Newron Pharmaceuticals SpA SIX: NWRN

Annual media & analyst conference

Zurich

March 1, 2016

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2015 – a year to be remembered

- EU approval of Xadago®
- CH approval of Xadago®
- Zambon launch of Xadago® (safinamide) in Germany and (post period) in Switzerland, Spain and Italy
- Xadago® - late-cycle review meeting completed with FDA
  – PDUFA date 29 March 2016
- Meiji Seika Pharma: initiation of Phase II/III and Phase III long-term trials with safinamide in Japanese patients
- ODD for the treatment of patients with Rett Syndrome for the EU and the US
- Plan for international double-blind, placebo-controlled efficacy study with sarizotan in patients with Rett Syndrome
- Completion of first in man US Phase I study of NW-3509
- U.S. Phase II study initiation with NW-3509 in patients with schizophrenia
- Completion of EUR28.3m Private Placements with leading EU and U.S. investors

About Newron Pharmaceuticals

- CHF300m Market Cap, listed on SIX Swiss Exchange (NWRN)
- Driven to deliver effective treatments to patients living with debilitating Central Nervous System (CNS) diseases
- Xadago® (safinamide) for Parkinson's disease:
  - EU Commission grants Marketing Authorization Feb. 24, 2015
  - Launched in key EU markets: Germany, Spain, Italy
  - Swissmedic grants Marketing Authorization Nov. 12, 2015
  - Launched in Switzerland: Jan. 2016
  - Accepted for filing by the FDA March 2, 2015
  - PDUFA date: March 29, 2016
- Material revenues from license agreements
- Moving towards a CNS-specialty, commercial orphan company

Licensing Revenues

- Xadago® (safinamide) for PD
- Development-stage assets
- Phase II asset for schizophrenia

Phase II Orphan Drug Portfolio

- Rett syndrome
- Orphan neuropathic pain

Management Team

Stefan Weber
CEO

- Biofrontera – Experts in dermatology
- Girindus
- Lohmann

Ravi Anand
CMO

- Roche
- SANDOZ
- NOVARTIS
- Organon

Marco Caremi
Executive VP Business Development

- Schering-Plough
- Polifarma
- SCHWARZ PHARMA

Roberto Galli
Vice President Finance

- pwc

Anders Haegerstrand
General Manager Newron Sweden

- Karolinska Institutet
- NeuroNova
- AstraZeneca

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Pipeline Overview

Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
Xadago® (safinamide)[1]					
Adjunctive to dopamine agonist early-stage PD					Zambon
Adjunctive to levodopa mid-to late-stage PD					Meiji Seika
Sarizotan[2]					
Rett syndrome					Yes
NW-3509[1]					
Schizophrenia					Yes
Ralfinamide[1]					
Orphan indication in neuropathic pain					Yes

[1] Safinamide, NW-3509 and Ralfinamide all developed from Newron's ion channel based research

[2] Sarizotan was licensed from Merck Germany

Newron Pharmaceuticals

Valuable Assets with Licensing and Commercial Opportunities

Xadago® (safinamide)

- Marketing Authorizations
  - EU: Feb. 24, 2015
  - Switzerland: Nov. 12, 2015
  - US PDUFA: Mar. 29, 2016
- Material revenue generating licenses with:
  - Zambon
  - Meiji Seika in Japan/ Asia
- Licensed worldwide; U.S. sublicense pending
- Peak sales potential: $450M+ to $700M+

Licensed

NW-3509

- Schizophrenia
- World-wide anti-psychotic market: $23B
- Phase II initiated Dec. 2015

Licensing Opportunity

Sarizotan

- Rett syndrome
- Orphan patient population: 35K-40K in U.S. and EU
  - ODD in US and EU
- Initiate Phase II/III potentially pivotal study in Q2/2016

Launch First Orphan Product by 2018

Xadago® (safinamide) – First NCE Approved for PD in a Decade

Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
Safinamide					
Adjunctive to dopamine agonist early-stage PD					Zambon
Adjunctive to levodopa mid-to late-stage PD					Meiji Seika

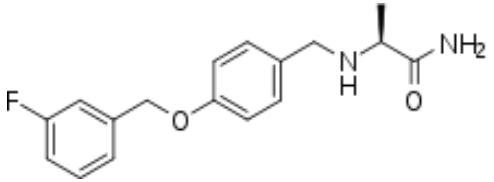
Xadago® (safinamide) – First NCE Approved for PD in a Decade

Parkinson's disease affects **7M to 10M** patients worldwide

First PD therapy working through dual mechanism

Once-Daily AZILECT® (rasagiline tablets)

Azilect (rasagiline) last NCE approved in 2006; No NCE pipeline candidates within 5 years



Xadago® (safinamide) – Once daily oral adjunctive therapy for all stages of PD

- Alpha-amino amide derivative, high solubility and bioavailability with quick onset and long lasting effects (> 2 years)
- First PD therapy working through dual mechanism; current PD treatments only enhance dopaminergic function
  - Enhances dopaminergic function
  - Reduces glutamatergic activity

Efficacy and safety demonstrated as add-on to

- dopamine agonists (early PD)
- L-dopa (mid to late stage PD)

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Xadago® (safinamide) Offers Multiple Benefits to PD Patients with Long Duration of Effect

Early PD Patients – add to dopamine agonist

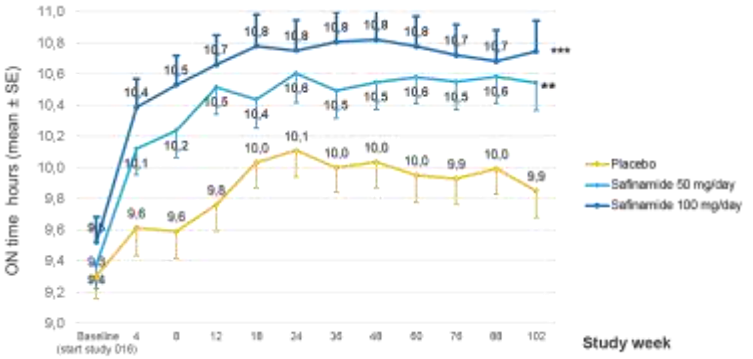
- Significant improvement of
  - UPDRS III - motor function, regulatory endpoint (mean change, responder rate)
  - Quality of life (PDQ-39, EQ5D)
- Reduction of number of interventions (first time use of L-dopa)
- Benefits seen after 6 and 18 months
- Delay levodopa

Mid- to late-stage PD Patients – add to dopamine replacement

- Significant improvement of
  - ON Time/OFF Time – regulatory endpoint
  - UPDRS II – activities of daily living
  - UPDRS III – motor function
  - UPDRS IV – treatment complications
  - CGI (clinical global impression) – severity and improvement
  - GRID HAMD (depression)
- Additional ON Time Without Any Increase In Any Dyskinesia
- Dyskinesia significantly improved
- Benefits seen after 6 and 24 months

Long-Term Duration of Effect

ON Time (without troublesome dyskinesia) - Change from Baseline



Clinical Trials Support Long-term Patient Benefits

Dopamine agonist Add-on

1120 patients

- Study NW 009 (172 pts) ✓
- Study NW 015 (269 pts) ✓
  - DB extension → Study NW 017 ✓
- Study 27918 (679 pts) ✓ **MOTION**
  - DB extension → Study 27938

L-Dopa Add-on

1218 patients

- Study NW 016 (669 pts) ✓
  - DB extension → Study NW 018 ✓
- Study 27919 (549 pts) ✓ **SETTLE**

→ Open-label Study ~1250 patients

6 month study (regulatory requirement)

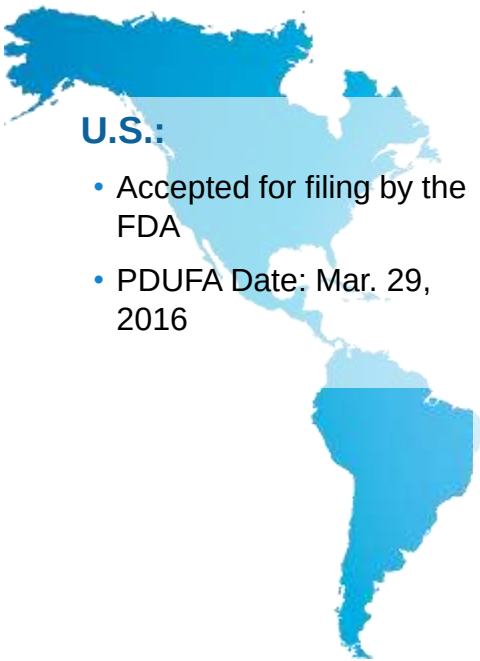
Double blind (DB) extension study

✓ Completed & positive

Xadago ® (safinamide) – Approved in EU and CH U.S. PDUFA Date March 29, 2016

EU Marketing Authorization:

- Both dopaminergic and non-dopaminergic mechanisms
- Sustained efficacy for 2 years for ON Time, OFF Time and UPDRS III
- “Very much/much improved” in Clinical Global Impression
- Significant improvement in activities of daily living (UPDRS III)
- Extremely well tolerated
- No drug interactions; no age, gender or race restrictions
- No dietary restrictions
- No requirement for laboratory tests, ECG, or any other examination
- Significant effects in early-stage PD patients



U.S.:

- Accepted for filing by the FDA
- PDUFA Date: Mar. 29, 2016

EU: Marketing Authorization Feb. 24, 2015
Launches:
D - May 15, 2015
E - Feb. 22, 2016
I - Feb. 29, 2016
Launches further EU territories Q1-2/2016

Switzerland: Marketing Authorization Nov. 12, 2015
Launch: Jan. 12, 2016

Xadago ® (safinamide) – Commercial Opportunity

Identifying parties for regional sublicensing

Milestone and royalty revenues to Newron since 2012

Long lasting market exclusivity (patent life: 2029 in EU, 2030 in the U.S.)

Sarizotan – Targeting respiratory disturbances in Rett syndrome

Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
Sarizotan					
Rett syndrome					

Rett Syndrome Causes Severe Disability, Reduces Life Expectancy in Girls

Rett Syndrome, or cerebroatrophic hyperammonemia

- Severe neurodevelopmental disorder primarily affecting females (1:10,000)
- Mutations in X-linked methyl CpG-binding protein 2 in majority of patients
- Normal development until 6-18 months of age, then lose fine motor skills, ability for social interaction, encounter cardiorespiratory dysregulation

Life Expectancy

71.5% chance of surviving to age **25** years (vs **99.9%**)

60% survival at 37 years (vs. appr. **98%**)

25% of sudden deaths in Rett linked to cardio-respiratory abnormalities

Unmet Need:

- No specific cure
- Focus on symptom management
- Medication needed for breathing irregularities, motor difficulties, seizures' control (anti-convulsant)

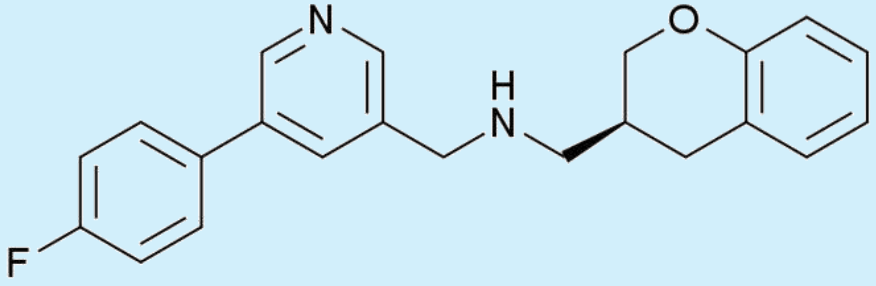
Sarizotan Has Potential to Treat Respiratory & Other Symptoms

- Aminomethyl chromane derivative; new chemical entity
- Breathing disturbance in Rett syndrome postulated to involve neuronal hyperactivity in the brainstem (Raphe nucleus, Kölliker-Fuse nucleus, Bötzinger complex)
- Dramatic effect demonstrated on respiration in null mutant MeCP2 mouse model of Rett syndrome
- Potential additional benefits in other core features of Rett syndrome

Behavior

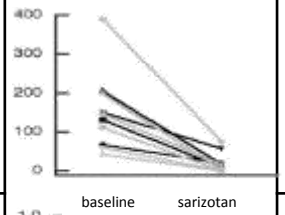
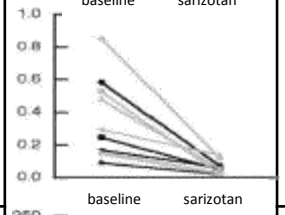
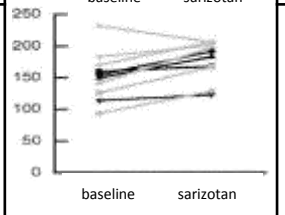
Cognition

Neurological deficits

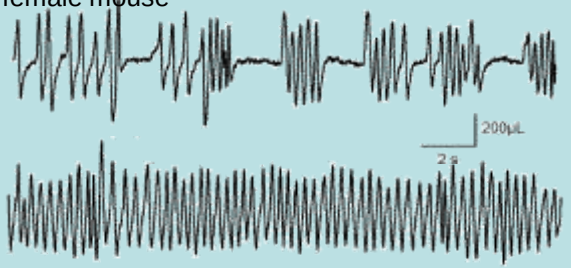


Sarizotan Reduced Respiratory Arrythmia in Pre-Clinical Studies

Effects of single administration of Sarizotan (5 mg/kg ip) in RTT female mice (Mecp2 $^{Jae/+}$ + Mecp2 $^{Bird/+}$)

Outcomes definition and units	Mean baseline data in vehicle treated RTT mice	Mean data in sarizotan treated RTT mice	Data from individual mice	Change vs baseline
Apnea Incidence (number apneas per hour)	143 ± 31	20 ± 8		**↓ by 86% (p=0.001)**
Irregularity score (variance)	0.34 ± 0.07	0.06 ± 0.01		**↓ by 82% (p= 0.0001)**
Respiratory Frequency (breaths per minute)	153 ± 12	177 ± 10		**↑ by 16% (p = 0.012)**

Plethysmograph in a vehicle treated Mecp2$^{Jae/+}$ female mouse



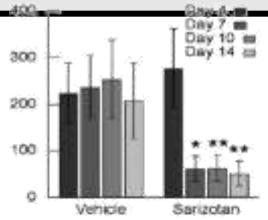
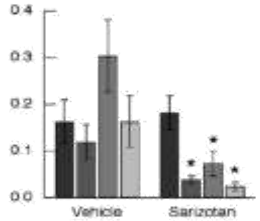
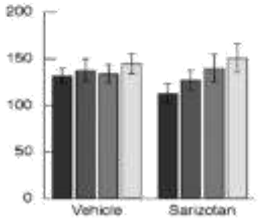
Plethysmograph in the same Mecp2$^{Jae/+}$ female mouse after administration of Sarizotan 5 mg/kg i.p.

Incidence of apnea and irregularity were significantly reduced by sarizotan at 20 mins compared to vehicle

Mecp2 $^{Jae/+}$ n=4
Mecp2 $^{Bird/+}$ n=6

Sarizotan Reduced Respiratory Arrythmia in Pre-Clinical Studies

Effects of 14-day treatment with Sarizotan in RTT female mice (Mecp2$^{R168X/+}$)

Outcomes definition and units	results	Change vs control (vehicle treated) group
Apnea Incidence (number apneas per hour)		**↓ by 73.9% on Day 7 (p < 0.05) ↓ by 75% on Day 10 (p < 0.01) ↓ by 75.6% on Day 14 (p < 0.01)**
Irregularity score (variance)		**significant decrease (p<0.05)**
Respiratory Frequency (breaths per minute)		**ns**

14-day treatment with Sarizotan (13.8 ± 1.9 mg/kg per day) was effective in improving respiration in Mecp2$^{R168X/+}$ female mice

A crossover design was used so that half of the Mecp2$^{R168X/+}$ female mice (n=4) received vehicle (1.25% DMSO + 0.1% saccharin) in their drinking water and half (n=4) received sarizotan (0.0625 mg/ml). At the end of 14 days, the treatment was reversed
30 min monitoring of respiratory pattern with plethysmography performed on the 4th, 7th, 10th and 14th day of vehicle or sarizotan. *p=<0.05, **p=<0.01 vs corresponding day receiving vehicle

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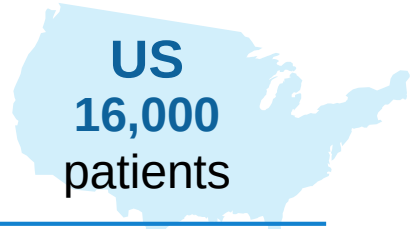
Sarizotan has Clear Clinical Development, Regulatory and Commercialization Path

- EU (Germany, Spain, UK) Health Authorities accepted proposed CMC/preclinical/clinical safety data package, agreed to single pivotal study: Q2/2015
- Similar agreements with Canadian (TPD) and US (FDA): Q2-3/2015
- Orphan Drug Designations obtained in EU and US: July 2015
- Interaction with Pediatric Development Committee (EMA) to extend age range to younger patients: Q3/2015
- Advocacy relationships being developed; Rett foundations for potential funding/co-sponsorship of activities
- ‘Rare Pediatric Disease’ voucher possibility



Orphan exclusivity
7.5 years post approval

Orphan exclusivity
12 years post approval

2016 Major Sarizotan Inititiatives

- Launch of first ever Phase 3 pivotal study in Rett syndrome under a US IND
  - Double-blind, randomized placebo-controlled, 28 week, multi-center design in min. 90 patients
  - Primary endpoint: Reduction in number of objectively defined apnea episodes
- Initiation of Global Caregiver Outreach Program
  - In partnership with Rett foundations
  - Collecting and distributing data on impact of respiratory abnormalities:
    - ER visits, hospitalizations, effect on development, lost school days, feeding problems, staring episodes, worsening of cardiac functioning including QTc abnormalities, cost of treatment
- Development of Caregiver Satisfaction Assessment Instrument
  - together with Rett foundations
- Discussions with Pharmacy Benefit Managers/Pricing and re-imbursement representatives of EU needs for Rett treatments
- Establishing Step guidelines for Rett Syndrome with Rett experts

NW-3509 – Schizophrenia

Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
NW-3509					
Schizophrenia					

NW-3509 Brings New Mechanism to Schizophrenia Treatment

- First in class voltage-gated sodium channel (VGSC) blocker for add-on 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), negative symptoms, mania, depression, obsessive behavior
- IND approval from FDA as add-on to antipsychotics for patients with psychosis
- Phase I study completed
  - Drug was well tolerated
  - Exposure increased with dose
  - Exposure overlaps with exposure in animals at doses proven to be efficacious
- Phase II placebo-controlled study started
- Large market opportunity (anti-psychotic market >$23bn)
- Composition of matter – USPTO, 2013 - Patent life 2028 plus extension

Unique MOA: selective Voltage-Gated Sodium Channel (VGSC) Blocker

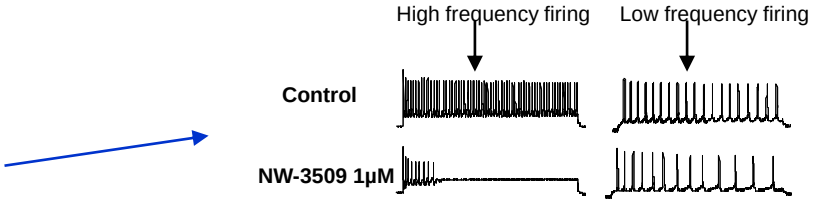
NW-3509

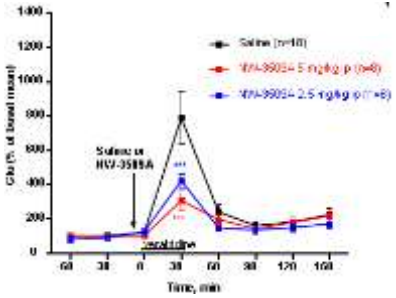
Selectively blocks VGSCs in a voltage-and use-dependent manner

Modulates sustained repetitive firing without inducing impairment of the normal neuronal excitability

Inhibits Glutamate Release

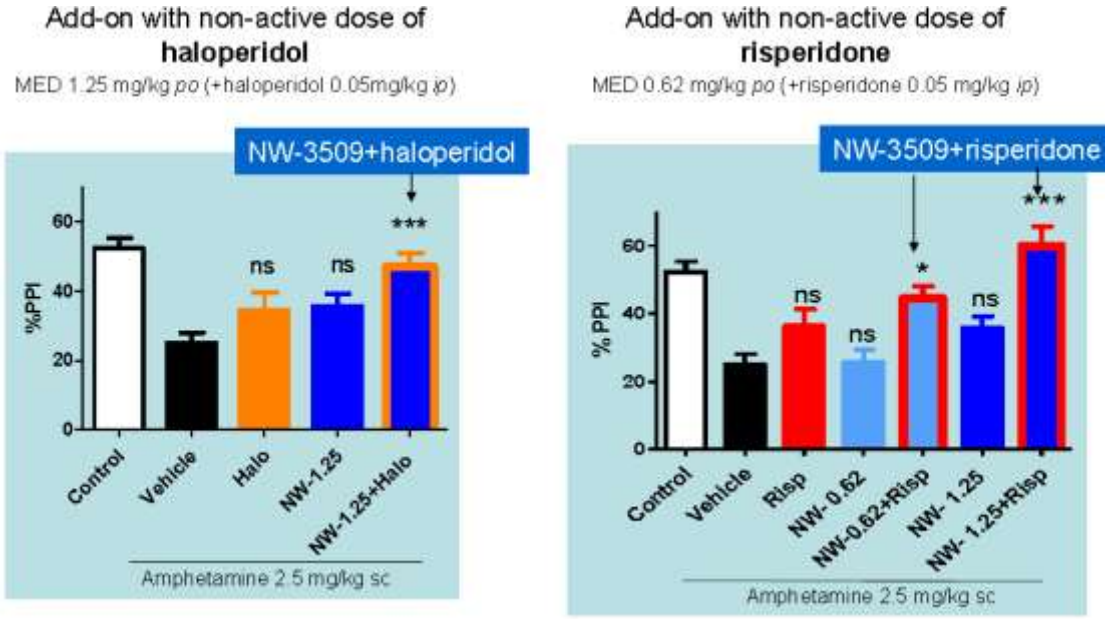
Inhibition of naive sodium channels expressed in rat cortical neurons	
K_{rest} (μM)	K_{inact} (μM)
25	0.4





Add-On: Amphetamine-induced PPI Deficit Model

NW-3509 augments the effect of typical and atypical antipsychotics in amphetamine-induced PPI deficit



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)

Newron

Preliminary Validation of a novel treatment concept

Phase II MTD study with NW-3509 as add-on in positive symptoms of schizophrenia

- NW-3509 as add-on treatment to patients with stable and adequate dose of standard therapy, experiencing break-through symptoms
- Double blind, placebo controlled, randomized, 4-week in/outpatient study in 2 US sites in minimally 60 patients receiving NW-3509 15-25 mg/daily (given BID) or placebo
- Selection Criteria:
  - Current diagnosis of schizophrenia in accordance with DSM-5
  - PANSS (Total) < 80; CGI-S rating of mildly, moderately, or moderately severely ill
  - Excludes patients with hallucinatory behavior, excitement, delusions, suspiciousness/persecution and hostility
  - Endpoints: Symptoms of schizophrenia, as assessed by
    - Positive and Negative Syndrome Scale (PANSS),
    - Clinical Global Impression - Change from baseline (CGI-C) and CGI - Severity of illness (CGI-S)
- Enrollment started: Jan 2016
- Results expected by end 2016

Newron Pharmaceuticals

Milestones/News Flow

2016/2017

Safinamide in PD

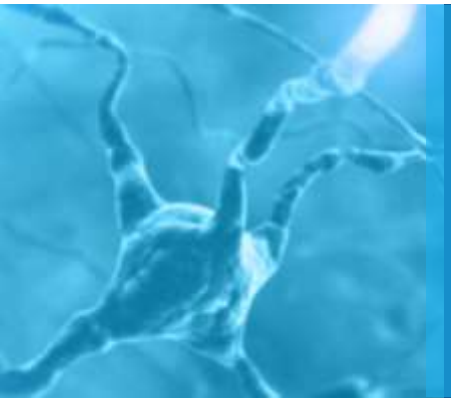
- Market approval/launch
  - EU next launches: **Q1,2/**2016
  - US PDUFA date: **March** 2016
    Launch **Q2/**2016
- US sublicense by Zambon: 2016

NW-3509 in Schizophrenia

- Phase II results **Q4/**2016
- License transaction

Sarizotan in Rett syndrome

- Phase II/III pot. Pivotal efficacy study initiate: **Q1/**2016
- Results from Phase II/III pot. pivotal study: 2017
- Commercialization by Newron: 2018

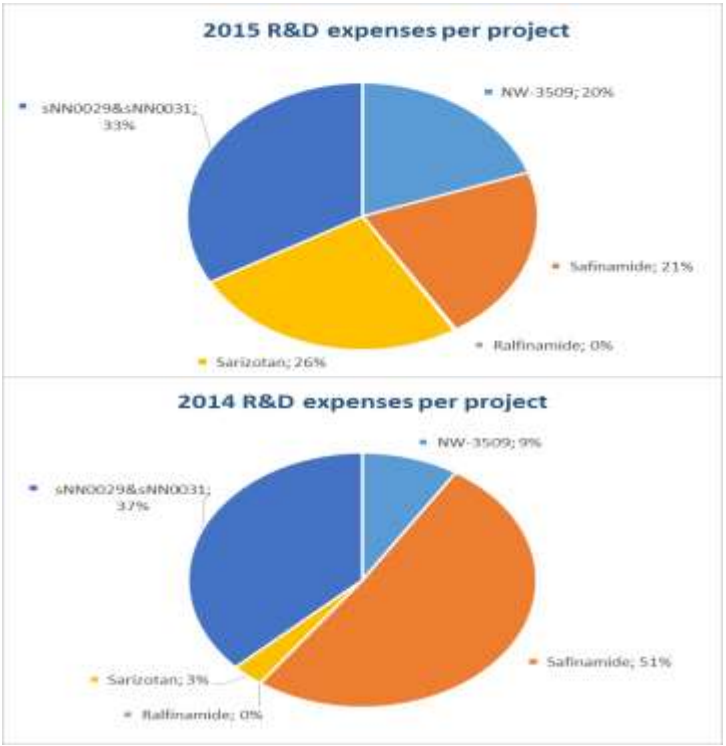


Group Consolidated Financials 2015 (IFRS)

Financial Highlights 2015 – Income statement

- First time ever, Newron P/L shows royalties (German sales from May 15, 2015 on)
- Substantial increase in R&D investments

€/000	2015	2014
Licence income	1,800	1,300
Royalties	475	0
Other income	105	257
Research and development expenses	**(18,449)**	**(6,017)**
Marketing and advertising expenses	(53)	(53)
General and administrative expenses	(8,278)	(6,702)
Operating loss	**(24,400)**	**(11,215)**
Financial result, net	(583)	492
Income tax	2,167	628
Net loss	**(22,816)**	**(10,095)**
Loss per share	**(1.66)**	**(0.80)**



Financial Highlights 2015
Balance Sheet and Cash flow statements

	2015	2014
Net cash used in operating activities	(12,862)	(9,998)
Net cash flows from/(used in) investing activities	2,085	(6,860)
Net cash flows from/(used in) financing activities	28,032	17,188
Net increase/(decrease) in cash and cash equivalents	17,255	330

	2015	2014
Non-current assets	406	7,686
Current assets	43,974	29,388
Total shareholders' equity	37,112	29,261
Non-current liabilities	755	3,324
Current liabilities	6,513	4,489

- Cash used in operating activities below 2015 losses
- Total funds available: €41m (beyond key value inflexion points)

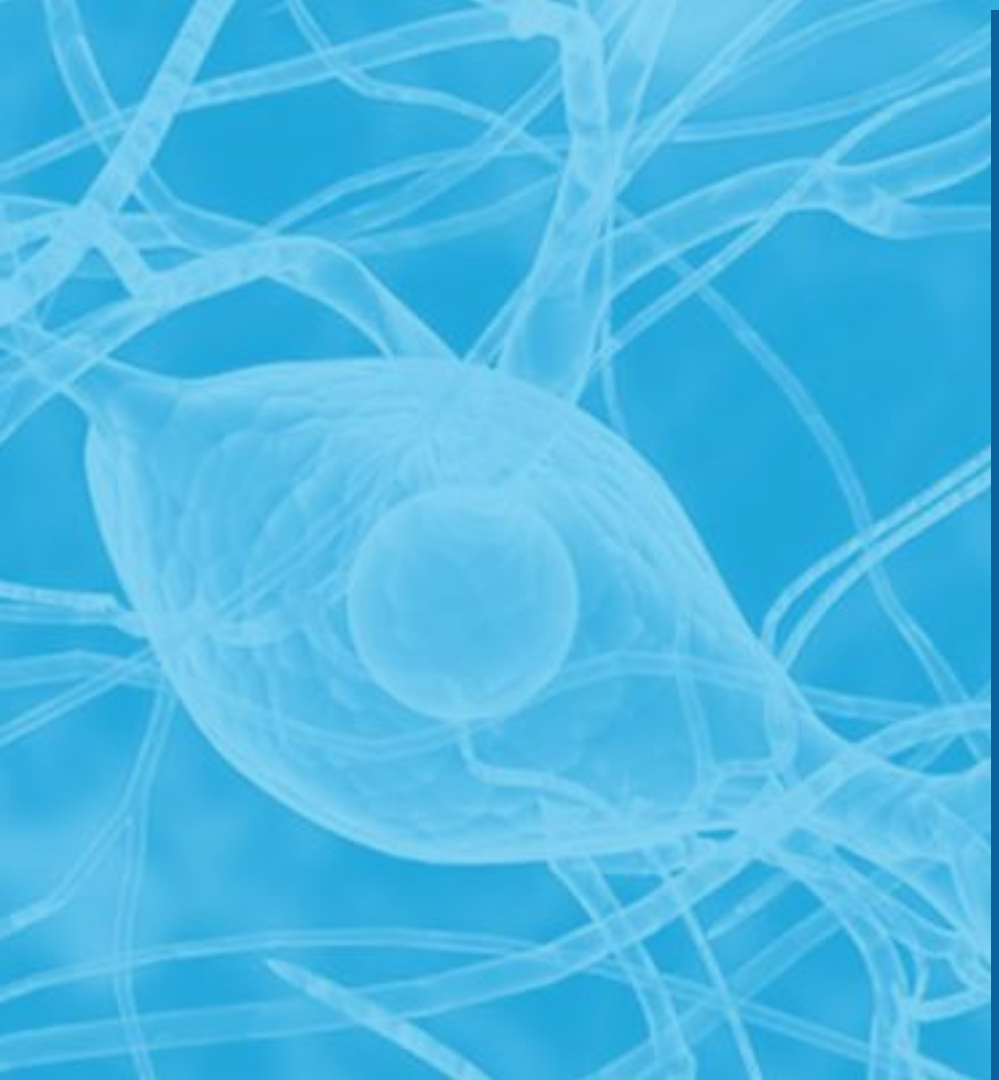
- Current assets increased because of capital increases (newly issued shares and options' exercise)

AGM/EGM March 22, 2016

AGENDA

- Approval of the balance sheet as at 31 December 2015
- Appointment of the statutory auditors for the three year time 2016-2018
- Appointment of the auditing company for the period 2016-2018
- Share capital increase pursuant to article 2443 of the Civil Code, in one or more time, severally (*in via scindibile*), even with the exclusion of the option right pursuant to article 2441, parts 4, first section, 5, 6 and/or 8 of the Civil Code, provided that in the whole the increases in the share capital can be executed for a maximum par value not higher than Euro 711.177,20 and therefore for a maximum of n. 3.555.886 ordinary shares
- Share capital increase pursuant to article 2420-ter of the Civil Code, to issue convertible bonds in one or more time, severally (*in via scindibile*), even with the exclusion of the option right pursuant to article 2441, part 5 and 6 of the Civil Code, provided that in the whole the increases in the share capital can be executed for a maximum par value not higher than Euro 711.177,20 and therefore for a maximum of n. 3.555.886 ordinary shares
- Increase in the share capital, severally (*in via scindibile*), for payment, with the exclusion of the option right, within the limit of 10% of the share capital pursuant to article 2441, part 4, second section, of the Civil Code, provided that in the whole the increases in the share capital can be executed for a maximum par value not higher than Euro 711.177,20 and therefore for a maximum of n. 3.555.886 ordinary shares
- Subject to approval and execution, even partial, of resolutions under points 4, 5 and 6 above, revocation:
  - of the resolution adopted on 27 March 2014, drafted by Notary Public Filippo Zabban of Milan, rep. 66.143/11.351 granting to the Board of Directors, pursuant to article 2443 of the Civil Code, the power, within 27 March 2019, to increase the share capital for payment, severally (*in via scindibile*), in one or more time, up to a maximum par value of Euro 375,844.00 and therefore up to maximum no. 1,879,220 Newron Pharmaceuticals S.p.A. ordinary shares having the same characteristics of the already issued ones, with exclusion of the option right pursuant to Article 2441, part 5, of the Civil Code;
  - of the resolution adopted on 2 April 2010, minuted by Notary Public Stefano Rampolla of Milan, rep. 34893/8887, upon the several (in via scindibile) share capital increase in option up to a maximum par value of Euro 375,844.00 through the issuance of maximum no. 1,879,220 ordinary Newron Pharmaceuticals S.p.A. shares

Q&A



Newron
Pharmaceuticals