Newron Pharmaceuticals SpA SIX: NWRN

Corporate presentation

March 2015

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About Newron Pharmaceuticals

- ~$475M 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
  - Accepted for filing by the FDA March 2,2015
- Material revenues from license agreements
- Moving towards a U.S.-based, CNS-specialty, commercial orphan company

Licensing Revenues

- Xadago® (safinamide) add-on therapy for Parkinson's disease (PD)
- Multiple development-stage assets
- Phase II-ready asset for schizophrenia

Phase II Orphan Drug Portfolio

- Rett syndrome
- Treatment resistant PD
- ALS
- 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

Newron

Pipeline Overview

Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
Safinamide[1]					Zambon
Adjunctive to dopamine agonist early-stage PD					Meiji Seika
Adjunctive to levodopa mid-to late-stage PD					
Sarizotan[3]					Yes
Rett syndrome					
sNN0031[2]					Yes
Orphan indication in PD					
sNN0029[2]					Yes
ALS					
NW-3509[1]					Yes
Schizophrenia					
Ralfinamide[1]					Yes
Orphan indication in neuropathic pain					

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

[2] sNN0031 and sNN0029 acquired by M&A

[3] Sarizotan was licensed from Merck Germany

Valuable Assets with Licensing and Commercial Opportunities

Safinamide

- Marketing Authorizations
  - EU: Feb. 24, 2015
  - Switzerland: 2015
  - US Q4: 2015
- Material revenue generating licenses with:
  - Zambon
  - Meiji Seika in Japan/ Asia
- Licensed worldwide; U.S. sublicenses pending
- Peak sales potential $540 to $650M

Licensed

NW-3509

- Schizophrenia
- World-wide anti-psychotic market: $23B
- Initiate Phase II in Q2:2015

Licensing Opportunity

Sarizotan

- Rett syndrome
- Orphan patient population: 35K-40K in U.S. and EU
- Initiate Phase 2 pilot efficacy study in Q3:2015
- Prepare for Phase II/III pivotal trial

sNN0031

- Severe, treatment-resistant PD
- Orphan patient population: 180K in U.S and EU
- Phase II study initiated in Jan. 2015

sNN0029

- Amyotrophic lateral sclerosis (ALS)
- Orphan patient population: 50K in U.S. and EU
- Phase II study initiated Jan. 2015

Plan: Launch First Orphan Product by 2017; Licensing potential

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

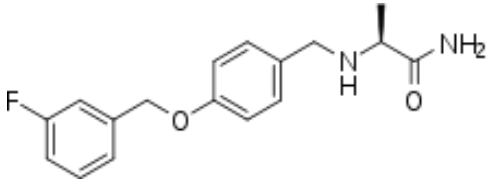
Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
Safinamide					
Adjunctive to dopamine agonist early-stage PD					Zambon
Adjunctive to levodopa mid-to late-stage PD					Meiji Seika

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

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

First PD therapy working through dual mechanism

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; potential new ATC, as 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)

Xadago® (safinamide) Shows Potential to Benefit Parkinson's Patients at All Stages

Current PD Paradigm

Early stage (mild) → Mid to late stage

Dopamine agonist

- First-line treatment in early patients, efficacy decreases over time, significant side-effects

Levodopa + adjunct

- Associated with dyskinesia, ON/OFF periods and other major side effects

Safinamide Enhances Existing Treatment Paradigm

Early stage (mild) → Mid to late stage

Dopamine agonist	Dopamine agonist + safinamide	Levodopa + (adjunct +) safinamide
	• Enhances dopamine agonist effects • Delays levodopa use	

Delay the use of levodopa as long as possible;
once you use levodopa, dose as low as possible

20 to **30** percent in early stage

70 to **80** percent in mid to late stage

>$4 Billion
worldwide market

Xadago® (safinamide) Offers Multiple Benefits to PD Patients w/ Duration of Effect

Early PD Patients – add to dopamine agonist

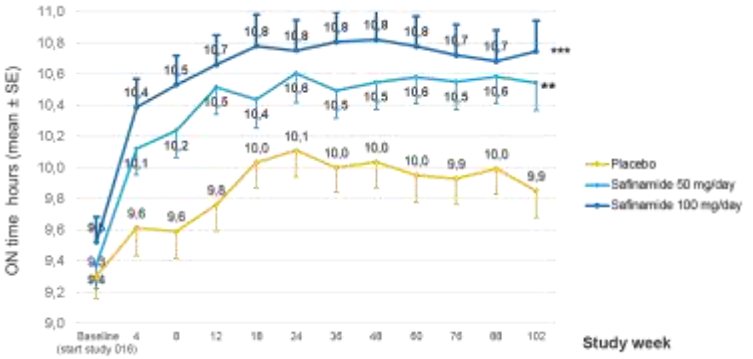
- Significant improvement of
  - UPDRS III - motor function, regulatory endpoint (mean change, responder rate)
  - Quality of life (PDQ-39, EQ5D)
- Reduction of number of interventions (first time use of L-dopa)
- Benefits seen after 6 and 18 months
- Delay levodopa

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)

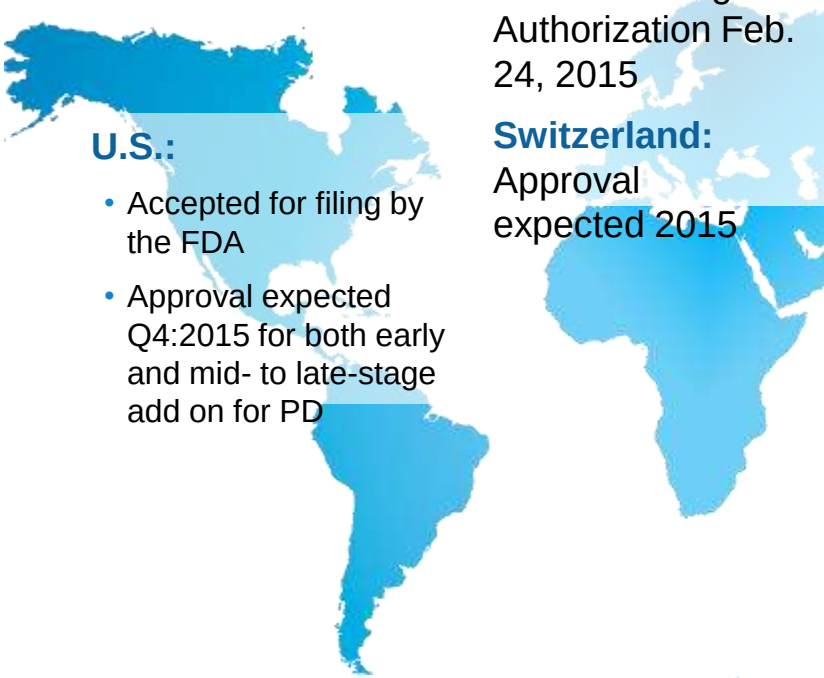
Double blind (DB) extension study

✓ Completed & positive

Xadago ® (safinamide) – Approved in EU U.S. Approval Expected End 2015

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



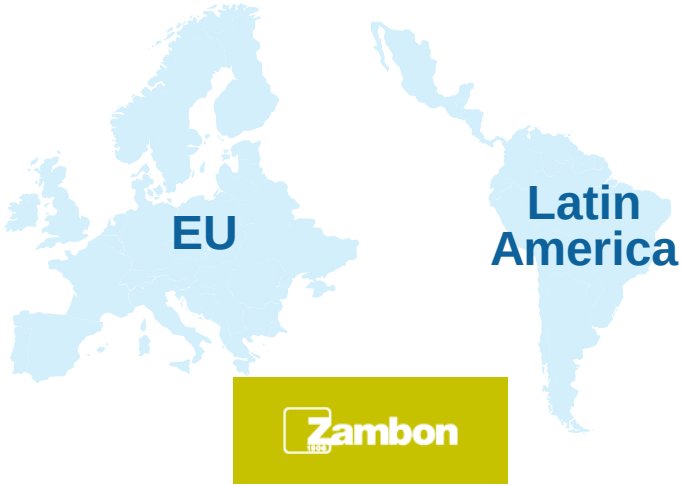
U.S.:

- Accepted for filing by the FDA
- Approval expected Q4:2015 for both early and mid- to late-stage add on for PD

EU: Marketing Authorization Feb. 24, 2015

Switzerland: Approval expected 2015

Xadago ® (safinamide) – Commercial Opportunity



Zambon

Identifying parties for regional sublicensing

Milestone and royalty revenues to Newron since 2012

Long lasting market exclusivity (patent life: 2029 in both EU and U.S.)

Newron

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)

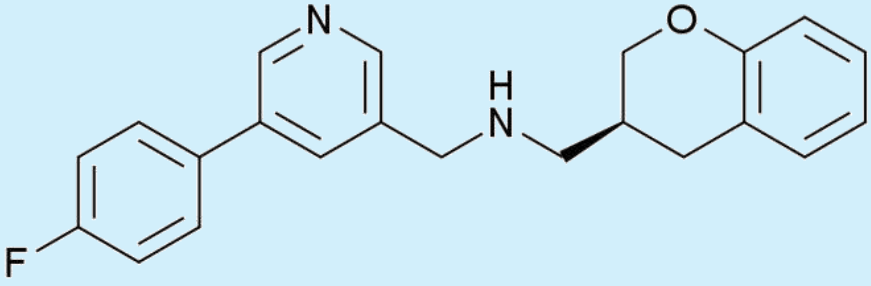
Sarizotan Has Potential to Treat Respiratory, Other Symptoms

- 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 $5HT_{1A}$ receptors, partial agonist / antagonist at 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

Behavior

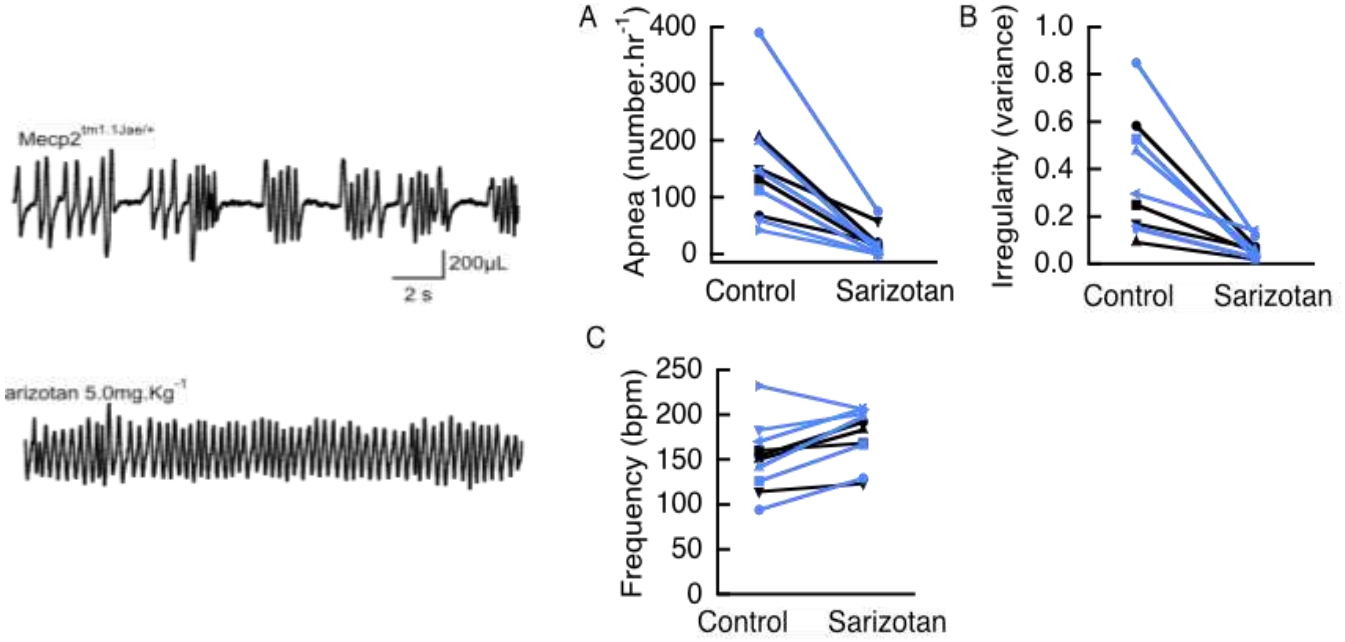
Cognition

Neurological deficits



Sarizotan Reduced Respiratory Arrythmia in Pre-Clinical Studies

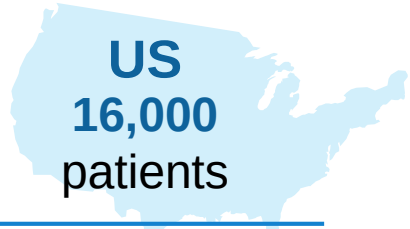
Effect of 5mg/kg ip of sarizotan on respiratory pattern in heterozygous females



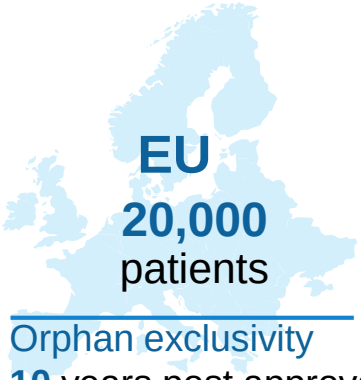
Reduced the incidence of apnea in **MeCP2 deficient mice** of ~85% of their pre-treatment levels. In addition, the irregular breathing pattern, characteristic of RTT subjects and mouse models was corrected to that of wild type (WT) littermates

Sarizotan has Clear Clinical Development, Commercialization Path

- Gain regulatory acceptance of CMC/preclinical/clinical safety data package and agreement to accept single positive study for approval Q2:2015
- Advocacy relationships being developed; Rett Foundation for potential funding/co-sponsorship of trials
- Double blind, placebo-controlled pilot study evaluating respiratory symptoms (EU/U.S. centers) Q3:2015
- Phase II/III single potentially pivotal study
  - Double blind, placebo-controlled, multi-center, randomized
  - Total duration 24 weeks, approx. 60 patients
  - Start 2015, reporting 2016



Orphan exclusivity
7 years post approval



Orphan exclusivity
10 years post approval

NW-3509 – Schizophrenia

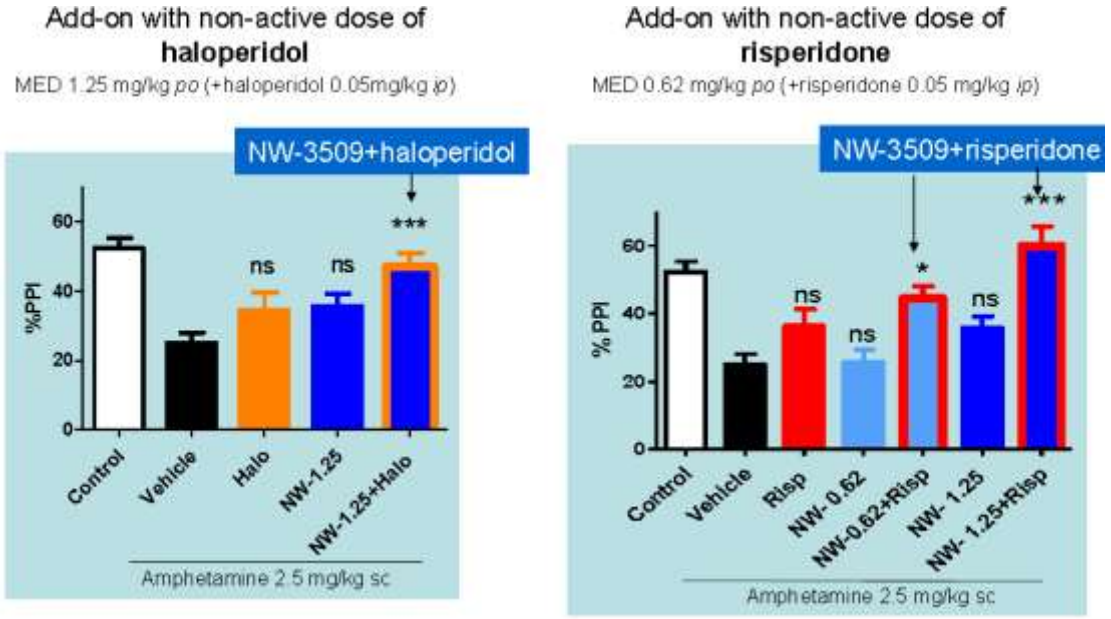
Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
NW-3509					
Schizophrenia					

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) 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 to start first half 2015
- Large market opportunity (anti-psychotic market >$23bn)
- Composition of matter – USPTO, 2013 - Patent life 2028 plus extension

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)

Additional Orphan Pipeline Programs

Products	Preclinical	Phase I	Phase II	Phase III	Commercial Rights
sNN0031 Orphan indication in PD					
sNN0029 ALS					
Ralfinamide Orphan indication in neuropathic pain					

- sNN0031 – severe, treatment resistant Parkinson's disease (orphan)
- sNN0029 – Amyotrophic lateral sclerosis (ALS) (orphan)
- Ralfinamide – Neuropathic pain (orphan)

Business Development: Outlicensing Assets, In-licensing CNS Orphan Assets

- Driven to deliver effective treatments to patients living with debilitating neurodegenerative diseases
- Funded through material licensing revenues and milestone payments
- Building commercial biopharmaceutical company and launching at least one orphan CNS drug in U.S.

Licensing Revenues

- Xadago® (safinamide) add-on therapy for Parkinson's disease (PD)
- Multiple development-stage assets
- Phase II-ready asset for schizophrenia

Phase II Orphan Drug Portfolio

- Rett syndrome
- Treatment resistant PD
- ALS
- Orphan neuropathic pain

Milestones/News Flow

2015/2016

Safinamide in PD

- Market approval/launch
  - EU launch **Q1**: 2015
  - CH 2015
  - US approval **Q4**: 2015; Launch **Q1**: 2016
- US sublicense by Zambon: 2015

NW-3509 in Schizophrenia

- Phase II initiate **Q2**:2015
- Phase II results **1H**:2016
- License transaction

sNN0029 in ALS

- Initiated in Jan. 2015
- Results from Phase II safety and exploratory efficacy study at higher dose 2016

sNN0031 in PD

- Initiated in Jan. 2015
- Results from Phase II safety and exploratory efficacy study 2016

Sarizotan in Rett syndrome

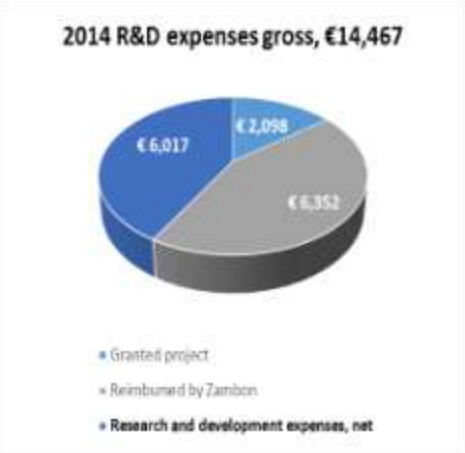
- Results from Phase II pilot efficacy study **Q1**: 2016
- Start of Phase II/III potentially pivotal study **Q4**: 2015

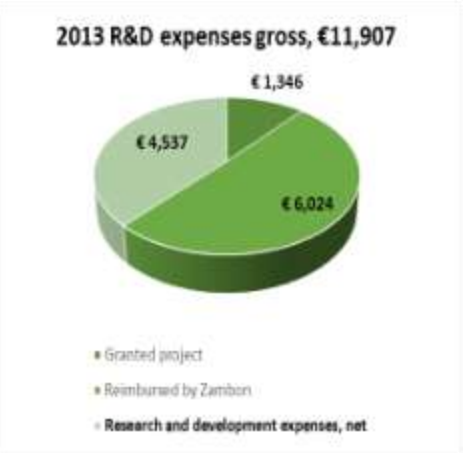
Group Consolidated Financials 2014 (IFRS)

Financial Highlights 2014 – Income statement

- License income EUR1.3m (2013: EUR3.2m) – milestone received from Zambon SpA upon filing of a the NDA for safinamide (May 2014) and down-payment under Zambon 2012 license/collaboration agreement (final tranche)
- Income tax is a consequence of Hunter Fleming HF0220 write-off

€/000	2014	2013
Licence income	1,300	3,213
Other income	257	326
Research and development expenses	**(6,017)**	**(4,537)**
Marketing and advertising expenses	(53)	(15)
General and administrative expenses	(6,702)	(6,763)
Operating loss	**(11,215)**	**(7,776)**
Financial result net	492	63
Income tax	628	615
Net loss	**(10,095)**	**(7,098)**
Loss per share	**(0.80)**	**(0.62)**





Financial Highlights 2014
Balance Sheet and Cash flow statements

- Total funds available: €27,7m
  - Cash position at year end 2014: €18.8m
  - Available for sale financial asset – current: €6.9m
  - Commitments by third parties at Dec 31, 2014: €2.0m
- Cash reach: 2Q 2016, beyond key value inflexion points

	2014	2013
Net cash (used in) operating activities	(9,998)	(10,686)
Net cash flows from/(used in) investing activities	(6,860)	226
Net cash flows from/(used in) financing activities	17,188	(357)
Net increase/(decrease) in cash and cash equivalents	330	(10,817)

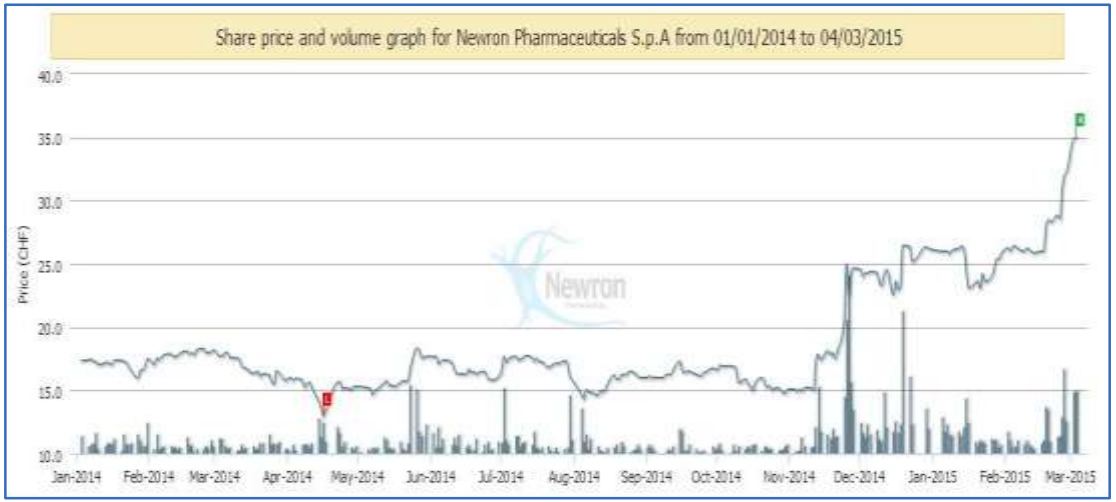
Financial Snapshot

Shares Outstanding
13,092,850

Market Cap
456.9 Million CHF
476.1 Million USD

52-week
High: 34.90 CHF ($36.37)
Low: 12.65 CHF ($13.33)

Liquidity of Stock 67,500/day
average trading volume



Main shareholders and analysts

Shareholder	%
Investor AB	12,72%
Zambon	11,34%
Aviva	7,98%
JP Morgan	4,67%
Omega	2,58%
Abingworth	1,67%
TVM	1,46%
Polar	1,06%
SWISSCANTO	0,99%
Trowe	0,75%
GWEISS	0,57%
Deka	0,49%
TAVAU	0,38%

Analyst Coverage

- Bruno Bulic, Bank Vontobel AG
- Bob Pooler, Valuation Lab
- Samir Devani, Rx Securities
- Philippa Gardner, Edison Investment Research

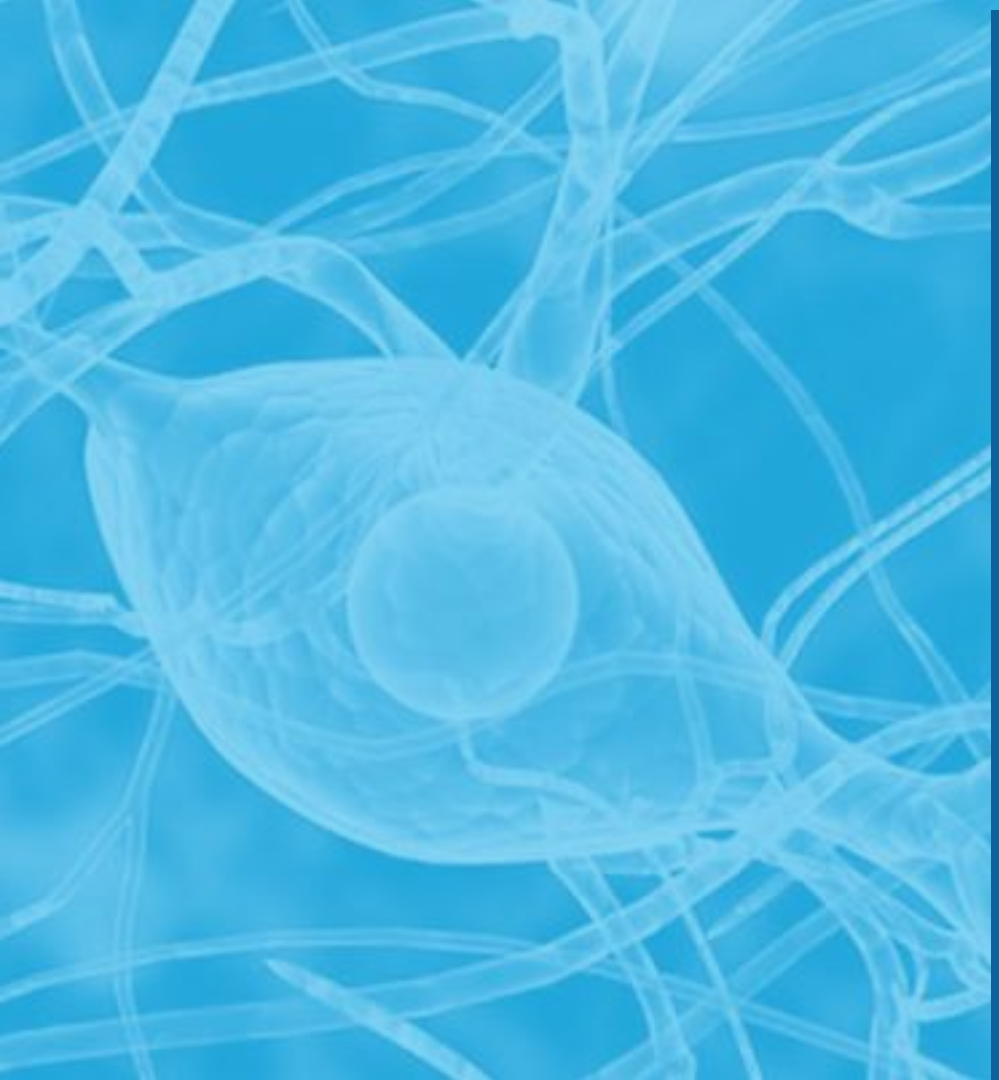
AGM March 24, 2015

24 March 2015

AGENDA

- Approval of the financial statements as at December 31st, 2014
- Share capital increase for payment, severable, with exclusion of the option right, for maximum nominal Euro 260,850, and therefore, for maximum n. 1,304,250 Newron Pharmaceuticals S.p.A. ordinary shares and, in any event, within the limits of the 10% of the share capital in accordance with article 2441, paragraph fourth, second part, of the Italian Civil Code and with article 6 of Company's By-Laws. Amendment of the article 6 of Company's By-Laws.
- Share capital increase for payment, severable, with exclusion of the option right, in accordance with article 2441, paragraphs 5 and 8, of the Italian Civil Code, for maximum nominal Euro 80,000, and therefore, for maximum n. 400,000 Newron Pharmaceuticals S.p.A. ordinary shares, nominal value Euro 0.20 each, to serve one or more stock incentive plans.

Q&A



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