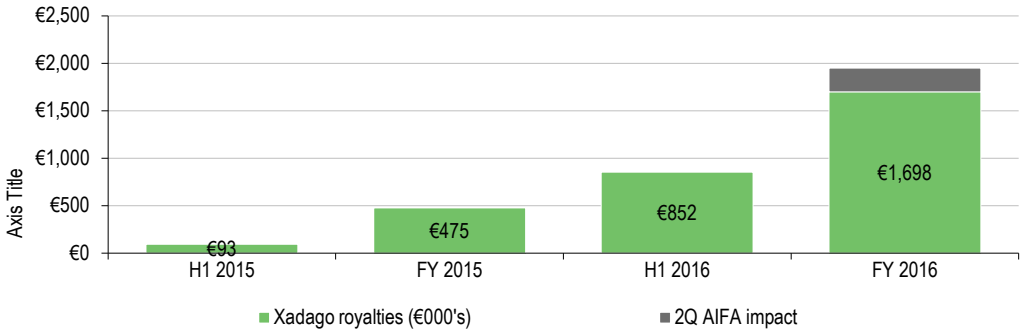
Xadago commercial and approval progress

Newron reported €1.7m in Xadago (salfinamide) royalties in FY16 from commercial partner, Zambon. Xadago is now available in 11 European countries as an add-on therapy to Levodopa in mid-to-late Parkinson's disease; given we assume a 12% royalty rate, this implies net sales of c €14.2m for the full year across the available territories in Europe. Zambon launched Xadago in 2015, but the drug was only commercialised in Germany for seven months. During the course of 2016 Xadago was rolled out to 10 additional countries in Europe; we anticipate a further uplift in the sales trajectory in 2017 given a full 12 months of product availability for the year. Importantly Xadago royalties are ramping up despite the Italian Medicines Agency's (AIFA's) imposed ceiling on 2016 and 2017 sales. Exhibit 1 highlights the increase in royalties reported by Newron and the impact of the AIFA cap in Q216 (in grey). A critical catalyst remains the US Xadago approval which is imminent (revised PDUFA date is 21 March); this will materially impact the share price performance. Zambon has sub licensed its US commercialisation rights to US WorldMeds and we anticipate US launch in H217. We forecast that the US FDA approval in late March will trigger a €9m milestone payment to Newron in 2017. FY17 sales will benefit from the ongoing European market roll-out by Zambon (including France by the end of 2017), plus an undisclosed territory ex Europe and the US launch by US WorldMeds.

Exhibit 1: Xadago royalty ramp up



Source: Edison Investment research, Newron presentations

Xadago's global development plan will benefit sales in the longer term, Japan partner Meiji has initiated the long term Phase III studies (we expect launch in 2020) and newly announced partner Seqirus is to submit an NDA to the Australia/New Zealand authorities. In January 2017, Seqirus and Zambon entered into a partnership for Xadago in Australia and New Zealand; Seqirus will be responsible for the registration and commercialisation of the drug and Zambon will supply the product. We expect Newron to receive a share of royalties and milestones on approval and commercial sales milestones.

We forecast global peak sales of €450m for Xadago in Parkinson's disease, which comprises ex-US peak sales of €200m based on use only in mid- to late-stage PD patients, a group which represents 75-80% of the PD market. In the US, our peak sales are €250m where we continue to include both early and mid- to late-stage patients. Our royalty rate forecasts are around 12-13%. We also risk-adjusted the contribution for safinamide in dyskinesia associated with PD, assuming peak sales of €390m; further studies evaluating safinamide's impact on dyskinesia will depend on what partner Zambon and sub-licenser US WorldMeds intend for its development. See our outlook note dated 21 July 2016 Back on Track for more details on our Xadago assumptions for PD and potential dyskinesia label expansion.

R&D catalysts to mid-2018

Evenamide detailed POC data, 24-28 March at ICSR

Evenamide (NW-3509) is an internally-developed asset that originates from Newron's ion channel discovery platform. It is a novel, new generation, oral, antipsychotic drug in development for schizophrenia that acts through pathways (sodium channel modulator, which regulates the hyperexcitability of neurons) that are not targeted by available antipsychotic drugs. Newron has reported encouraging preliminary Phase IIa proof of concept (POC) evenamide data (good tolerability, safety and preliminary evidence of efficacy) as an add-on to antipsychotics in the treatment of schizophrenia. This Phase II study addressed the drug's ability in reducing positive symptoms and psychotic worsening in patients with schizophrenia experiencing breakthrough symptoms while on adequate doses of risperidone or aripiprazole. This is a double-blind, placebo controlled, four-week in/outpatient study evaluating 15-25mg of evenamide (twice daily) in a minimum of 90 patients across study centres based in the US and India. Detailed results of this novel mechanism of action drug will be presented at the 16th International congress on Schizophrenia research on March 24th to 28th 2017.

We forecast conservative evenamide peak sales of €380m and Newron estimates that the antipsychotic market is worth around $23bn (source: FiercePharma 2011), suggesting that evenamide could have significant potential. However, until full proof-of-concept data are available, estimating the potential market opportunity for evenamide is not straightforward given its potential would be dependent on the breadth of clinical trials conducted. Although we have limited visibility on the timing and terms of any potential out-licensing, we continue to assume standard terms including a double-digit royalty on sales, commensurate with an asset out-licensed with proof-of-concept data.

Evenamide will eventually be a partnering candidate, given the potential size of the indication and scope of development and its differentiating mode of action. Newron is planning an adequately designed, well-controlled, and placebo-controlled, well-powered (potentially pivotal) study to provide compelling evidence of the efficacy and safety of Evenamide. The study could be performed on the company or with/by a partner. The announcement of a partnering deal would represent upside to our numbers.

Sarizotan the first orphan drug for RS

Sarizotan is a highly selective serotonin (5-HT1a) and dopamine (D2) antagonist that in preclinical studies demonstrated activity in normalising the abnormal breathing patterns in animal models of Rett syndrome, a rare, genetic neurodevelopmental disorder that generally affects girls. This severe brain disorder arises from a non-inherited genetic mutation (X-linked methyl CpG-binding protein 2). The mutation causes severe disability and a reduction in life expectancy. There is no curative treatment for RS and current treatment is therefore more symptomatic. Sarizotan is not being developed to address the underlying cause of RS but as a potential treatment for these life-threatening breathing disorders

In July 2015 the FDA designated orphan drug status to sarizotan for the treatment of RS; Newron received sarizotan's IND approval by FDA in May 2016. STARS (Sarizostan Treatment of Apneas in Rett syndrome), a potentially pivotal clinical study to evaluate breathing disorders associated with RS has now begun; the first US study centre initiated is the Rush Medical Center, Chicago. STARS is a global study that will recruit around 129 RS patients (three groups of 43) aged 13 and over; the primary endpoint of the study is the reduction in the number of clinically significant apnoea (>10seconds) episodes at 24 weeks. Newron has sought advice from both regulators and key

opinion leaders in the design of this study. Data from STARS is expected mid-2018. Newron is planning to apply for a global filing and approval strategy once the STARS data are through.

A c 750 patient, c 210 caregiver burden of disease study is ongoing which the company believes will aid in the pricing reimbursement discussions once the approval process has been initiated.

Our forecasts assume first approval in the US during H218, with launch shortly thereafter, with sarizotan potentially eligible for accelerated review given the unmet medical need. Given the small size of the indication (20,000–30,000 patients), Newron will commercialise sarizotan alone in key markets, including the US and major European countries. Our €260m peak sales forecast is based on pricing of €60,000 a year, reflecting the ultra-orphan indication and assumes a 40% penetration of the targeted patients (which we assume is a quarter of the overall market). Pricing and penetration will ultimately depend on sarizotan's magnitude of benefit; if it can command pricing of €80,000 a year with 70% penetration of our assumed target market (one quarter of RS patients), this would suggest peak sales of around €600m.

Valuation

Following the FY16 results we have pushed out our assumption for a safinamide launch in Japan to 2020 from 2019. We have not made any other changes to our underlying product assumptions, which include €450m of Xadago peak sales in Parkinson's disease, in addition to risk-adjusted contributions for Xadago in dyskinesia and the pipeline of orphan opportunities: sarizotan in Rett syndrome and evenamide in schizophrenia, which Newron is planning to partner. We have, however, increased our R&D expense forecasts in 2017 and 2018 to reflect phasing of R&D costs for sarizotan and evenamide (NW-3509). Our valuation has been rolled forward in time and updated for net cash (which comprises last reported gross cash of €46.5m, and last reported total debt of €0.3m, equating to €46.2m. Our revised valuation is CHF530m (previously CHF504m), or CHF33.6 per share.

Exhibit 2: Newron sum-of-the-parts valuation

Product	Indication	Launch	Peak sales (€m)	Value (€m)	Value (CHFm)	Probability (%)	rNPV (€m)	rNPV (CHFm)	NPV/share (CHF/share)
Xadago	Parkinson's disease	2015	450	259.6	347.3	90-100	247.4	330.9	20.9
	Dyskinesia	2020	390	82.8	110.8	40	33.1	44.3	2.8
Sarizotan	Rett syndrome	2018	260	229.1	306.5	30	64.3	86.0	5.4
NW-3509	Schizophrenia	2019	380	80.1	107.2	20	13.8	18.5	1.2
Net cash/(debt) at December 2016				46.2	50.6	100	46.1	50.6	3.2
Valuation				1,025.2	922.4		404.7	530.3	33.6

Source: Edison Investment Research

Exhibit 3: Key news flow in the next 18 months

News	Period	Comments
Xadago EU next launches	2017	Pricing and uptake rates
Xadago/safinamide US approval	21 March 2017	PDUFA date is 21 March 2017; potential launch in H217 by US WorldMeds
Evenamide Phase II data (detailed)	24–28 March 2017	Will provide first proof of concept data
Evenamide partnering	2017	Alternatively a partnering deal could come after the availability of Phase II data
Sarizotan PII/III potential pivotal data	Mid 2018	
Sarizotan approval and launch	H218	

Source: Edison Investment Research, Newron

Financials

At the FY16 results, Newron reported the receipt of Xadago-related royalties (from partner Zambon on sales in 11 European countries) of €1.7m to end December 2016. Based on our assumed 12% royalty rate (we assume a tiered royalty starting at 12% with a step-up to 18%), this suggests sales of c €14m in the year; we highlight a staggered launch in Europe such that the product has not been available across all territories for the full year. Newron reported total revenues of €6.7m in 2016, which aside from the Xadago royalties received includes a €3.0m milestone payment from Zambon related to the granting of pricing approval in certain European countries and identification of the US partner.

Our FY17 revenue forecast of €15.3m is based on royalty income related to Xadago sales in Europe and the US of € 6.3m plus €9m milestone-related income (if Xadago is approved in the US, we believe Newron will be eligible to receive a milestone payment from Zambon).

Reported R&D expenses (gross) in FY16 were €19.2m, compared to €18.4m FY15 which was affected by a one-off €6.725m impairment charge relating to termination of the sNN0029 and sNN0031 development programmes in 2015. We allocate the impairment charge (and similar €2.125m R&D impairment charge in FY14) to exceptional items. As such, our R&D expenses in the P&L reflect net expenses, which in FY16 were €12.4m (compared to €11.7m in FY15). Our net R&D forecasts for FY17 have increased to €13.3m, from €12m, mainly related to the completed Phase IIa Evenamide (NW-3509) study and additional work in schizophrenia and the ongoing pivotal sarizotan PII/III trial, which could conclude in Q218. Any delays to the pipeline development in 2016 could result in a phasing of R&D costs from 2017 to 2018. In addition, if the regulatory bodies request further clinical trials for sarizotan or if Newron decide to progress NW-3509 alone (beyond the ongoing phase II), then our 2017 R&D forecasts will need to be materially upgraded.

G&A expenses in FY16 were €9.1m (FY15 €8.3m), the rise accounted for by an increase in staff costs, costs relating to the issuance of new shares, plus other expenses relating to charitable donations to Rett's syndrome organisations.

Newron reported cash and equivalents of €46.5m at end December 2016 (following one private placement of new shares in FY16 and the exercise of one 2015 option raising net proceeds of €26.8m) and has modest debt of €0.3m. We continue to expect that current cash resources should be sufficient to fund operations for the foreseeable future.

Exhibit 2: Financial summary

€000s	2014	2015	2016	2017e	2018e	2019e
Year end December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	1,557	2,380	6,726	15,293	15,560	25,107
Cost of Sales	0	0	0	0	0	0
Gross Profit	1,557	2,380	6,726	15,293	15,560	25,107
Research and development (net)	(3,892)	(11,724)	(12,398)	(13,300)	(9,960)	(10,152)
EBITDA	(9,057)	(17,604)	(15,290)	(7,611)	(4,484)	4,369
Operating Profit (before amort. and except.)	(9,077)	(17,668)	(15,318)	(7,633)	(4,506)	4,345
Intangible Amortisation	(13)	(7)	(7)	(24)	(24)	(24)
Exceptionals	(2,125)	(6,725)	0	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(11,215)	(24,400)	(15,325)	(7,657)	(4,530)	4,322
Net Interest	492	(583)	121	401	648	1,305
Profit Before Tax (norm)	(8,585)	(18,251)	(15,197)	(7,232)	(3,858)	5,650
Profit Before Tax (reported)	(10,723)	(24,983)	(15,204)	(7,256)	(3,882)	5,626
Tax	628	2,167	(33)	0	0	0
Profit After Tax (norm)	(7,957)	(16,084)	(15,230)	(7,232)	(3,858)	5,650
Profit After Tax (reported)	(10,095)	(22,816)	(15,237)	(7,256)	(3,882)	5,626
Average Number of Shares Outstanding (m)	12.7	13.7	14.7	15.8	15.8	15.8
EPS - normalised (€)	(0.63)	(1.17)	(1.04)	(0.46)	(0.24)	0.36
EPS - (reported) (€)	(0.80)	(1.66)	(1.04)	(0.46)	(0.25)	0.36
Dividend per share	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
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A	17.4
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A	17.3
BALANCE SHEET						
Fixed Assets	7,686	406	451	478	504	529
Intangible Assets	6,993	265	261	240	219	198
Tangible Assets	67	79	120	168	215	261
Investments	626	62	70	70	70	70
Current Assets	29,388	43,974	56,140	49,916	48,302	57,646
Stocks	102	38	5	98	98	98
Debtors	3,320	3,005	9,667	3,883	3,883	3,883
Cash	25,702	40,931	46,468	45,935	44,321	53,665
Other	264	0	0	0	0	0
Current Liabilities	(4,489)	(6,513)	(6,645)	(5,426)	(5,434)	(6,891)
Creditors	(4,131)	(6,151)	(6,281)	(5,413)	(5,434)	(6,891)
Short term borrowings	(358)	(362)	(364)	(13)	0	0
Long Term Liabilities	(3,324)	(755)	(199)	(199)	(199)	(199)
Long term borrowings	(729)	(364)	0	0	0	0
Other long term liabilities	(2,595)	(391)	(199)	(199)	(199)	(199)
Net Assets	29,261	37,112	49,747	44,770	43,173	51,084
CASH FLOW						
Operating Cash Flow	(9,370)	(10,695)	(19,616)	(495)	(2,178)	8,111
Net Interest	107	121	102	401	648	1,305
Tax	(628)	(2,167)	33	(8)	0	0
Capex	(22)	(60)	(69)	(69)	(69)	(69)
Acquisitions/disposals	0	0	0	0	0	0
Financing	17,547	28,392	25,448	0	0	0
Other	0	(4)	(3)	(3)	(3)	(3)
Dividends	0	0	0	0	0	0
Net Cash Flow	7,634	15,587	5,895	(175)	(1,601)	9,344
Opening net debt/(cash)	(16,981)	(24,615)	(40,205)	(46,104)	(45,922)	(44,321)
HP finance leases initiated	0	0	0	0	0	0
Other	0	3	4	(7)	0	0
Closing net debt/(cash)	(24,615)	(40,205)	(46,104)	(45,922)	(44,321)	(53,665)

Source: Edison Investment Research, Newron

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