EDISON

Newron Pharmaceuticals

FY15 results

Xadago European roll-out continues

Pharma & biotech

At its FY15 results Newron reported €0.5m (vs our €0.8m estimate) in royalties from commercial partner, Zambon after seven months of Xadago (Parkinson's disease therapy) sales in Germany. So far in 2016 Zambon has also launched Xadago in Italy, Switzerland and Spain. The Xadago US PDUFA date is 29 March 2016, and a Xadago sublicensing deal in the US and a potential partnership for NW-3509 are on the cards. We have lowered our valuation slightly to CHF504m (vs CHF522m) primarily to reflect an increase in R&D expenses to support the mid-stage pipeline.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14**	1.6	(8.6)	(0.63)	0.0	N/A	N/A
12/15	2.4	(18.3)	(1.17)	0.0	N/A	N/A
12/16e	4.0	(21.4)	(1.51)	0.0	N/A	N/A
12/17e	12.2	(5.5)	(0.39)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation, exceptional items. ** FY14 PBT is restated.

Xadago roll-out continues

So far in 2016 Zambon has launched Xadago in three new territories (Italy, Switzerland and Spain). Newron received €0.5m in royalties on product sales for the seven months following the May 2015 launch in Germany; given we assume a 12% royalty rate, this implies net sales of c €4m in Germany. We expect FY16 sales to benefit from the ongoing EU roll-out and a launch in the US by end 2016.

Xadago price premium suggests upside potential

Following the FY15 results we maintain our forecasts for Xadago, with peak sales of €450m assuming that Xadago is priced in line with Azilect. If Xadago can achieve the premium pricing to Azilect it has demonstrated so far in Germany, then all else being equal our peak sales would increase to c €660m, resulting in an increment of CHF160m to our valuation (or CHF12/share). However, until further pricing in Europe is agreed, and US partnership/pricing is resolved, we make no changes to our forecasts at this stage. Xadago has a US PDUFA date of 29 March 2016 and Zambon continues to focus on securing a sub-licensee for the US market.

Pipeline opportunities to yield data late 2016

A Phase II proof-of-concept study with NW-3509 as an add-on to antipsychotics in schizophrenia has started, with data expected in Q416. A pivotal Phase II/III study with sarizotan in Rett syndrome (RS) is planned to start in Q216, designed to determine efficacy in RS-related fatal-breathing disorders.

Valuation: rNPV of CHF504m or CHF35.5/share

Our updated Newron valuation is CHF504m (from CHF522m), reflecting an increase in R&D, a push back of a potential safinamide US label extension PD related dyskinesia) and adjusted for 2015 year-end net cash of CHF44.1m (vs CHF52m previously). Our valuation includes risk-adjusted contributions for Xadago in dyskinesia, sarizotan in Rett syndrome and NW-3509.

15 March 2016

Price	**CHF19.20**
Market cap	**CHF273m**
	€0.91/CHF
Net cash (€m) at 31 December 2015	40.2
Shares in issue	14.2m
Free float	77%
Code	NWRN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(10.7)	(26.0)	(41.8)
Rel (local)	(14.7)	(22.7)	(33.6)
52-week high/low	CHF33.0		17.9

Business description

Newron Pharmaceuticals is an Italian CNS-focused biotechnology company. Xadago (safinamide) for Parkinson's disease has been launched in Europe; the US PDUFA date is 29 March 2016. Xadago is partnered with Zambon (EU+US) and Meiji Seika (Japan); a US sub-licensee is sought.

Next events

US safinamide FDA approval decision (PDUFA)	29 March 2016
NW-3509 Phase II data	Q416
Partnering agreements for safinamide (US) and/or NW-3509	2016/17

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Xadago on the go

So far in 2016, commercial partner, Zambon has launched Xadago (safinamide) as an add-on therapy to Levodopa in mid-to-late Parkinson's disease, in three additional territories (Italy, Switzerland and Spain). In the seven months following its launch in Germany in May 2015, Newron received €0.5m in royalties on product sales; given that we assume a 12% royalty rate this implies net sales of c €4m in Germany. The royalties were slightly lower than our €0.8m forecast; however, it remains early days and thus our Xadago forecasts remain unchanged. Xadago pricing in Germany is at a 40-60% premium to its closest comparable, Teva Pharmaceutical's Azilect . This suggests to us that health authorities in Germany recognise that Xadago can offer advantages over Azilect (including long-term benefits), which should also aid with physician and patient uptake. We expect the roll-out of Xadago to continue in additional EU countries, as pricing and reimbursement are agreed in the coming months/quarters.

Our current forecasts and valuation assume that Xadago is priced broadly in line with Azilect outside Germany, leading to peak sales of c €450m based on a 10% penetration of the PD patient market. If Xadago can achieve premium pricing to Azilect across Europe and the US, as it has in Germany so far, then all else being equal our peak sales forecast would be closer to €660m. This would contribute a further CHF160m to our valuation, or CHF12/share. Until further pricing is agreed, particularly in the US, we make no changes to our forecasts at this stage.

Xadago remains under review in the US with a PDUFA decision date of 29 March 2016; Zambon continues to focus on sublicensing Xadago in this region with a deal potentially this year, on which Newron is entitled to a share of upfront and milestone payments, in addition to royalties. Zambon does not have a significant presence in the US, hence sublicensing Xadago will be key to maximising its potential. Furthermore, as highlighted in a previous publication (26 March 2015 Progression, partnering and prioritisation) we believe further studies investigating Xadago in dyskinesia associated with PD could form part of any potential sub-licensing deal(s). A label expansion detailing an improvement in dyskinesia with Xadago use could allow for potentially earlier use of L-dopa in PD and expand the market opportunity for safinamide. We include a risk-adjusted contribution for safinamide in dyskinesia, assuming peak sales of €350m until there is more clarity on the potential magnitude of benefit. It is estimated that dyskinesia affects around 40% of PD patients treated with L-dopa for four to six years, with limited treatment options aside from the L-dopa dosing adjustment. With around one million PD patients in each of the US and Europe, this therefore represents a large opportunity. We assume the safinamide label could be expanded to include dyskinesia following a single clinical trial, which could potentially start once approval has been granted in the US. We have updated our valuation for a potential label expansion to 2020 (vs 2018), however, we highlight the fate of this extension will lie in the hands of the sub-licensee.

Planning to advance the pipeline in 2016

Newron has now started the Phase II proof-of-concept trial with NW-3509 as an add-on to antipsychotics in schizophrenia; NW-3509 is a probable partnering candidate, given the potential size of the indication. Phase II data could become available in Q416 and we would expect Newron to seek a deal after the publication of this. Sarizotan has been awarded orphan drug status in both the US and Europe for Rett syndrome (RS), and thus a fast-track clinical development and regulatory process is possible. A 24-week, double-blind, placebo-controlled efficacy study (Phase II/III) to investigate breathing disorders is being planned to start in Q216, with results likely in Q317. If successful, the company believes a potential launch mid 2018 is possible given sarizotan's orphan drug status.

Valuation

Following the FY15 results we have pushed out our assumption for a safinamide US dyskinesia label expansion to 2020 from 2018. 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 NW-3509 in schizophrenia, which Newron is planning to partner. We have, however, increased our R&D expense forecasts to reflect investment in sarizotan and NW-3509.

Our valuation has been rolled forward in time and updated for net cash (which comprises last reported gross cash of €40.2m, and last reported total debt of €0.7m relating to a loan from the Italian government, equating to €40.2m, or CHF44.1m at current FX rates of €0.91/CHF). Our revised valuation is CHF504m (previously CHF522m), or CHF35.5 per share.

Exhibit 1: Financial summary

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	264.6	354.0	90-100%	252.0	337.1	23.7
	Dyskinesia	2020	390	72.9	97.5	40%	29.2	39.0	2.7
Sarizotan	Rett syndrome	2018	260	202.6	271.0	30%	53.8	72.0	5.1
NW-3509	Schizophrenia	2019	380	66.8	89.3	20%	8.9	11.9	0.8
Net Cash/(Debt)				40.2	44.1	100%	40.2	44.1	3.1
Valuation				928.9	856.0		384.0	504.1	35.5

Source: Edison Investment Research

Exhibit 2: Key newsflow in the next 12-18 months

News	Period	Comments
Xadago EU next launches	2016	Pricing and uptake rates.
Xadago/safinamide US approval	29 March 2016	PDUFA date is 29 March 16; potential launch in H216, subject to securing US partner.
Xadago/safinamide sublicensing in the US	2016	Zambon is working to sub-license safinamide in ex. EU regions, including the US.
NW-3509 partnering	2017	A partnering deal could come after the availability of Phase II data.
Sarizotan PII/III start	Q216	24-week pivotal efficacy study.
NW-3509 Phase II data	Q416	Will provide first proof of concept data.
Sarizotan PII/III potential pivotal data	2017	

Source: Edison Investment Research

Financials

At FY15 results, Newron reported receipt of Xadago-related royalties (on sales in Germany alone) of €0.5m to end December 2015 (compared to our last published FY15 forecast of €0.8m), following the drug's launch by partner Zambon in mid-May. Based on our assumed 12% royalty rate (we assume a tiered royalty starting at 12% with a step-up to 18%), this suggests initial sales of c €4m in the seven months between May and December. Newron also reported milestone income of €1.8m for the European approval.

Our FY16 revenue forecast of €4.0m is based purely on royalty income related to Xadago sales in Europe and does not include any potential milestone related income. If Xadago is approved in the US, we believe Newron will be eligible to receive a milestone payment from Zambon (we estimate around €9m). Furthermore, if Zambon successfully sub-licenses Xadago in the US, which could be facilitated once US approval is granted, Newron is entitled to receive a portion of any upfront or milestone payments; we estimate the payment to be around 25% of the income that Zambon negotiates (and around 50% of any royalties that Zambon receives).

Reported R&D expenses in FY15 were €18.5m, 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 FY15 were €11.7m. This was higher than our prior €10m net R&D estimate, mainly due to accelerated development of NW-3509 and sarizotan. Our net R&D forecasts for FY16 have increased to €18m, from €12m, mainly related to the ongoing Phase II NW3509 study in schizophrenia and to the start of the pivotal sarizotan PII/III trial, which could conclude in Q317. Our forecast €10m in R&D expenses for 2017 reflects the ongoing spend associated with this trial (we introduce FY17 estimates in Exhibit 3).Any delays to the pipeline development in 2016 could result in a phasing of R&D costs from 2016 to 2017. 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.

Newron reported gross FY15 R&D spend of €23.3m (vs €14.5m in FY14), which aside from the €6.725m impairment charge also included a €3.2m reimbursement from Zambon and €1.6m in grant project reimbursement.

G&A expenses in FY15 were €8.3m, also higher than our prior forecast of €7.1m, although our projected operating expenses of €19.8m for FY16 remains unchanged.

Newron reported cash and equivalents of €40.9m at end December 2015 (following two private placements of new shares in FY15 raising net proceeds of €28.4m) and has modest debt of €0.7m relating to an Italian government grant. We continue to expect that current cash resources should be sufficient to fund operations for the foreseeable future.

Exhibit 3: Financial summary

€000s	2013	2014	2015	2016e	2017e
Year end December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	3,539	1,557	2,380	3,964	12,229
Cost of Sales	0	0	0	0	0
Gross Profit	3,539	1,557	2,380	3,964	12,229
Research and development (net)	(4,537)	(3,892)	(11,724)	(18,000)	(10,000)
EBITDA	(7,737)	(9,057)	(17,604)	(21,791)	(5,913)
Operating Profit (before amort. and except.)	(7,766)	(9,077)	(17,668)	(21,812)	(5,934)
Intangible Amortisation	(10)	(13)	(7)	(24)	(24)
Exceptionals	0	(2,125)	(6,725)	0	0
Other	0	0	0	0	0
Operating Profit	(7,776)	(11,215)	(24,400)	(21,836)	(5,958)
Net Interest	63	492	(583)	386	401
Profit Before Tax (norm)	(7,703)	(8,585)	(18,251)	(21,425)	(5,534)
Profit Before Tax (reported)	(7,713)	(10,723)	(24,983)	(21,449)	(5,557)
Tax	615	628	2,167	0	0
Profit After Tax (norm)	(7,088)	(7,957)	(16,084)	(21,425)	(5,534)
Profit After Tax (reported)	(7,098)	(10,095)	(22,816)	(21,449)	(5,557)
Average Number of Shares Outstanding (m)	11.5	12.7	13.7	14.2	14.2
EPS - normalised (€)	(0.62)	(0.63)	(1.17)	(1.51)	(0.39)
EPS - (reported) (€)	(0.62)	(0.80)	(1.66)	(1.51)	(0.39)
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	9,821	7,686	406	425	444
Intangible Assets	9,125	6,993	265	245	225
Tangible Assets	79	67	79	118	156
Investments	617	626	62	62	62
Current Assets	21,797	29,388	43,974	24,770	19,819
Stocks	301	102	38	98	98
Debtors	2,088	3,320	3,005	3,883	3,883
Cash	18,426	25,702	40,931	20,789	15,838
Other	982	264	0	0	0
Current Liabilities	(6,070)	(4,489)	(6,513)	(4,846)	(3,233)
Creditors	(5,712)	(4,131)	(6,151)	(4,488)	(3,220)
Short term borrowings	(358)	(358)	(362)	(358)	(13)
Long Term Liabilities	(4,458)	(3,324)	(755)	(404)	(391)
Long term borrowings	(1,087)	(729)	(364)	(13)	0
Other long term liabilities	(3,371)	(2,595)	(391)	(391)	(391)
Net Assets	21,090	29,261	37,112	19,945	16,639
CASH FLOW					
Operating Cash Flow	(10,071)	(9,370)	(12,490)	(20,597)	(4,930)
Net Interest	1	107	48	336	401
Tax	(615)	(628)	(299)	542	0
Capex	(56)	(22)	(60)	(60)	(60)
Acquisitions/disposals	301	0	0	0	0
Financing	0	17,547	28,392	0	0
Other	(20)	0	(4)	(4)	(4)
Dividends	0	0	0	0	0
Net Cash Flow	(10,460)	7,634	15,587	(19,784)	(4,593)
Opening net debt/(cash)	(27,441)	(16,981)	(24,615)	(40,205)	(20,418)
HP finance leases initiated	0	0	0	0	0
Other	0	0	3	(3)	0
Closing net debt/(cash)	(16,981)	(24,615)	(40,205)	(20,418)	(15,825)

Source: Edison Investment Research, Newron Pharmaceuticals accounts.

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