EDISON

Newron Pharmaceuticals

Progression, partnering and prioritisation

FY14 results and corporate outlook

Pharma & biotech

With Xadago (safinamide) now formally approved in Europe this should trigger first royalty income from commercial partner Zambon upon launch, which is initially targeted in Germany. Safinamide in the US is now back on track with an approval decision expected by YE15. A safinamide sub-licensing deal in the US, in addition to partnering NW-3509 are both on the cards. Our valuation is increased to CHF496m (€466m) with a higher safinamide royalty in addition to a risk-adjusted contribution in dyskinesia.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/13	3.5	(7.7)	(0.62)	0.0	N/A	N/A
12/14	1.6	(10.7)	(0.80)	0.0	N/A	N/A
12/15e	7.1	(11.3)	(0.86)	0.0	N/A	N/A
12/16e	5.8	(11.7)	(0.89)	0.0	N/A	N/A

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

Ready to go with Xadago

Commercial partner Zambon is preparing to launch Xadago (safinamide) in Europe, targeting initial sales in Germany, following the recent final European approval. This should trigger a milestone payment in addition to first recurring royalties to Newron. In the US, the safinamide filing has been accepted with a PDUFA decision date of 29 December 2015. Zambon continues to focus on sub-licensing safinamide with a deal potentially this year, on which Newron is entitled to a share of any upfront and milestone payments, in additions to royalties.

Preparing to partner NW-3509 for schizophrenia

Newron is planning to start a Phase II proof-of-concept trial with NW-3509 in coming months as an add-on to antipsychotics for patients with breakthrough symptoms. This could be a large opportunity beyond Newron's scope and therefore a partnership is being sought. Phase II data are expected H116 but a deal could be agreed sooner if suitable terms are offered.

Orphan opportunities: prioritising sarizotan

Newron has prioritised sarizotan given the potentially rapid clinical development path in addition to the size of Rett syndrome (RS) market (c 36,000 patients US/EU). A small pilot study to study to investigate sarizotan's effect on breathing disorders in RS patients is planned to start this year with data expected in early 2016. Newron believes only a small pivotal trial in 60 patients could be needed to secure regulatory approvals.

Valuation: Increased rNPV of CHF496m

Our rNPV has increased with higher safinamide royalty rate assumptions in addition to a contribution for safinamide for dyskinesia. We have also increased the probability for NW-3509 as this has now completed a Phase I safety study. Our updated valuation is CHF496m (from CHF401m) or CHF37.9/share.

26 March 2015

Price	**CHF31.3**
Market cap	**CHF410m**
	€0.94/CHF
Net cash (€m) at end December 2014	24.6
Shares in issue	13.1m
Free float	75%
Code	NWRN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(1.6)	21.0	94.9
Rel (local)	(3.9)	18.8	76.0
52-week high/low	CHF35	CHF13	

Business description

Newron Pharmaceuticals is an Italian CNS focused biotechnology company. Safinamide/Xadago for Parkinson's disease has been approved in mid-late PD in Europe; the US regulatory PDUFA decision date is 29 December 2015. Safinamide is partnered with Zambon and Meiji Seika.

Next events

EU safinamide launch (by Zambon)	H115
US safinamide regulatory decision	Q415
Safinamide sub-licensing	2015
NW-3509 out-licensing	2015/2016

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Edison profile page

Investment summary

Company description: CNS focus with an approved PD drug

Newron is an Italian company focused on CNS (central nervous system) disorders. Lead product Xadago/safinamide recently gained approval in Europe for the treatment of Parkinson's disease (PD) and is under regulatory review in the US. Safinamide is partnered with Meiji Seika in Japan/Asia and with Zambon in the rest of the world. Partner Zambon is seeking to sub-license safinamide in the US. Newron also has a pipeline of earlier stage orphan drug candidates and is prioritising development of sarizotan for the genetic disorder Rett syndrome (RS), which could represent the first product for Newron to commercialise alone.

Newron floated on the SIX at the end of 2006, raising CHF118m (€74.3m) at CHF55/share. In 2008 it acquired UK-based Hunter-Fleming and at the end of 2012 acquired NeuroNova. During 2014 Newron raised CHF22.2m gross proceeds (CHF3.6m at CHF17/share in January and CHF18.6m at CHF15.75/share in April). Newron is headquartered in Bresso, Italy, and employs around 25, including in its operations in Stockholm/Sweden, Morristown/NJ/USA and Basel/Switzerland.

Exhibit 1: Newron pipeline

Product	Indication		Stage	Comments
Safinamide	Parkinson's disease	Partnering	Approved (EU); Filed (US)	Formally approved in Europe; US PDUFA date 29 December 2015
sNN0031	Treatment resistant Parkinson's disease	Orphan	Phase II	Phase II started January 2015; data in 2016
sNN0029	ALS	Orphan	Phase II	Phase II at higher dose started January 2015; data 2016
Sarizotan	Rett syndrome	Orphan	Phase II	Start of pilot Phase II trial around mid-2015
NW-3509	Schizophrenia	Partnering	Phase I complete	Phase II planning to start Q215; Newron seeking to partner
Ralfinamide	Neuropathic pain	Non-core	Phase II	Partnering candidate

Source: Edison Investment Research

Valuation: Risk-adjusted NPV of CHF496m or CHF37.9/share

Our Newron valuation has increased with revised, higher safinamide royalty rate assumptions in both Europe and the US following management comments on the FY14 conference call, in addition to a risk-adjusted contribution for the treatment of dyskinesia. We have made only minor changes to our underlying assumptions for the earlier stage pipeline, although we have increased the probability for NW-3509 as this has now completed a Phase I safety study and a Phase II is planned. Our updated valuation is therefore CHF496m (from CHF401m) or CHF37.9/share.

Sensitivities: Safinamide EU launch and US approval

The main near-term sensitivities for Newron relate to safinamide, with launch in Europe by commercial partner Zambon following the recent approval, and the ongoing US regulatory process. In the US, safinamide has now been successfully re-filed with a PDUFA decision date of 29 December 15. Zambon, together with Newron, continues to work towards sub-licensing safinamide in certain regions, particularly in the US. A lack of US partner prior to FDA approval could delay launch beyond our current forecasts, although the European approval could help to secure a deal.

Financials: Cash to mid-2016 excluding any milestones

Newron reported end December net cash of €24.6m, which we estimate should be sufficient to fund operations to around mid-2016, excluding the €6m milestone payment due from partner Zambon for the recent European approval and upcoming first pricing of safinamide. Shareholders recently voted and authorised at the recent AGM a 1.3m (10%) share capital increase which, if executed, could raise around CHF40m based on the current market capitalisation. This would provide Newron with the financial flexibility to move forward swiftly with clinical development of the earlier-stage pipeline without being dependent on milestone or royalty income.

Outlook: Ready to go with Xadago

Xadago (safinamide) has now been formally approved in Europe which should trigger both a milestone payment from commercial partner Zambon, in addition to first royalties on sales, which are initially targeted in Germany. The US filing is now back on track, with recent acceptance of the NDA (new drug application) following the previous Refusal to File (RTF); the PDUFA decision date is 29 December 2015. The focus now is on securing pricing and reimbursement across Europe, in addition to sub-licensing safinamide in the US, which could be imminent now that approval has been granted in Europe and there are no further US filing headwinds. We now include a risk-adjusted contribution for safinamide in dyskinesia, for which development could form part of any sub-licensing deal.

Xadago formally approved in Europe; Zambon prepping launch

Following the CHMP (Committee for Medicinal Products for Human Use) positive recommendation in December 14, the EMA (European Medicines Agency) formally approved Xadago in February 15 as an add-on treatment to Levodopa (L-dopa) in mid-late stage PD patients. The EMA approval includes all 28 EU member countries in addition to Iceland, Lichtenstein and Norway. A separate filing has been made in Switzerland with a decision expected in coming months.

Commercial partner Zambon is now preparing for launch and is targeting Germany for initial sales. In Europe, pricing and reimbursement needs to be secured on a country-by-country basis and so the initial sales ramp is generally shallower than in the US owing to the more fragmented nature of the European market. Zambon already has a commercial presence in Europe, which it has recently strengthened as part of the Xadago approval and hence we do not expect significant sub-licensing activity in Europe in the near-term, particularly in the major countries.

Under the terms of the deal with Zambon, Newron is due a milestone related to European approval which we estimate at around €6m, which we include in our valuation and financial forecasts. We have increased our royalty rate forecast that Newron could earn on direct sales by Zambon following the FY14 results call, now estimating an average mid double-digit royalty (versus our previous average royalty of around 11%). A summary of the terms we estimate for the Newron/Zambon deal are summarised in Exhibit 2.

European label includes a number of secondary efficacy endpoints

Clinical data contained in the European Xadago label includes the primary endpoint of the pivotal studies in mid-late stage PD (the SETTLE and 016/018 trials), which was the change in ON time without troublesome dyskinesia (ON time is a measure of controlled symptoms). The label also highlights that the improvement in ON time was maintained at 24 months. In addition, certain secondary endpoints are highlighted on the label, including the improvement in OFF time (OFF time is when mobility is impaired), improved motor symptoms, and responder data. Newron believes that all of these could help to potentially secure premium pricing for Xadago which could provide upside to our forecasts.

US decision expected by end 2015

The FDA recently accepted the re-filed safinamide application in the US assigning a PDUFA decision date of 29 December 2015. This follows the previous Refusal to File (RTF) owing to administrative oversights (including issues such as hyperlinking of tables and conformity of the package insert to FDA guidelines). If approved, safinamide could therefore be launched in the US, assuming a sub-licensing partner is in place, in early 2016. The filing includes safinamide in early PD as an add-on to dopamine agonists, in addition to mid-late stage PD as an add-on to L-Dopa.

US sub-licence could be signed this year

Commercial partner Zambon is seeking to sub-license safinamide in the US. Although the timing and terms of any deal is difficult to predict, Zambon recently stated in a press release that they were in "…late stage negotiations with interested potential partners for Xadago in the US". Hence, a deal could be imminent, with discussions potentially aided by both the European approval and the FDA filing acceptance, in our view.

Although the precise deal terms with Zambon have not been disclosed, we believe that Newron could be entitled to around 25% of any milestone or upfront income that Zambon secures in addition to around 50% of any royalty income. Royalty rates typically associated with a filed asset are around 25-30%, which would therefore suggest that Newron could be entitled to a mid double-digit royalty on US sales (versus our previous average royalty forecast of around 11%).

Exhibit 2: Assumed deal terms with Zambon

	Zambon – direct sales	Zambon – sub-licensed
Milestones	Approval milestone in Europe (estimate €6m)	25% of any upfront/milestones
Royalty rate	Tiered; starting at low double-digit with second tranche at 1.5x first tranche; estimate an overall average of 12-13%	50% of royalty income; we assume Zambon can secure a 25-30% royalty

Source: Edison Investment Research

Xadago sales could peak at €450m in PD

We continue to forecast peak Xadago sales of €450m in PD, which comprises ex-US peak sales of €200m based on use only in the mid-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 the early and mid-late stage patients. Our valuation and forecasts include our assumed deal terms with Zambon including the potential deal terms Zambon could secure for safinamide in the US given the current stage of development. As explained earlier, we have updated our royalty rate forecasts to around 12-13% (from an average 11%).

The closest comparable (and competitor) for Xadago/safinamide, in our view, is Azilect (rasagiline) a monoamine oxidase type B (MAO-B) inhibitor which is used as monotherapy and as an add-on to L-dopa. Azilect is sold by Teva and Lundbeck and generated sales of $650m in 2014; it will go generic in 2017. In contrast to other MAO-B inhibitors, safinamide does not appear to have a tyramine interaction, hence avoiding any dietary restrictions (such as cheese and red wine).

Dyskinesia could expand the market opportunity

A subset analysis of a previous clinical trial (study 018) found that safinamide could improve dyskinesia in patients with moderate dyskinesia at baseline. This could present an attractive and differentiated market opportunity for safinamide. Safinamide is thought to improve dyskinesia owing to inhibition of glutamate release, with glutamate expression associated with dyskinesia. We believe further studies investigating this effect could form part of any potential sub-licensing deal(s).

Although L-dopa is an effective treatment for PD, its use is associated with the development of dyskinesia. The ability to improve dyskinesia could therefore allow for potentially earlier use of L-dopa in PD and to expand the market opportunity for safinamide.

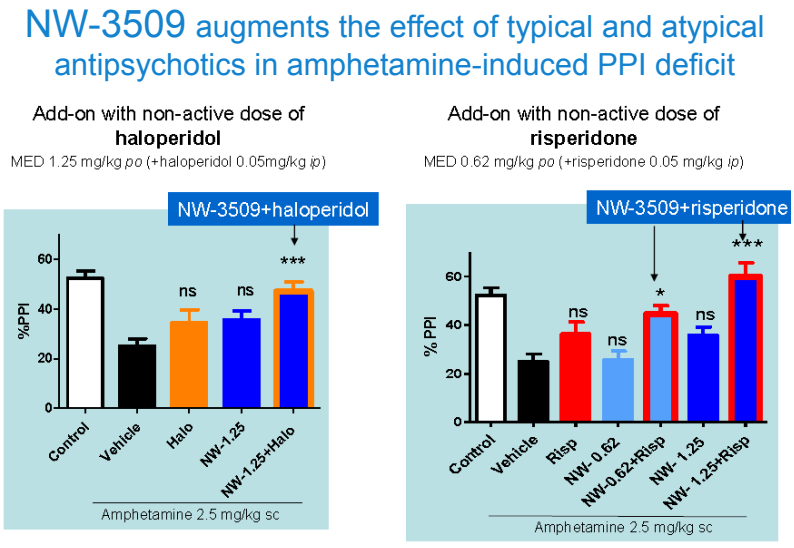
We do now include a risk-adjusted contribution for safinamide in dyskinesia, assuming peak sales of €350m until there is more clarity on the potential magnitude of benefit. It is estimated that dyskinesia affects around 40% of PD patients treated with L-dopa for 4-6 years, with limited treatment options aside from L-dopa dosing adjustment. With around 1m 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 and could therefore lead to potential launch in early 2018.

Preparing to partner NW-3509

NW-3509 is a potential add-on therapy to antipsychotics for the treatment of schizophrenia. It recently completed a Phase I trial assessing safety and Newron now plans to initiate a Phase II trial in Q215, data from which could become available in H116. Given the potential size of the market and scope of development, Newron plans to out-license NW-3509 and a deal could come either before or after the planned Phase II is complete; the former should help to maximise deal terms although Newron would be prepared to partner sooner if suitable deal terms were offered.

NW-3509 has shown benefits in preclinical models of psychosis, mania, depression, anxiety and cognition. In particular, improved effects were noted with the combination of NW-3509 with either haloperidol or risperidone (both typically used to treat schizophrenia) in a preclinical model, shown in Exhibit 3. NW-3509 could therefore have utility as an add-on treatment to antipsychotics in patients with schizophrenia who are experiencing breakthrough symptoms despite being on standard of care.

Exhibit 3: Preclinical data demonstrating the improved effect from the combination of NW-3509 with typical antipsychotics



Amph (2.5 mg/kg sc) and NW-3509A (1.25 or 0.62 mg/kg po) were administered 5 min before PPI session. Haloperidol and risperidone were administered ip 30 min before PPI session at 0.05 mg/kg. Statistics: Tukey's multiple comparison test *p<0.05, ***p<0.001 vs Vehicle+Amp (n=6-18 rats per group) (Studies performed by Dr Bortolato, Dept. of Pharm. Sciences, Univ. Cagliari- USCLA)

Source: Newron. Note: PPI or prepulse inhibition deficit is an excessive startle response, which is typically associated with schizophrenia; it results in an inability to recognise weak stimuli which is thought to lead to the typical symptoms of schizophrenia (including hallucinations and delusions).

A Phase I safety study including doses of NW-3509 up to 30mg was recently completed in 54 healthy volunteers. NW-3509 was generally well tolerated and Newron now plans to start a Phase II proof-of-concept trial in Q215. This 4-week study will include schizophrenic patients whose symptoms are not controlled by antipsychotics. Given the short 4-week assessment period, data could become available around a year later ie H116.

Newron estimates that the antipsychotic market is worth around $23bn, suggesting that NW-3509 could have significant future potential. However, until proof-of-concept data are available, estimating the potential market opportunity for NW-3509 is not straightforward. For the purposes of our valuation we include base-case assumptions, which conservatively assume that NW-3509 could achieve peak sales of c €380m, representing only c 2% of the current market. 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.

NW-3509 originates from Newron's ion channel discovery platform. It is an orally available sodium channel blocker with a fast onset of action. NW-3509 is patent protected in the US and other territories until around 2028, excluding any extensions.

Other non-core assets could also be partnering opportunities

Newron also has a number of other non-core assets, both from internal development and from acquisitions, which could all be candidates for partnering. These include ralfinamide and other compounds in various stages of early clinical development acquired with Hunter-Fleming. Investment into these is limited.

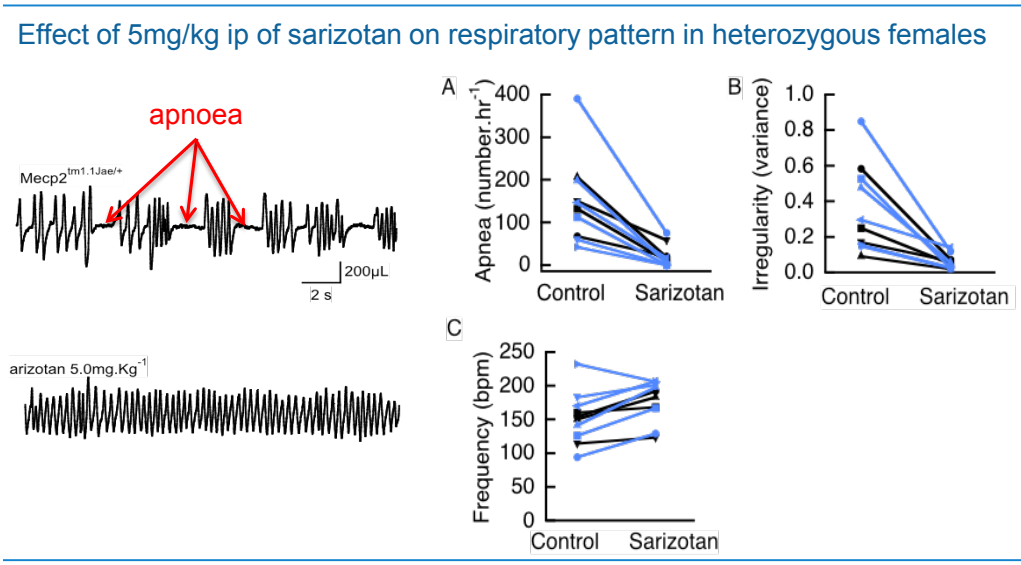
Sarizotan could be the first marketed orphan product

Development of sarizotan has been prioritised given the potentially rapid development path, requiring only small trials, in addition to the size of the indication, making it an attractive prospect for Newron to commercialise alone. Sarizotan is being developed for the treatment of life-threatening breathing disorders associated with Rett syndrome (RS), a niche genetic condition. Given the number of patients and the existing safety database, Newron believes that only a small pilot and then pivotal study will be needed to secure approval. This could therefore potentially allow for launch in 2017.

RS is a genetic neurodevelopmental disorder that generally affects girls, and arises from a genetic mutation. Newron estimates that there are around 36,000 RS patients in the US and Europe, with sudden death occurring in around 25%. Suggested causes of this sudden death include respiratory failure and apnoea, owing to an underlying disorder in the heart's electrical activity.

Sarizotan modulates the activity of serotonin and dopamine receptors in the brain. In preclinical mouse studies sarizotan was found to reduce apnoea and corrected breathing irregularities, as shown in Exhibit 4.

Exhibit 4: Sarizotan reduced apnoea and breathing irregularities in preclinical studies



Source: Newron

Newron plans to start a pilot study in RS patients with respiratory abnormalities, investigating apnoea reduction during 2015 which could yield first data early 2016. In parallel, Newron will be planning a potentially pivotal Phase II/III trial in around 60 patients which could start towards the end of this year and also potentially report data in 2016. Although RS is a small indication, all

patients are included on a patient registry which should facilitate recruitment. There is already a substantial safety database for sarizotan given previous development at Merck KGaA in PD, which was terminated following the failure of two Phase III trials in 2006 (Newron in-licensed sarizotan from Merck KGaA in 2011 and Merck retains a buy-back option).

Given the unmet medical need in RS, with no treatment options available, if the pilot study is positive, there could be the potential for accelerated access or conditional approval, although we more conservatively continue to forecast first launch in 2017, assuming a pivotal study will be needed prior to any commercial revenues, and maintain our peak sales forecast of €260m.

Neuronova orphan opportunities '029 and '031

In addition to sarizotan, Newron acquired two compounds with Neuronova, both of which are infused into the brain via an implanted catheter: (1) sNN0031 for severe PD; and (2) sNN0029 for amyotrophic lateral sclerosis (ALS). Both entered additional Phase II development at the start of this year and could be around one year behind sarizotan for commercialisation. These could both potentially be commercialised by Newron, and therefore, if successful could potentially provide operating leverage.

sNN0031 complements safinamide

sNN0031 is a potential treatment for severe PD which has shown initial signs of efficacy in a Phase I/II trial where an improvement in motor symptoms was observed in most patients and sNN0031 and a dose response in dopamine activity in areas of the brain damaged by PD was observed, indicating recovery of the dopamine system. Importantly, given the method of administration, there were no drop-outs and no severe side effects. Data were published in the Journal of Clinical Investigation in February 2015, along with a positive expert commentary. A further Phase II study was initiated at the start of this year to gain additional experience with the dose and device; data are expected in 2016.

Once data from the ongoing Phase II are available Newron could potentially start a pivotal Phase II/III trial in around 180 patients, subject to sufficient cash resources (Newron has been awarded a €6m grant from the European Commission to support additional studies). If this starts in 2016, this could allow for data in 2017 and potential launch in 2018.

At this stage we make no changes to our peak sales forecast of €200m and our valuation continues to assume that Newron will commercialise this alone, rather than with a partner. However, with around 180,000 patients in the US and Europe who could be eligible for treatment with sNN0031, Newron may elect to seek a partner outside of the US as this could be beyond the scope of a small commercial operation.

sNN0029 for ALS (Lou Gehrig's disease)

sNN0029 is a potential treatment for ALS or Lou Gehrig's disease, which has already demonstrated some early signs of efficacy in a previous Phase I/II trial in 18 patients and data were presented at the annual ALS meeting in Brussels in December 2014. An additional Phase II study was initiated early in 2015 investigating a higher dose and data are expected in 2016. In 2013 a €2.5m grant was awarded by the UK Wellcome Trust to support this study.

With around 25,000 ALS patients in the US and a similar number in Europe, sNN0029 would represent an ideally sized opportunity for Newron to commercialise alone. However, there have been a number of high profile failures in recent times in ALS including Biogen Idec's dexpramipexole and Trophos' olesoxime which both failed to demonstrate efficacy in large Phase III trials and development risk is high. In addition, the most recent trials were large and lengthy (500-

900 patients over 18 months) and if similar clinical development is required for approval, Newron will likely seek a partner for development. However, given the unmet need (the only approved treatment for ALS is Rilutek/riluzole, which has modest efficacy) if Newron can agree an expedited path to market, then it could potentially fund development alone.

Hence, following data from the higher dose study in 2016, Newron could initiate a potentially pivotal Phase II/III in 2016, if the trial design can be agreed by health authorities, with data in 2017, suggesting potential launch in 2018. We maintain our peak sales forecast of €250m, based on a relatively conservative 10% penetration of the c 50,000 US/EU ALS patient market and our valuation continues to assume that Newron retains rights to this product and can agree a development path with regulators.

Sensitivities

Newron is subject to the usual biotech risks, including clinical development delays or failures, regulatory risks, competitor successes, partnering setbacks, financing and commercial risks. With safinamide now approved in Europe the main sensitivity in the near-term will be the launch process, including securing favourable pricing and reimbursement, in addition to the launch trajectory, which will likely be on a country-by-country basis.

Commercial partner Zambon, together with Newron, continues to work towards sub-licensing safinamide in certain regions, particularly in the US where Zambon has a limited presence. In addition, sub-licences could be sought in various countries or regions in Europe. However, we have limited visibility on the timing and terms of any potential deals. The European approval could help to secure partner(s), our view.

In the US, safinamide has now been successfully re-filed and a regulatory decision date (PDUFA) is set for 29 December 2015. A lack of US partner prior to FDA approval could delay launch beyond our current forecasts. Safinamide has been filed in both early PD as an add-on to dopamine agonists, and in mid-late stage PD as an add-on to L-dopa. In Europe, approval was granted in mid-late stage PD.

Newron has four earlier stage programmes (NW-3509, sarizotan, sNN0029 and sNN0031) that it is advancing into later stage development and clinical data could become available in the next 12-18 months, which will help to shape future developments plans or to crystallise value through partnering. Success or failure with any of these compounds could have an impact on our valuation and financial forecasts.

Newron has sufficient cash and equivalents to fund operations into mid-2016 according to our model. We do include royalty income in our future forecasts, but this cash reach does not include the milestone payment due from partner Zambon for the European approval, nor any further safinamide related milestone income, including sub-licensing in the US, which could extend the cash runway. Current cash should be sufficient to fund ongoing clinical development (Phase II trials of sNN0029 and sNN0031), in addition to the planned Phase II trial of NW-3509 and the planned pilot study of sarizotan. Additional funds will likely be needed for further development.

Valuation

Our Newron valuation has been updated to reflect a number of revised assumptions. The bulk of these are related to safinamide, where we now include a higher royalty rate in both Europe and the US, in addition to a risk-adjusted contribution for the treatment of dyskinesia. We have made only minor changes to our underlying assumptions for the earlier stage pipeline, although we have

increased the probability for NW-3509 to 20% (from 15%) as this has now completed a Phase I safety study and a Phase II is planned. In addition, we have rolled our valuation forwards in time and have updated net cash (see the Financials section below).

Our updated valuation is now CHF496m (€466m) or CHF37.9/share. The breakdown of our rNPV valuation, which uses a 12.5% discount rate for all products in development (ie excluding safinamide in PD where it was recently approved in Europe), is shown in Exhibit 5.

Exhibit 5: Newron rNPV valuation

Product	Indication	Launch	Peak sales (€m)	NPV (CHFm)	Probability	rNPV (CHFm)	NPV/share (CHF/share)
Safinamide	Parkinson's Disease	2015	450	311.5	90-100%	296.6	22.7
	Dyskinesia	2018	390	128.8	40%	51.5	3.9
sNN0031	Severe Parkinson's Disease	2018	200	136.1	25%	29.8	2.3
sNN0029	ALS	2018	250	178.2	25%	40.1	3.1
Sarizotan	Rett syndrome	2017	260	233.5	20%	39.7	3.0
NW-3509	Schizophrenia	2019	380	77.8	20%	12.2	0.9
Net cash at end December of €24.6m (equivalent to CHF26.2m at €0.94/CHF)				26.2	100%	26.2	2.4
Valuation				**1,092.2**		**496.2**	**37.9**

Source: Edison Investment Research

As explained earlier in this report, for safinamide we now assume that Newron could be entitled to receive an average 12-13% royalty on sales by Zambon or through any sub-licensing deal (versus our previous 11%). We maintain our 100% probability of success in Europe where it is approved and 90% in the US where it is under regulatory review. For safinamide, we now also include a contribution for its potential to treat dyskinesia, which is likely to be included as part of any sub-licensing agreement in the US; we assign a 40% probability of success as there is already data supporting safinamide in this setting.

We maintain our peak sales forecast for NW-3509 but we have increased the probability of success to 20% (from 15%) given the successful completion of a Phase I trial. With potential in the large antipsychotic market, in addition to broader indications which could include mania and bipolar disorder, these could prove conservative.

For the orphan drug portfolio of sarizotan, sNN0031 and sNN0029 our valuation continues to assume that Newron will commercialise these alone, rather than with a partner. For sNN0029, Newron may elect to seek a co-development partner if large and long clinical studies are required to gain approval in ALS. For sNN0031, Newron may seek a commercial partner outside of the US. However, until there is further clarity on either of these, we maintain our current assumptions.

Key newsflow in the next 12-18 months

The key catalysts in the next 12-18 months will predominantly be safinamide related, with European launch in coming months and a US approval decision by end 2015, in addition to potential sub-licensing in the US. This will be crucial for maximising safinamide's sales potential. A summary of anticipated newsflow is shown in Exhibit 6.

Exhibit 6: Anticipated newsflow

News	Period	Comments
Safinamide EU launch	H115	Zambon is initially targeting sales in Germany once pricing and reimbursement have been secured
NW-3509 start of Phase II trial	Q215	
Sarizotan start of pilot study	mid-2015	Small pilot trial prior to a pivotal trial in 2015
Safinamide US approval	Q415	PDUFA date is 29 December
Sarizotan start of potentially pivotal study	Q415	
Safinamide sub-licensing	2015	Zambon is working to sub-license safinamide in regions including the US
NW-3509 partnering	2015-2016	A partnering deal could come before or after the availability of Phase II data
Sarizotan data from pilot study	Q116	Will validate preclinical models and provide insights into ability to reduce apnoea
NW-3509 Phase II data	H116	Will provide first proof of concept
sNN0029 data from ongoing Phase II trial	2016	Could trigger a decision on the development and commercial strategy (alone or with a partner)
sNN0031 data from ongoing Phase II trial	2016	Could trigger a decision on the development and commercial strategy (alone or with a partner)

Source: Edison Investment Research

Financials

Newron reported cash and equivalents at end December of €25.7m, which together with debt of €1.1m, relating to an Italian government grant of €5m awarded in 2008 that is repayable over 10 years, suggests net cash at end 2014 of €24.6m.

We estimate current cash, excluding any milestone payments, should be sufficient to fund operations to around mid-2016, funding the ongoing sNN0029 and sNN0031 trials, in addition to the planned Phase II NW-3509 and the pilot sarizotan study. Our forecasts do include a €6m milestone from partner Zambon for the recent formal European approval of safinamide however we exclude unknown/uncertain future milestones from our forecasts, which could include the share of any upfront payment that Zambon can secure through safinamide sub-licensing.

Any milestone payments, in particular the estimated €6m from Zambon, could extend the cash runway and reduce the need for any further cash to run future trials, including the pivotal sarizotan trial. Shareholders recently authorised at the recent AGM a 1.3m (10%) share capital increase which, if executed, could raise around CHF40m based on the current market capitalisation. This would provide Newron with the financial flexibility to move forward swiftly with clinical development of the earlier stage pipeline without being dependent on milestone or royalty income.

FY14 results

FY14 financial results were broadly in-line with our expectations. Our future forecasts have been updated to reflect a number of changes. These include a higher royalty rate on safinamide sales, driving higher revenues in future years. We have also revised our R&D estimates given the phasing of clinical trials and to reflect the most recent FY14 update and clinical trial plans; our 2015 forecasts now include Phase II development costs for both sNN0029 and sNN0031 which started in January 2015, in addition to NW-3509 Phase II costs and the start of sarizotan pilot study planned for later this year. The main changes to our forecasts are shown in Exhibit 7.

Exhibit 7: Newron reported FY14 and key changes to our financial forecasts

(€m)	2014 Forecast	2014 Reported	Change (%)	2015 Old	2015 New	Change (%)	2016 Old	2016 New	Change (%)
Revenue	1.401	1.557	+11	6.854	7.130	+4	3.251	5.822	+79
Research and development	(6.000)	(6.017)	+0	(7.500)	(11.500)	+53	(7.000)	(10.000)	+43
EBITDA	(11.771)	(11.248)	-4	(8.174)	(11.511)	+41	(11.650)	(11.673)	+0
Operating profit (reported)	(11.715)	(11.215)	-4	(8.117)	(11.460)	+41	(11.593)	(11.620)	+0
Profit before tax (reported)	(11.412)	(10.723)	-6	(7.821)	(11.269)	+44	(11.366)	(11.635)	+2
Profit after tax (reported)	(11.412)	(10.095)	-12	(7.821)	(11.269)	+44	(11.366)	(11.635)	+2

Source: Edison Investment Research

Newron is based in Italy and reports financials in euros. It is listed in Switzerland on the SIX with the share price quoted in Swiss francs (CHF). Our valuation is based on an FX rate of €0.94/CHF.

Exhibit 8: Financial summary

€000s	2010	2011	2012	2013	2014	2015e	2016e
Year end December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue	806	4,289	8,924	3,539	1,557	7,130	5,822
Cost of Sales	0	0	0	0	0	0	0
Gross Profit	806	4,289	8,924	3,539	1,557	7,130	5,822
Research and development	(15,922)	(3,822)	(3,534)	(4,537)	(6,017)	(11,500)	(10,000)
EBITDA	(21,789)	(6,570)	(2,760)	(7,815)	(11,248)	(11,511)	(11,673)
Operating Profit (before amort. and except.)	(21,667)	(6,499)	(2,710)	(7,786)	(11,228)	(11,484)	(11,644)
Intangible Amortisation	27	17	13	10	13	24	24
Exceptionals	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0
Operating Profit	(21,640)	(6,482)	(2,697)	(7,776)	(11,215)	(11,460)	(11,620)
Net Interest	(33)	45	200	63	492	191	(14)
Profit Before Tax (norm)	(21,700)	(6,454)	(2,510)	(7,723)	(10,736)	(11,293)	(11,659)
Profit Before Tax (FRS 3)	(21,673)	(6,437)	(2,497)	(7,713)	(10,723)	(11,269)	(11,635)
Tax	1,128	(8)	122	615	628	0	0
Profit After Tax (norm)	(20,572)	(6,462)	(2,388)	(7,108)	(10,108)	(11,293)	(11,659)
Profit After Tax (FRS 3)	(20,545)	(6,445)	(2,375)	(7,098)	(10,095)	(11,269)	(11,635)
Average Number of Shares Outstanding (m)	6.6	7.3	8.2	11.5	12.7	13.1	13.1
EPS - normalised (€)	(3.11)	(0.89)	(0.29)	(0.62)	(0.80)	(0.86)	(0.89)
EPS - normalised and fully diluted (€)	(3.11)	(0.89)	(0.29)	(0.62)	(0.80)	(0.86)	(0.89)
EPS - (IFRS) (€)	(3.11)	(0.89)	(0.29)	(0.62)	(0.80)	(0.86)	(0.89)
Dividend per share (EUR)	0.0	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	100.0
EBITDA Margin (%)	-2703.3	-153.2	-30.9	-220.8	-722.4	-161.5	-200.5
Operating Margin (before GW and except.) (%)	-2688.2	-151.5	-30.4	-220.0	-721.1	-161.1	-200.0
BALANCE SHEET							
Fixed Assets	6,026	5,937	11,900	9,821	7,686	7,741	7,795
Intangible Assets	5,188	5,171	11,199	9,125	6,993	6,975	6,957
Tangible Assets	128	56	72	79	67	140	211
Investments	710	710	629	617	626	626	626
Current Assets	13,106	7,629	32,747	21,797	29,388	19,011	15,427
Stocks	396	246	233	301	102	102	102
Debtors	2,557	1,469	2,811	2,088	3,320	3,320	3,320
Cash	8,087	5,367	29,243	18,426	25,702	15,530	11,946
Other	2,066	547	460	982	264	59	59
Current Liabilities	(4,635)	(2,827)	(11,585)	(6,070)	(4,489)	(4,564)	(4,298)
Creditors	(4,635)	(2,472)	(11,230)	(5,712)	(4,131)	(4,206)	(3,940)
Short term borrowings	0	(355)	(355)	(358)	(358)	(358)	(358)
Long Term Liabilities	(2,306)	(4,154)	(5,454)	(4,458)	(3,324)	(2,966)	(10,107)
Long term borrowings	0	(1,802)	(1,447)	(1,087)	(729)	(371)	(7,512)
Other long term liabilities	(2,306)	(2,352)	(4,007)	(3,371)	(2,595)	(2,595)	(2,595)
Net Assets	12,191	6,585	27,608	21,090	29,261	19,222	8,817
CASH FLOW							
Operating Cash Flow	(17,973)	(4,884)	6,015	(10,071)	(9,370)	(10,056)	(10,604)
Net Interest	0	0	0	1	7,053	191	(14)
Tax	(1,128)	8	(122)	(615)	(628)	157	0
Capex	(7)	(1)	(11)	(56)	(22)	(100)	(100)
Acquisitions/disposals	0	0	9,971	301	0	0	0
Financing	3,185	0	8,378	0	17,547	0	0
Other	1,602	0	0	(20)	(6,946)	(6)	(6)
Dividends	0	0	0	0	0	0	0
Net Cash Flow	(14,321)	(4,877)	24,231	(10,460)	7,634	(9,814)	(10,725)
Opening net debt/(cash)	(22,408)	(8,087)	(3,210)	(27,441)	(16,981)	(24,615)	(14,801)
HP finance leases initiated	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0
Closing net debt/(cash)	(8,087)	(3,210)	(27,441)	(16,981)	(24,615)	(14,801)	(4,076)

Source: Edison Investment Research, Newron Pharmaceuticals accounts.

Contact details	Revenue by geography
Newron Pharmaceuticals SpA via Ludovico Ariosto 21 20091 Bresso (Mi) Italy +39 02 610 3461 www.newron.com	N/A

CAGR metrics		Profitability metrics		Balance sheet metrics		Sensitivities evaluation	
EPS 2012-16e	N/A	ROCE 2015e	N/A	Gearing 2015e	N/A	Litigation/regulatory	●
EPS 2014-16e	N/A	Avg ROCE 2012-16e	N/A	Interest cover 2015e	N/A	Pensions	○
EBITDA 2012-16e	N/A	ROE 2015e	N/A	CA/CL 2015e	N/A	Currency	◖
EBITDA 2014-16e	N/A	Gross margin 2015e	N/A	Stock days 2015e	N/A	Stock overhang	◖
Sales 2012-16e	-10.1%	Operating margin 2015e	N/A	Debtor days 2015e	N/A	Interest rates	○
Sales 2014-16e	93.4%	Gr mgn / Op mgn 2015e	N/A	Creditor days 2015e	N/A	Oil/commodity prices	○

Management team

CEO: Stefan Weber

Mr Weber was appointed CEO in 2012, having been CFO since 2005 and having successfully executed the 2006 IPO. Mr Weber has more than 25 years' industry experience in general management and finance and has been responsible for numerous equity, debt, mezzanine and grant funding transactions. He holds a master's degree in business management from Fern Universität Hagen.

CMO: Ravi Anand

Mr Anand has been Newron's CMO since 2005. He has over 20 years of experience in drug development, including positions at Roche and Sandoz/Novartis. These were focused on CNS and incorporated all stages of clinical development and post-marketing. Mr Anand completed his medical training in the US, specialising in psychiatry and neurology.

VP Business Development: Marco Caremi

Mr Caremi has held senior positions at Newron since 2002. He has more than 30 years of experience in the pharmaceutical industry, including business development at both Schwarz Pharma and Schering-Plough. He holds a degree in natural sciences from the University of Milan and the Advanced Development Programme from the London Business School.

General Manager Newron Sweden: Anders Haegerstrand

Mr Haegerstrand joined Newron through its acquisition of NeuroNova, where he was CSO since 2004, having previously been CEO since 2000. Prior to this, he was at both Astra and then AstraZeneca involved in the CNS and pain teams. He has a medical degree from the Karolinska Institute in Stockholm, where he also completed a PhD and became associate professor in Neuroscience.

VP Finance: Roberto Galli

Mr Galli has held various positions within finance at Newron since joining in 2002 and has more than 16 years of experience in biotech, finance and auditing. He holds a degree in business economics from the University Luigi Bocconi, Milan and he is a chartered auditor.

Principal shareholders	(%)
Investor AB	12.7%
Zambon Group	11.3%
Aviva	8.0%
JPMorgan	4.7%
Omega	2.6%
Abingworth	1.7%
TVM	1.5%

Companies named in this report

Merck KGaA (MRK GR); Meiji Seika Pharma, part of Meiji Holdings (2269 JP); Zambon Group (private)

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