

# Newron Pharmaceuticals S.p.A.

Full year results 2013

Media and analyst conference
Zurich
Conference call
March 4, 2014

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# Newron's equity story?



# **No-brainer**

(Samir Devani, Charles Stanley)

# Persistence pays off

(Bob Pooler, ValuationLab)

# Agenda



- Highlights (Stefan Weber, CEO)
- Safinamide (Ravi Anand, CMO)
- Other pipeline products (Ravi Anand, CMO, Anders Haegerstrand, GM NS)
- Financial statements 2013 (Roberto Galli, VP Finance)
- March 27, 2014 AGM/EGM agenda (Stefan Weber, CEO)
- Q&A

# Key highlights



Developing innovative therapies for CNS disorders with special focus on rare diseases Safinamide - major late-stage asset

- Licensed worldwide (Zambon, Meiji)
- Substantial revenues expected from sublicensing, milestones, royalties
- First human trial completed in Japan
- MAA filed to EMA (Dec. 5, 2013)
- NDA filing to FDA expected by end of April 2014

# Well balanced pipeline

- Orphan drug development projects
  - sNN0031 in PD, initiation of Phase II Q1/2014
  - sNN0029 in ALS, initiation of Phase II Q1/2014
  - Sarizotan in Rett Syndrome, initiation of Phase II efficacy study Q3/2014
- NW-3509, first add-on therapy for positive symptoms in schizophrenia,
   Phase I ongoing

Management with significant track record in developing CNS drugs to market €25m of cash in the bank and commitments, funded way into 2015 Major newsflow through next 18 months

# Achievements over 18 months



# Safinamide in Parkinson's Disease (PD)

- License of Japan/key Asian rights to Meiji Seika
- Strategic collaboration for ROW with Zambon
- Positive MOTION/SETTLE PhIII results
- Pre-NDA meetings with FDA completed
- Significantly improved patent protection (2030+ in both EU/US)
- EMA filing executed/FDA filing process in final stages

Acquisition of NeuroNova – private Swedish company (now Newron Sweden)

- Two innovative programs in PD and ALS
- Restructured, debt-free, fully funded (€18.5m) operations in Stockholm
- Investor and Healthcap strengthen shareholder base
- Purchase price: abt. €15m in newly issued shares

# **NW-3509 US IND**

FDA approval for ralfinamide trial in severe orphan neuropathic pain indications Available 450,000 shares placed to J.P. Morgan AM, Aviva, Zambon Market cap back to CHF213m

# Achievements over 18 months - 2



# Newron Pharmaceuticals S.p.A.



# Next steps



### Safinamide

- Preparation of regulatory filing in US
- Support Zambon in sublicensing efforts
- Support Meiji in Japan/Asian clinical development

### sNN0031

Initiation of Phase II safety and exploratory efficacy study

## sNN0029

Initiation of Phase II safety and exploratory efficacy study at higher dose

# Sarizotan in Rett Syndrome

- Initiation of Phase II pilot efficacy study
- Preparation of Phase II/III potentially pivotal trial

NW-3509 Completion of Phase I/Initiation of Phase IIa

Attract further investment by leading institutional investors

# Strategy



Home run on key value driver/cash generator

- Submit safinamide NDA in the US
- Participate in US sublicensing
- Support development of safinamide in Japan and Asia by Meiji Seika
   Focus development resources on value-creating steps
  - Portfolio of orphan drug candidates (sNN0029, sNN0031, Sarizotan)
    - Substantial advantages
      - Higher speed to market
      - Lower development cost, regulatory hurdles
      - Higher selling prices and gross profit
      - Better visibility for the company/stock
  - NW 3509 Phase I/IIa PoC, potential partnering/co-development

# Partner or monetize non-core assets

Ralfinamide, HF0220, Trident equity holding

>> Make Newron a mid-cap



# Safinamide A unique proposition for PD filed in EU / US filing upcoming MOTION and SETTLE results disclosed at AAN, MDPD, MDS 2013

# Safinamide overview



>\$4bn market with no significant therapies introduced in recent years No other NCE expected to be approved for PD in the mid-term Alpha-amino amide derivative, high solubility and bioavailability Unique mechanism of action (potential new ATC)

- Enhancement of dopaminergic function
- Reduction of glutamatergic activity

First once a day oral adjunctive therapy for all stages of PD

Efficacy and safety demonstrated as add-on to dopamine agonist (early PD) and L-dopa (mid to late stage PD)

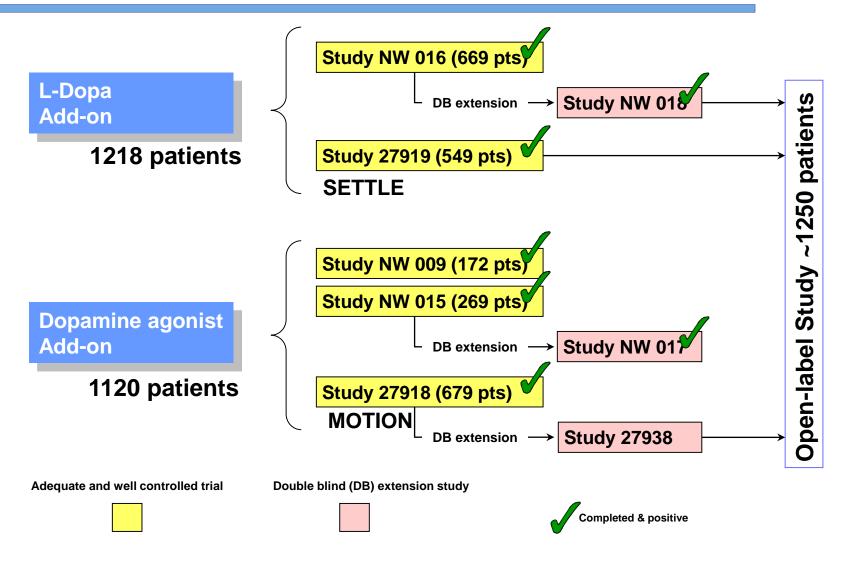
Anti-dyskinetic effect demonstrated in PD patients with dyskinesia

Global licence (except Japan/Asia) to Zambon for development and marketing in May 2012

Sublicense of US rights expected

# Safinamide: Clinical Registration Program

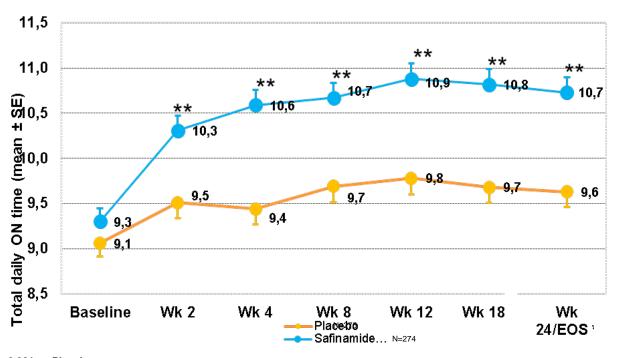




# SETTLE: Primary efficacy endpoint



The primary efficacy objective was to evaluate the change from baseline to Week 24 in daily ON Time (ON Time without dyskinesia plus ON Time with non-troublesome dyskinesia)



	Safinamide 50-100 mg/day
LS Mean	1.52
LS Diff. vs. placebo (95% CI)	0.96 ( 0.56, 1.37)
p-value vs. placebo	<0.001

\*\* p<0.001 vs Placebo

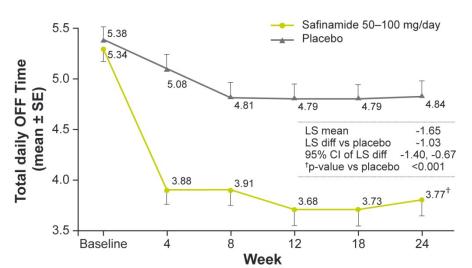
Safinamide was associated with significant improvement in ON Time (approximately 1 hour vs. placebo; p<0.001) with no increase in troublesome dyskinesia.

# SETTLE: Secondary efficacy endpoints

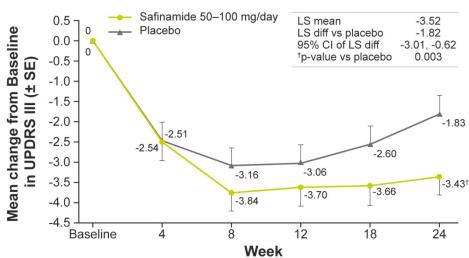


There was significant improvement in total daily OFF Time and UDPRS III assessed during ON Phase

# **Total daily OFF Time On-Treatment** (ANCOVA LOCF - ITT).



# Mean change from Baseline in UPDRS III assessed during ON Phase (ANCOVA LOCF - ITT)

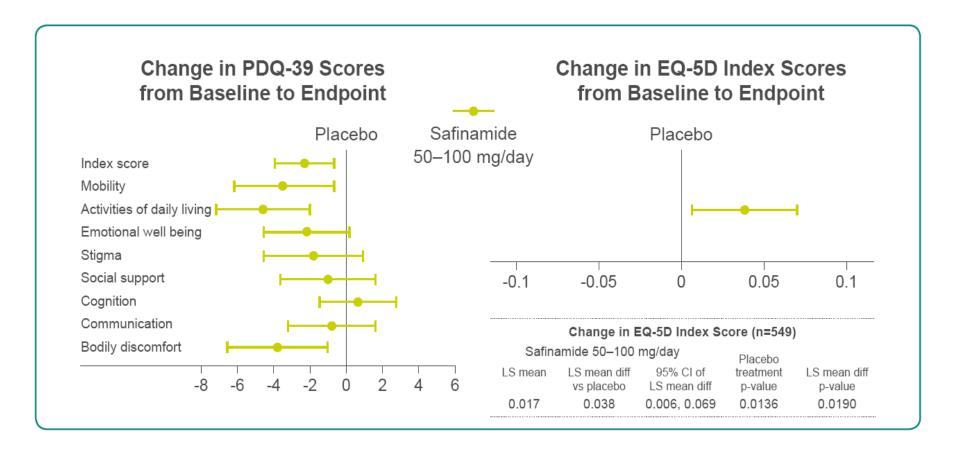


# There was also significant improvement in:

- PDQ-39 and EQ-5D scores
- OFF Time post morning dose of L-dopa

# SETTLE - Significant benefit on Quality of Life from Baseline to Endpoint: EQ-5D and PDQ-39

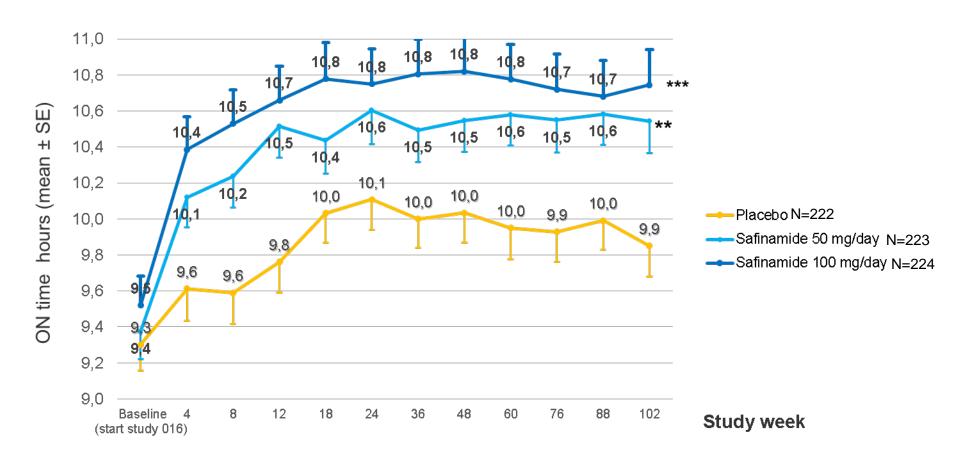




# 2-year Placebo-controlled International Study in PD Patients with Motor Fluctuations (Study 016/018)



# **ON Time** (without troublesome dyskinesia) - Change from Baseline



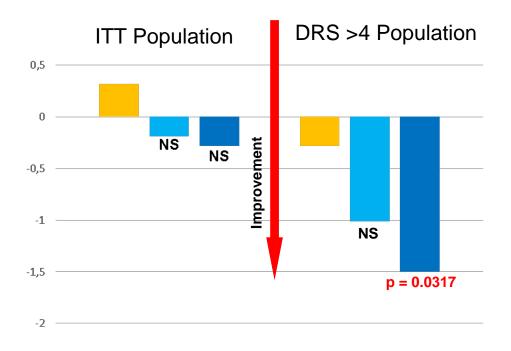
# Previous results from study 016/018 showed significant benefit of safinamide is maintained for at least 2 years



	24 week (Study 016)		24 months (Study 018)	
ENDPOINTS	50 mg/day	100 mg/day	50 mg/day	100 mg/day
PATIENT RATED OUTCOMES				
TOTAL ON Time (ON+ON with minor dyskinesia)	0.0031	0.0002	0.0068	0.0006
OFF Time	0.001	<.0001	0.0076	0.0005
ON Time without dyskinesia	0.019	0.007	0.034	0.036
ON Time with minor dyskinesia	NS	NS	NS	NS
ON Time with troublesome dyskinesia	NS	NS	NS	NS
PDQ Total	NS	0.0267	NS	0.019
PHYSICIAN RATED OUTCOMES				
Dyskinesia Rating Scale	NS	NS	NS	NS
UPDRS II Total	0.0742	0.006	NS	0.0068
UPDRS III Total	0.0075	0.0002	NS	0.0063
UPDRS IV Total	0.0381	0.0004	NS	0.0003
CGI - Severity	0.0038	0.0219	0.0068	0.015
CGI - Improvement	0.0003	0.0097	0.0085	0.0625
GRID-HAMD Total	NS	NS	NS	<b>0.0047</b> <sub>17</sub>

# Study 018: Dyskinesia Rating Scale (DRS)



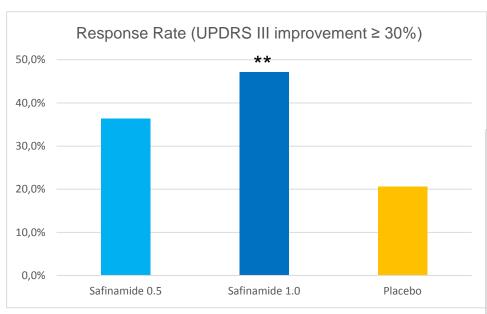


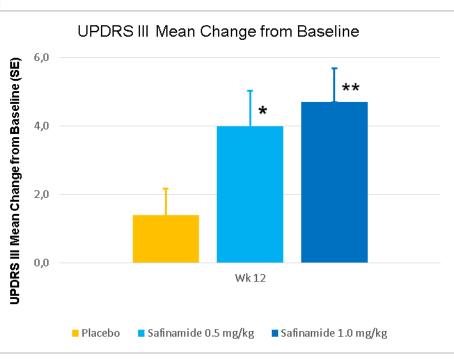
- Placebo
- Safinamide 50 mg
- Safinamide 100 mg

# Three-month Placebo-controlled International Study in Early PD Patients (Study 009, safinamide add-on to dopamine agonist)



# **UPDRS III** – Responder Rate and Mean Change from Baseline





<sup>\*</sup> p <0.05 vs placebo; \*\* p<0.01 vs placebo

# Six-month Placebo-controlled International Study in Early PD Patients (MOTION Study, safinamide add-on to dopamine agonist)

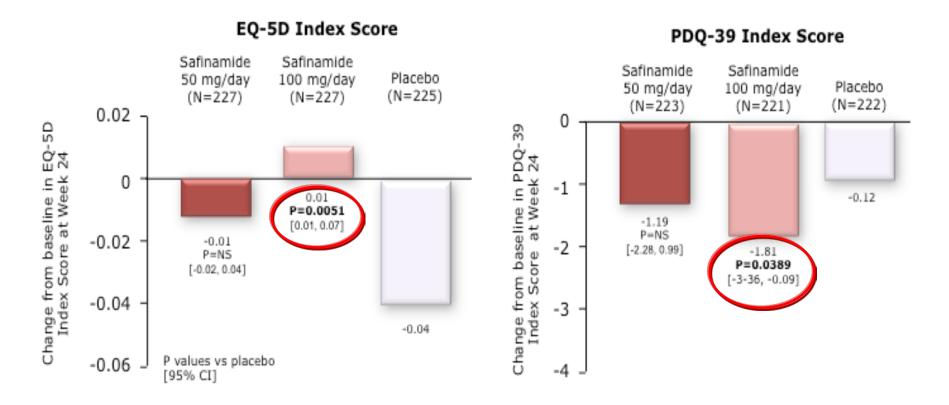


# **UPDRS III, PDQ-39 and EQ5D** – Mean Change from Baseline

		DA-agonist Monotherapy Population (n=666)		
		Safinamide		
		50 mg/day	100 mg/day	
UPDRS III (On treatment)	N	223	221	
	LS Mean Diference [95% CI]	-0.70 [-1.85, 0.44]	-1.20 [-2.35, -0.06]	
	P-value	0.2280	0.0396	
PDQ-39 Index Score	N	223	221	
	LS Mean Diference [95% CI]	-0.64 [-2.28, 0.99]	-1.72 [-3.36, -0.09]	
	P-value	0.4393	0.0389	
EQ5D	N	223	221	
	LS Mean Diference [95% CI]	0.01 [-0.02, 0.04]	0.01 [0.01, 0.07]	
	P-value	NS	0.0051	

# MOTION - Significant benefit on Quality of Life: EQ-5D and PDQ-39 from Baseline to Endpoint (DA-ITT)





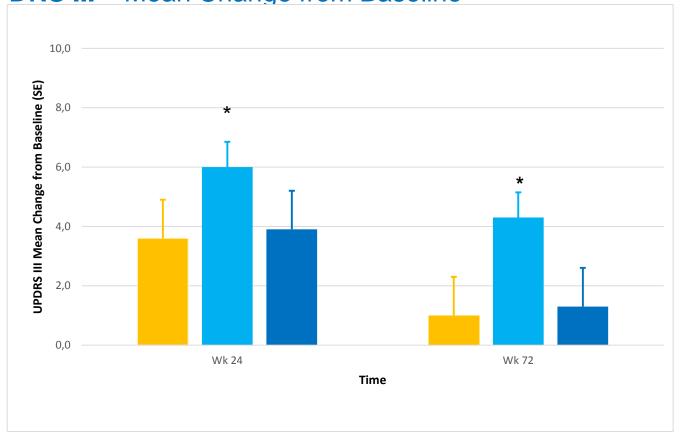
**EQ-5D European Quality of Life PDQ39 Parkinsons Disease Quality of Life** 

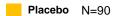
# Six-month and 18-month Placebo-controlled International Study in Early PD Patients



(Study 015-017, safinamide add-on to dopamine agonist)

**UPDRS III** – Mean Change from Baseline





Safinamide 50-100 mg N=90

Safinamide 150-200 mg N=89

# Safinamide outlook



Safinamide clinical program demonstrated significant benefits as

- Add-on to a stable dose of a single dopamine agonist in patients with early PD, and
- Add-on to L-dopa and other PD medications at stable doses in patients with motor fluctuations (mid to late stage PD)

Health authority meetings with European and US regulators completed

MAA filed on Dec. 5, 2013, for both indications, with over 1,500 patients of whom approx. 1,000 treated for at least one year

US filing expected by end of April 2014

First add-on therapy to treat early and mid to late stage PD patients

Potential development as anti-dyskinetic treatment



# A perfect complement to safinamide Severe, treatment resistant PD Orphan

# sNN0031 for severe, treatment resistant PD



## Indication:

PD patients with

- Severe disability
- Poor QoL
- Despite optimized standard of care
- Using oral PD medication

# Compound:

Recombinant human Platelet Derived Growth Factor (rhPDGF-BB)

First ICV treatment for severe, resistant PD

Intermittent administration

Targeting pre-existing stem/progenitor cells

Positive results in primate model

Previous Phase I/II studies:

- Demonstrated clinical safety and tolerability
- Long term follow-up, >2 years, w.o. safety concerns
- Dose dependent trend for efficacy on DAT
- Results presented at 2013 MDS meeting

EU grant of €6m to support next clinical development steps

# sNN0031 for severe, treatment resistant PD



### **Commercial considerations:**

Will qualify as orphan indication (reference: Duodopa)
About 180,000 patients in the USA and Europe
Treatment cost consistent with existing orphan therapies
Granted method of use patents in the US and EU (2025+, plus ODD)

# **Next steps:**

New study in PD patients to gain additional data/experience with device and dose for pivotal study

FDA pre-IND meeting (2013) agreed on

- Phase II/III single potentially pivotal study (~180 pts) as currently planned
  - No carcinogenicity/long term toxicology studies
  - 6 month endpoint/12 months safety data using intermittent treatment in patients on optimized PD therapy
  - Primary efficacy measure to be finalized during Special Protocol Assessment (FDA), and scientific advice (CHMP) in 2014
  - Start 2015, reporting 2016



# A ray of light for patients with ALS Orphan

# sNN0029 for Amyotrophic Lateral Sclerosis



### Disease:

ALS, or Motor neurone disease, or Lou Gehrig's

- Debilitating disease, rapidly progressive weakness, muscle atrophy, fasciculations, muscle spasticity, difficulty speaking, swallowing, breathing
- Fatal outcome within few years of diagnosis
- Unknown cause for 95% of patients
- Mostly of age 40-60 years, men slightly more affected than women

# Compound:

Recombinant human Vascular Endothelial Growth Factor 165 (rhVEGF165)
Permanent ICV administration

First treatment targeting motor neurons by blocking activity of apoptotic genes Strong pre-clinical data supporting VEGF role in ALS

Previous Phase I/II study:

- Demonstrated clinical safety and tolerability
- Long term follow-up, >2 years, w.o. safety concerns
- Dose dependent trends for efficacy (ALSFRS, SVC and QoL)

New safety/exploratory/efficacy study at higher dose to select dose for phase III with Wellcome Trust funding (€2.5m); will measure motor unit activation

# sNN0029 for Amyotrophic Lateral Sclerosis



# Strong pre-clinical data supporting a role for VEGF in ALS

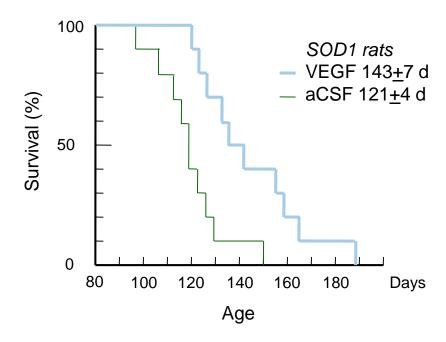
- VEGF deficient animals show ALS like disease development
- VEGF treatment prolongs life in ALS model rats



VEGF+/+



VEGF∂/∂



# sNN0029 for Amyotrophic Lateral Sclerosis



## **Commercial considerations:**

Orphan disease, about 25,000 patients in the US, same exp. in EU Only one drug approved (Rilutek from Sanofi), with limited efficacy/safety issues Treatment cost consistent with orphan drugs Biogen's dexpramipexole recently failed in Phase III study Granted method of use patents in the US and EU (2025+, plus ODD) Licensed from VIB/Genentech, Genentech opt-in right for US, CAN, MEX

# **Next steps:**

FDA Pre IND meeting

Phase II safety and exploratory efficacy study at higher dose

- 3 months permanent treatment
- Start and reporting 2014

Phase II/III single potentially pivotal study

Start 2015, reporting 2016

Licensing/filing in key territories



# Targeting respiratory disturbances in Rett Syndrome Orphan

# Sarizotan in Rett Syndrome



# Disease:

Rett Syndrome, or cerebroatrophic hyperammonemia

- Severe neurodevelopmental disorder primarily affecting females (1:10,000)
- Accounting for 10% of mental retardation of genetic origin in women
- Mutations in X-linked methyl CpG-binding protein 2 in majority of patients
- Patients develop normally until 6-18 months of age, then lose fine motor skills, ability for social interaction, encounter cardiorespiratory dysregulation
- 26% of deaths in girls with Rett Syndrome due to respiratory arhythmia

# Compound:

New chemical entity from the group of aminomethyl chromanes Breathing disturbance in Rett Syndrome postulated to involve hyperexcited expiratory neurons in brain stem (Kölliker-Fuse nucleus)

Full agonist at  $5 \mathrm{HT}_{1\mathrm{A}}$  receptors, partial agonist / antagonist at  $\mathrm{D}_2$  receptors Dramatic effect demonstrated in null mutant MeCP2 mouse model of Rett Syndrome

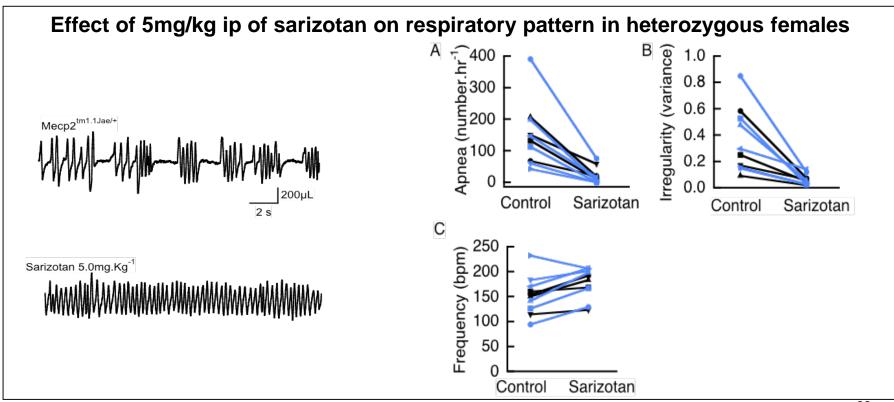
Potential additional benefit in other core features of Rett Syndrome

- Behaviour
- Cognition
- Neurological deficits

# Sarizotan in Rett Syndrome



Sarizotan (5 mg/kg ip in heterozygous female and 10mg/kg ip in null males) reduced the incidence of apnea in **MeCP2 deficient mice** of ~85% of their pre-treatment levels. In addition, the irregular breathing pattern, characteristic of RTT subjects and mouse models was corrected to that of wild type (WT) littermates



# Sarizotan in Rett Syndrome



## **Commercial considerations:**

Orphan disease

United States approximately 16,000, EU approximately 20,000 patients

**Current treatment:** 

- No specific cure for Rett Syndrome
- Multidisciplinary approach, focusing on the management of symptoms
- In particular medication are needed for breathing irregularities, motor difficulties, seizures' control (anticonvulsant)

Orphan status granted by EMA for desipramine chlorhydrate (antidepressant) in 2009 Market protection under ODD

# **Next steps:**

- Regulatory interactions to gain acceptance of CMC/preclinical/clinical safety data package and agreement to accept single positive study for approval
- Interactions with Rett Foundation for buy-in/potential funding/co-sponsorship of trials
- Open Label Pilot Study focusing on breathing symptoms (EU/possibly US centers)

Followed by Phase II/III single potentially pivotal study

- Double Blind, placebo-controlled, multicenter, randomized, cross-over study
- Total duration 29 weeks, approx. 40 patients
- Start 2015, reporting 2016



# First add-on therapy for positive symptoms in schizophrenia A fast value creation step

# NW-3509 in schizophrenia - Overview



NW-3509 is a first in class voltage-gated sodium channel (VGSC) blocker for addon treatment in schizophrenia, schizo-affective and bipolar disorders

Novel small molecule, oral available, rapid onset of action, high availability in the brain

Potential to address poorly responding patients with schizophrenia/mania

Benefit shown in models of positive symptoms, aggression, cognition (schizophrenia) mania, depression, obsessive behavior

IND approval from FDA as add-on to antipsychotics for patients with psychosis

Phase I study ongoing

Large market opportunity (anti-psychotic market >\$23bn)

Composition of matter – USPTO, 2013

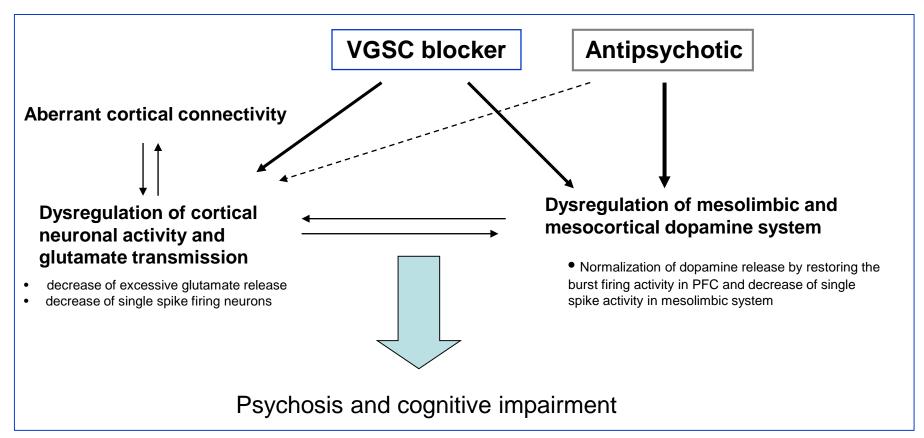
Patent life 2028 plus extension

Potential for extensive commercial exclusivity in a growing market

## Hypofunction of NMDAr and altered electrophysiological activity are also mechanisms underlying schizophrenia

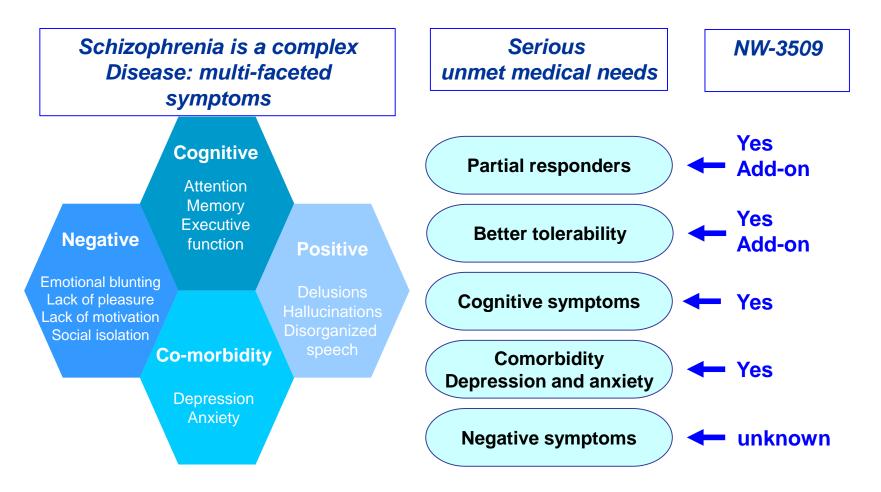


Synergic activity of VGSC blockers with antipsychotics in schizophrenia therapy



# NW-3509 has the potential to address unmet medical needs in schizophrenia





# Ongoing study: Single dose tolerability study in healthy male volunteers in US



A Phase I, prospective, randomized, double-blind, placebo-controlled, sequential-cohort, escalating, single-dose study designed to determine the maximum tolerated oral dose of NW-3509A in healthy, male volunteers

Prospective, 8-day, randomized, double-blind, placebo-controlled, sequential-cohort

Single oral doses of 1, 2, 5 and 10 mg administered; next dose of 20 mg planned Plasma concentrations at current doses in humans overlap with the extrapolated plasma concentration required to achieve efficacy in animal models of schizophrenia

To be followed by safety and exploratory efficacy study in patients with positive symptoms of schizophrenia who are experiencing breakthrough symptoms on current standard of care

## Next steps



#### Safinamide

- Preparation of regulatory filing in US
- Support Zambon in sublicensing efforts
- Support Meiji in Japan/Asian clinical development

#### sNN0031

 Initiation of Phase II safety and exploratory efficacy study sNN0029

Initiation of Phase II safety and exploratory efficacy study at higher dose

### Sarizotan in Rett Syndrome

- Initiation of Phase II pilot efficacy study
- Preparation of Phase II/III potentially pivotal trial

NW-3509 Phase I completion/Initiation of Phase IIa



## Group Consolidated Financials 2013 (IFRS)

## Financial Highlights 2013



- License income EUR3.2m (2012: EUR8.9m) milestone received from Zambon SpA upon filing of a the MAA for safinamide and down-payment under Zambon 2012 license/collaboration agreement
- Gross R&D expenses €11.9m (2012: €8.4m)
- Net R&D expenses €4.5m (2012: €3.5m), net of MS/Zambon reimbursement of safinamide related expenses of €6.0m (2012: €4.8m) and grants of €1.4m (2012: €0.1m)
- SG&A expenses €6.8m (2012: EUR8.0m)
- Net loss €7.1m (2012: EUR2.4m)
- Net cash from/used in operating activities €10.7m (2012: + €5.8m)
- Total funds available: €25,2m
  - Cash position at year end 2013: €18.4m
  - Commitments by third parties at year end 2013: €3.9m
  - Proceeds from issuing remaining 211,473 shares to JPM in Jan. 2014: €2.9m
- Cash reach: 3Q 2015, beyond key value inflexion points

# Consolidated Financial Statements 2013 (IFRS)



Consolidated Income statement		
€('000)	2013	2012
License income	3,213	8,907
Other income	326	17
R&D expenses	(4,537)	(3,534)
Marketing and advertising expenses	(15)	(62)
General and administrative expenses	(6,763)	(8,025)
Operating Loss	(7,776)	(2,697)
Financial income, net	63	200
Income tax	615	122
Net loss	(7,098)	(2,375)
Loss per share in €	(0.62)	(0.29)

Consolidated Cash flow statement			
€('000)	2013	2012	
Net cash from/used in operating activities	(10,686)	5,825	
Net cash flows from investing activities	226	10,028	
Net cash flows from financing activities	(357)	8,023	
Net increase/decrease in cash and cash equivalents	(10,817)	23,876	

Consolidated Statement of Financial Position			
€('000)	31/12/2013	31/12/2012	
Non-current assets	9,821	11,900	
Current assets	21,797	32,747	
Total assets	31,618	44,647	
Deferred tax liability/income, borrowings - non-current	3,992	4,978	
Employee severance indemnity/cash settled share-based liabilities	466	476	
Deferred income	2,031	4,396	
Current liabilities	4,039	7,189	
Total shareholders' equity	21,090	27,608	
Total equity and liabilities	31,618	44,647	

## Stock at a glance



SIX Swiss Exchange Code: NWRN

Number of fully paid in shares: 11,835,977

Market cap: CHF213m (February 25, 2014)

### Major Shareholders:

•	Investor AB	12.8 %

Zambon Group 12.5 %

Aviva 6,0 %

Omega 2.9 %

TVM 2.5 %

Abingworth 1.8 %

JPMorgan 1.8 %

Polar 0.9 %

TRowe 0.8 %

Deka 0.6 %

Lansdowne ? %

### Analysts:

- Bank Vontobel, Andrew Weiss
- Nomura Code, Samir Devani
- Value Lab, Bob Pooler
- Edison, Philippa Gardner



# Agenda for March 27, 2014 AGM/EGM

## Strategy



Home run on key value driver/cash generator

- Submit safinamide NDA in the US
- Participate in US sublicensing
- Support development of safinamide in Japan and Asia by Meiji Seika

Focus development resources on value-creating steps

- Portfolio of orphan drug candidates (sNN0029, sNN0031, Sarizotan)
  - Substantial advantages
    - Higher speed to market
    - Lower development cost, regulatory hurdles
    - Higher selling prices and gross profit
    - Better visibility for the company/stock
    - Option to build commercial operations
- NW 3509 Phase I/IIa PoC, potential partnering/co-development

Partner or monetize non-core assets

Ralfinamide, HF0220, Trident equity holding

>> Make Newron a mid-cap

## Mid-cap?





### AGM/EGM March 27, 2014 1/2



- Approval of the financial statements as at December 31<sup>st</sup>, 2013
- Change of by-laws to increase number of Directors' from "up to 7" to "up to 8"
- Election of 8 members of the Board of Directors for the financial years 2014, 2015 and 2016 and determination of the relevant remuneration
  - Ulrich Köstlin as Chairman and non-executive Director
  - Stefan Weber as executive Director
  - Patrick Langlois as non-executive Director
  - Hanns Moehler as non-executive Director
  - Bo Jesper Hansen as non-executive Director
  - Robert Leslie Holland as non-executive Director
  - Luca Benatti as non-executive Director
     Conditional to point 2 above being positively resolved:
  - Donald deBethizy as non-executive Director
- Share capital increase, with exclusion of the option right for a maximum nominal amount of Euro 236,719,40 and, therefore, for maximum n. 1,183,597 Company's ordinary shares (i.e. 10% of Newron's ordinary share capital)

### AGM/EGM March 27, 2014 2/2



- Delegation to the Board of Directors a share capital increase, with exclusion of the option right, for a maximum nominal amount of Euro 375,844, and, therefore, for maximum n. 1,879,220 Newron ordinary shares
  - Option to participate for shareholders
  - Allowing also qualified investors to participate
  - Significantly reduced timelines to closing of transaction
  - At same terms for all subscribers

Conditional to and to the extent that point 1 above being exercised:

 Waiver of the already existing capital increase (1,879,220 shares) with option rights from 2010



Q&A