SUCCESS IN CNS DRUG DEVELOPMENT – INNOVATION IN RARE DISEASES

Corporate Presentation | October 2016

Newron
Pharmaceuticals

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Newron Leadership Team

STEFAN WEBER
CEO

- 30 years of experience
- Previously worked at: Lohmann Group, Girindus and Biofrontera

RAVI ANAND
CMO

- >30 years of experience
- Previously worked at: Roche (CH), Sandoz (US), Novartis and Organon (NL)

ROBERTO GALLI
Vice President Finance

- 20 years of experience
- Previously worked at: Coopers & Lybrand and PricewaterhouseCoopers

MARCO CAREMI
EVP Business Development

- >35 years of experience
- Previously worked at: Schwarz Pharma and Schering-Plough

Anders Haegerstrand
General Manager

- >16 years of experience
- Previously worked at: NeuroNova, Karolinska Institute, Astra Pain Control and AstraZeneca

NON-Executive Chairman of the Board of Directors

ULRICH KÖSTLIN:
Former Executive at
Bayer Schering Pharma AG

DENNIS DIONNE
Executive Director, Commercial Operations

- >26 years of experience
- Previously worked at: Novartis and Johnson & Johnson

STEPHEN GRAHAM
Executive Director, Clinical Development

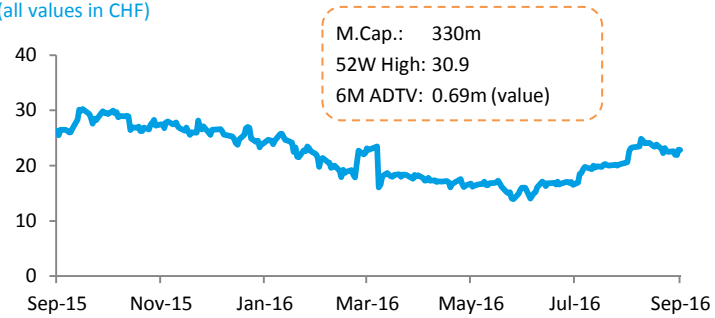
- 30 years of experience
- Previously worked at: Boots Pharmaceuticals, Sandoz/ Novartis and Forest Laboratories/ Forest Research Institute

Company Snapshot

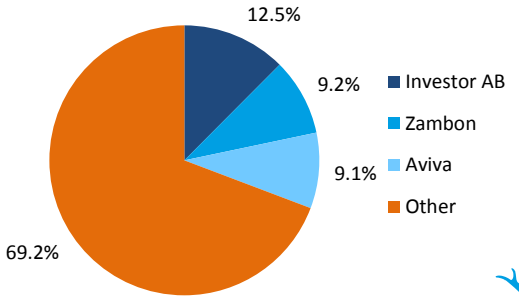
- 3 novel CNS product candidates
  - Already generating royalty revenues from PD product via partnership with Zambon in Europe
  - Sub-licensing agreement with US WorldMeds for USA, expected to generate revenues once regulatory approval received
  - Significant upside opportunity with orphan drug development for Rett Syndrome
  - Proprietary discovery project for treating Schizophrenia
- Total Revenues (HY June 2016): €3.9m (HY2015: €2.0m)
  - Licence income: €3.0m (HY2015: €1.8m)
  - Royalties: €0.9m (HY2015: €0.1m)
- Headquarters: Bresso/Milan, Italy
- Subsidiary: Morristown, NJ USA

SIX:NWRN LTM Share Price Performance(1)

(all values in CHF)



Key Shareholding(2)

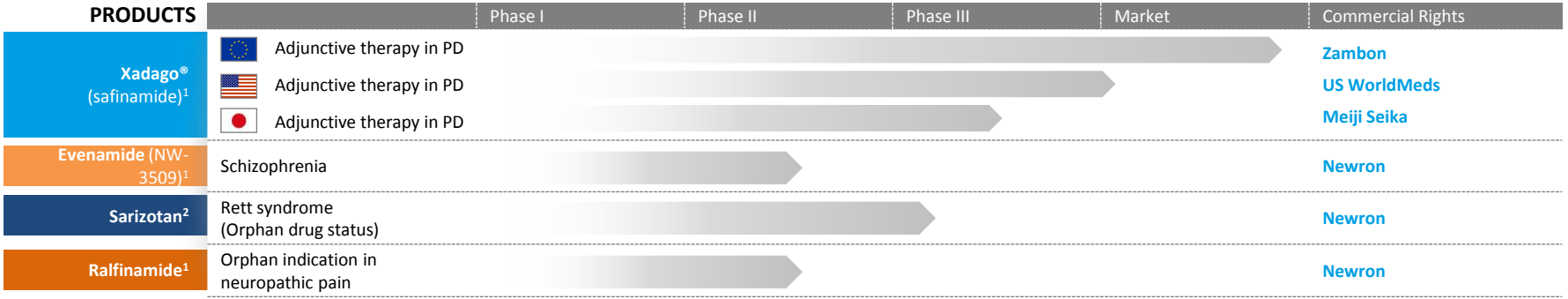


(1) Capital IQ as of 23 Sep, 2016
(2) Company filings, SIX filings

Company Highlights

1. Diversified Portfolio of Innovative CNS Product Candidates
2. Xadago® - Commercialized in 11 Countries with Clear Path to US Registration
3. Sarizotan for Rett Syndrome in Late Stage Development
4. Evenamide® - a Novel Mechanism to Address Schizophrenia
5. Multiple Catalysts on the Horizon
6. Management Team with Proven Track Record

Innovative Clinical Pipeline with Multiple Near Term Catalysts



Expected Milestones

Xadago: **further EU launches expected in H2 2016; re-submitted NDA to US FDA in September 2016**

Evenamide: **Phase II results Q4 2016; licensing**

Sarizotan: **potentially pivotal study commenced July 2016; results Q1 2018; commercialization 2018**

Ongoing search for strategically-relevant assets to in-license

1 Safinamide, NW-3509 and Ralfinamide all developed from Newron's ion channel based research
2 Sarizotan was licensed from Merck KGaA

Pipeline Expansion Targets

- Strategic field of search
  - CNS and pain with priority on orphan & pediatric indications
    (non-CNS orphan opportunities may be considered depending on the indication)
- Targets
  - Compounds from small biotech with preclinical package almost completed
  - Generic drugs to be repositioned in new indications with limited preclinical work to perform
  - Clinical stage (Ph. II or III) compounds failed during development to be repurposed in other indications
  - Commercial stage products requiring development and regulatory optimization
- Opportunities should meet Newron's plans to directly commercialize its pipeline (preferably in the US)

Successful Track Record in CNS Product Development

NOVEL CNS PRODUCT CANDIDATES

Xadago®

…(safinamide) commercialized in 11 European markets for Parkinson's disease (PD); in late stage regulatory approval for US market

Newron receives milestone and royalty payments from sales of safinamide in PD

Sarizotan

Developing Sarizotan for Rett syndrome, an orphan disease, in a potentially pivotal trial ongoing

Opportunity to commercialize Sarizotan for Rett syndrome directly

Evenamide®

…(NW-3509) in Phase II trial in patients with schizophrenia

Opportunity for out-licensing Evenamide for schizophrenia

… INNOVATION
in rare diseases

Xadago®: 1st New Chemical Entity Approved in US or Europe in a Decade for Parkinson's Disease

A progressing disorder, no cure available yet

- PD 2nd most common chronic progressive neurodegenerative disorder in the elderly
- Affecting 1-2% of individuals aged ≥ 65 years worldwide

First PD therapy working through dual mechanism

EARLY PD PATIENTS – add-on 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
- Benefits seen after 6 and 18 months
- Delay levodopa

MID- TO LATE-STAGE PD PATIENTS – add-on 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

Sources:
- Parkinson's Disease – Global Drug Forecast and Market Analysis – Event-Driven Update -GlobalData, June 2015
- Parkinson's Disease Foundation: Statistics on Parkinson's
- Treatment of Advanced Parkinson's Disease, Varanese et al., 2010, NCBI

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Xadago® (Safinamide) Approved and Launched in Europe for the Treatment of Parkinson's Disease

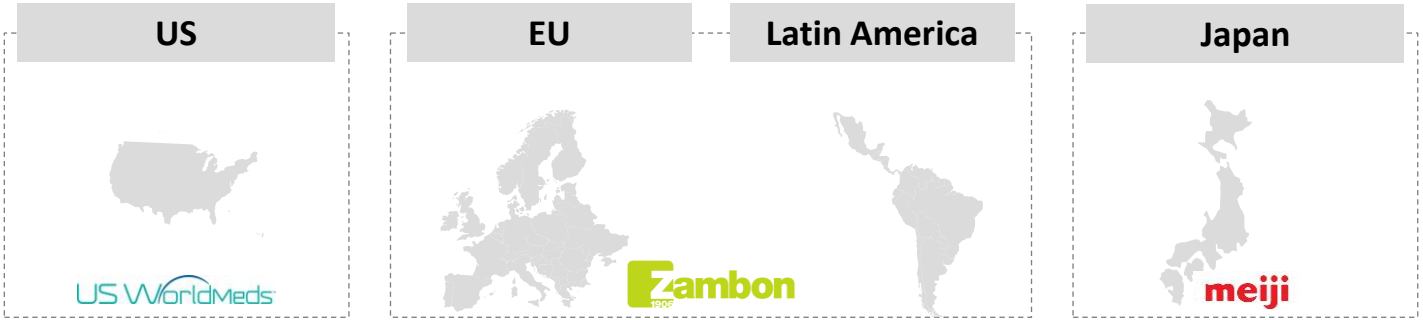
EU MARKETING AUTHORIZATION (RECEIVED FEBRUARY 2015)

- 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)
- Well tolerated
- No drug interactions; no age, gender or race restrictions
- No dietary restrictions
- No requirement for laboratory tests, ECG, or any other examination

ANTICIPATED PATH TO US APPROVAL

- FDA agrees no additional evaluation of abuse liability or dependence / withdrawal effects in humans is required
- NDA re-submitted Sept 2016:
  Class II re-submission – 6 month review

Significant Commercial Opportunity in Safinamide (Xadago®)



7 to 10 million world wide

20 to 30 percent in early stage

70 to 80 percent in mid to late stage

>$4 Billion worldwide market

Milestone and royalty revenues to Newron since 2012

Long period of market exclusivity (patent life: 2029 in EU, 2031 in the U.S.)

Launched in Germany, UK, Italy, Spain and other EU territories, plus Switzerland
US: Re-submitted to US FDA in September 2016

Peak sales potential $450m - $700m+ (analyst estimates)

Sources:

- Rx Securities report, Sep 2016 and VALUATIONLAB report, Jun 2016
- Parkinson's Disease – Global Drug Forecast and Market Analysis – Event-Driven Update – GlobalData, June 2015
- Parkinson's Disease Foundation: Statistics on Parkinson's
- Treatment of Advanced Parkinson's Disease, Varanese et al., 2010, NCBI

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Rett Syndrome: Severe Neuro-developmental Orphan Disease with No Specific Treatment Options

- 95-97% of patients have spontaneous mutations in the X-linked MeCP2 gene
- Disease manifests almost exclusively in females with one affected X-chromosome
- Normal development until 6-18 months of age, then loss of skills and ability for social interaction
- Respiratory abnormalities, motor and severe intellectual impairment, sleep abnormalities and seizures in most patients (70-90%)
- 25% of sudden deaths in RTT linked to cardio-respiratory abnormalities
- Focus on symptom management
- Estimated 36,000 patients in US and EU combined

Sarizotan: Targeting Respiratory Disturbances in Rett Syndrome Patients

- First RTT drug candidate targeting respiratory disturbances as primary efficacy outcome
- Deficits in serotonergic transmission due to the MeCP2 mutation in the mid-brain nucleus underlie the respiratory abnormalities in MeCP2 deficit mice
- Sarizotan, a full agonist at the serotonergic 5HT1A receptor, has demonstrated dramatic improvement of respiration in genetic (MeCP2) mouse model of RTT
- Development path/regulatory requirements for approval agreed upon with FDA/EMA/HPB; clear commercialization strategy
- Orphan drug designation in EU and US
- Potentially pivotal STARS study initiated July 21, 2016

EFFECTS OF 14-DAY TREATMENT WITH SARIZOTAN IN RTT FEMALE MICE ($MECP2^{R168X/+}$)

Apnea in MeCP2-deficient mice

Apnea in MeCP2-deficient mice treated with Sarizotan 5.0 mg/kg

STARS: First Ever International Phase III Potentially Pivotal Study in RTT

- Randomized, double blind, placebo-controlled, 6 months' treatment study under US IND
- Will enroll minimally 129 RTT patients , 13 years or older who experience at least 10 apnea episodes of >10 sec/ hour as verified by a validated device over at least 3 hours of recording time while patient is awake and at home
- Primary endpoint: percent reduction in number of objectively defined clinically significant (>10 sec) apnea episodes over an extended period of time
- Centres of excellence in the United States, Italy and India
- Study protocol designed in accordance with regulatory authorities in the United States, Europe and Canada
- Expected completion Q1 2018

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Sarizotan Market Opportunity Commercialization by Newron

Initiation of a Health Economic Outcome Research Study (HEOR) → ”burden of illness”

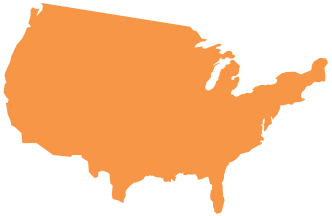
- Fostering partnership and collaborations with Rett advocacy, thought leaders & governing payers
- Global survey to quantify the ways in which patient “respiratory breathing abnormalities” affect daily life
- Meets Health Technology Assessment (HTA) requirements, including European Network of countries requiring information for treatment access

Goals

- Identify gaps & unmet need for improving disease management
- Align economic & clinical outcomes
- Create awareness to breathing abnormality burden
- Optimize market uptake, access, reimbursement
- Build Newron leadership

Rare pediatric disease voucher possibility

US 16,000 patients



Orphan exclusivity
7.5 years post approval

EU 20,000 patients

Orphan exclusivity
12 years post approval

Sources:
- RettSyndrome.org Foundation
- National Institute of Health – NINDS
- US Census Bureau, 2012
- Eurostat Census, 2011

No Effective Treatment that Reduces Burden of Schizophrenia in Last 20 Years

- Onset of disease occurs in early adulthood affecting 1% of the population worldwide
  - Need for life-long treatment
- Disease characterized by either positive or negative symptoms or both:
  - Hallucinations, delusions, paranoia and disorganized speech (positive)
  - Progressive deterioration of cognition and behavior & presence of negative symptoms such as apathy, lack of emotion, socially inappropriate behavior and lack of ability to feel contentment
- High rates of suicide, multiple physical illnesses and lower life expectancy

- Efficacy of current treatment options insufficient
  - Typicals (e.g. haloperidol) less effective against negative symptoms and can cause neurological side effects
  - Efficacy limited and wanes over 18 months; 60-70% of patients switch but without additional benefit

Source: FiercePharma, 2011

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Evenamide (NW-3509): Novel MOA to Benefit Poorly Responding Schizophrenia Patients

- First-in-class voltage-gated sodium channel (VGSC) blocker for add-on treatment in schizophrenia, schizo-affective and bipolar disorders
  - Small molecule, orally available, rapid onset of action, high availability in the brain
- Unique mechanism of action (MoA):
  - Selectively blocks VGSCs in a voltage- and use-dependent manner – no effect on dopaminergic, serotonergic, histaminergic neurotransmission
  - Modulates sustained repetitive firing without impairment of normal neuronal excitability
  - Reduces stimulated glutamate release
- Benefit shown in models of positive symptoms, aggression, cognition (schizophrenia), negative symptoms, mania, depression, obsessive behavior
- IND approval from FDA as FIRST EVER ADD-ON TO ANTIPSYCHOTICS for patients with positive symptom schizophrenia
  - Improvement of symptoms in patients not responding to current treatments
- Well tolerated in Phase I study
  - Exposure increased with dose; exposure achieved overlaps with plasma levels in animals at doses proven to be efficacious
- Composition of matter – USPTO, 2013 - patent life 2028 plus extension

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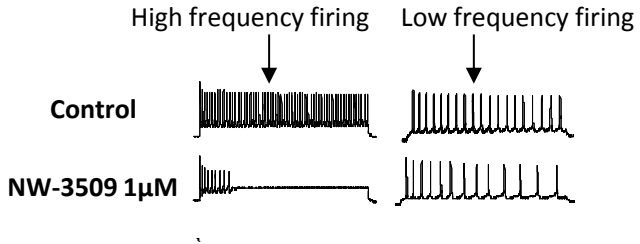
Unique MOA Demonstrated

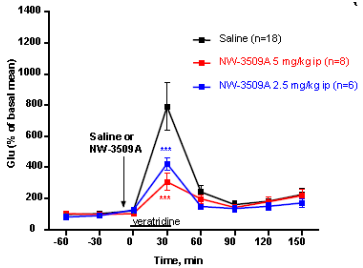
NW-3509 may be considered a selective Voltage-Gated Sodium Channel (VGSC) Blocker

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



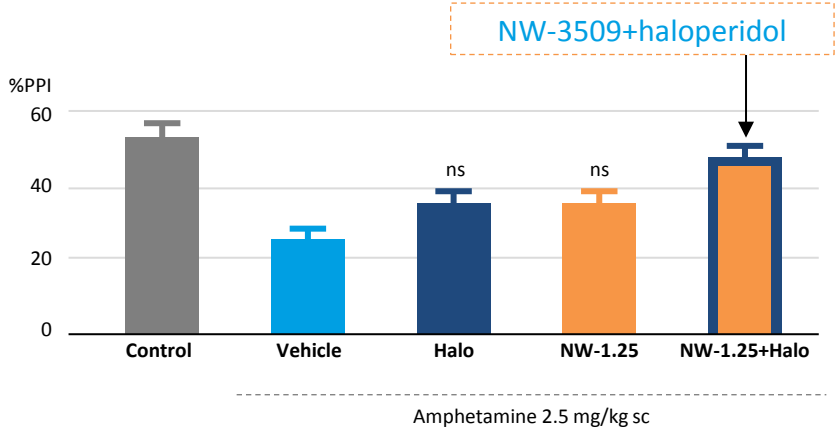


Amphetamine-Induced Prepulse Inhibition (PPI) Deficit Model
NW-3509 Augments the Effect of Typical and Atypical Antipsychotics

Typical

Add-on with non-active dose of **haloperidol**

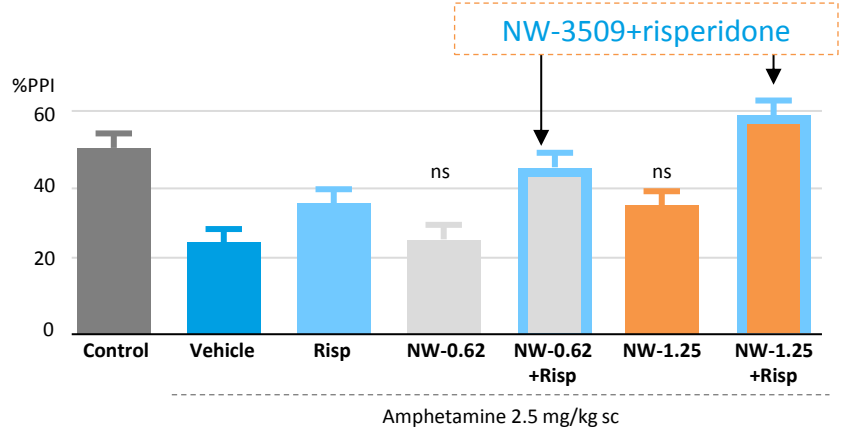
MED 1.25 mg/kg *po* (+ haloperidol 0.05 mg/kg *ip*)



Atypical

Add-on with non-active dose of **risperidone**

MED 0.62 mg/kg *po* (+ risperidone 0.05 mg/kg *ip*)



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)

Phase II Study: Preliminary Validation of a Novel Treatment Concept

- NW-3509 as add-on treatment in positive symptoms of schizophrenia
  - Patients with stable and adequate dose of standard therapy, experiencing break-through symptoms
- 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
- Double-blind, placebo-controlled, randomized, 4-week in/outpatient study in US and India in minimum 90 patients receiving NW-3509 15-25 mg/ twice daily or placebo
- 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 in January 2016, results expected by end 2016
- Newron to partner the program after Phase II

Financial Snapshot

€'000	2014	2015		HY 2016
Revenue	**1,557**	**2,380**		**3,908**
Research & development expenses	(6,017)	(18,449)		(8,240)
General & administrative expenses	(6,702)	(8,278)		(4,402)
Operating loss	**(11,215)**	**(24,400)**		**(8,877)**
Net loss	**(10,095)**	**(22,816)**		**(8,754)**
Operating cash outflow	(9,998)	(12,862)		(8,945)
Financing activities	17,188	28,032		2,821
Investing activities	(6,860)	2,085		570
Net change in cash	**330**	**17,255**		**(5,554)**
Closing net cash[(1)]	**25,702**	**40,931**		**34,879**
Cash Position as of 30 Jun 2016[(1)]				**€34.9m**

(1) Includes available for sale financial assets

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