
Newron Pharmaceuticals S.p.A.

Media, investors and analyst conference call
Full year results 2010

Milan

April 5, 2011

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Overview



- **Focused on the development of innovative NCEs for the treatment of CNS disorders**
- **Management with significant track record in developing CNS drugs**
- **Safinamide in PD**
 - Approaching regulatory filing, label extension (POC) studies initiated
 - Significant revenues from Merck Serono collaboration
- **NW-3509 and Ralfinamide**
 - Originated by in-house ION channel program, significant upside potential
- **HF projects**
 - HF0220 ready for Phase II POC in large indications
 - HF1020 (Trident SPV)
- **Collaboration with Merck group extended on March 31, 2011**
 - License of sarizotan and pruvanserin
- **Listed on SIX Swiss Exchange, headquartered in Bresso (MI, Italy)**
- **CHF3.5m private placement (Great Point Partners)**
- **CHF4.8m Government grant**
- **Funded well through 2012**



Group Consolidated Financials 2010 (IFRS)

Financial Highlights 2010



- License income EUR0.6m (2009: EUR0.9m) - revenue recognition from MS downpayment
- Other income EUR0.2m (2009: EUR1.6m) - grants, tax credits I, UK for years prior to 2010
- Gross R&D expenses €17.0m (2009: €22.9m), incl. safinamide-related expenses as well as R&D covered by tax credits and grants, excl. write-offs (€3.8m)
- Net R&D expenses €15.9m (2009: €18.5m), net of MS reimbursement of safinamide of €4.3m (2009: €5.2m), tax credits and grants of €0.6m (2009: €2.1m)
- SG&A expenses €6.5m (2009: EUR8.5m)
- Financial income €0m (2009: EUR0.2m)
- Net loss €20.5m (2009: EUR23.5m)
- Net cash used in operating activities €19.1m (2009: €23.1m)
 - Of which €6.4m for second half year (excl. one-time restr. cost)
- Cash position at year end 2010: €8.1m, plus €3.7m from government grant (2011), plus new funds from Merck Serono (2011)
- Cash reach: towards end of 2012 + option to up to CHF27.5m under equity line

Consolidated Financial Statements 2010 (IFRS)



Consolidated Income statement

€('000)	2010	2009
License income	626	946
Other income	180	1,596
R&D expenses	(15,922)	(18,544)
Marketing and advertising expenses	(73)	(86)
General and administrative expenses	(6,451)	(8,468)
Operating Loss	(21,640)	(24,556)
Financial income, net	(33)	205
Income tax expense	1,128	870
Net loss	(20,545)	(23,481)
Loss per share in €	(3.11)	(3,86)

Consolidated Cash flow statement

€('000)	2010	2009
Net cash used in operating activities	(19,127)	(23,056)
Net cash flows from investing activities	1,621	(1,444)
Net cash flows from financing activities	2,904	5,922
Net decrease in cash and cash equivalents	(14,602)	(18,578)

Consolidated Statement of Financial Position

€('000)	31/12/2010	31/12/2009
Non-current assets	6,026	9,940
Current assets	13,106	31,738
Total assets	19,132	41,678
Deferred tax liability/income, borrowings - non-current	1,718	2,858
Employee severance indemnity/cash settled share-based liabilities	588	801
Deferred income	400	1,027
Current liabilities	4,235	7,709
Total shareholders' equity	12,191	29,283
Total equity and liabilities	19,132	41,678

Corporate Snapshot



- SIX Swiss Exchange Code: NWRN
- Number of fully paid in shares: 7,264,378
- Market cap: CHF49m (April 1, 2011)
- Major Shareholders:
 - Goodman & Co 9.7 %
 - Great Point Partners 9.1 %
 - 3i Group 7.4 %
 - NWB (Apax) 5.7 %
 - Founders 5.0 %
 - TVM 3.8 %
 - Aviva 3.2 %
- Analysts:
 - Bank Vontobel
 - Helvea
 - Jefferies
 - Kepler Equities
 - Bank Bellevue

Safinamide

A unique proposition for PD

Safinamide in PD – Overview

High income potential no further Newron investment



- >\$4bn market with no significant therapies introduced in recent years
- First once a day oral adjunctive therapy for all stages of PD
- Unique mechanism of action
 - Enhancement of dopaminergic function
 - Reduction of glutamatergic activity
- Efficacy and safety achieved in early and advanced PD
- Low risk
- Label extension (POC) studies initiated
- Partnered with Merck Serono
 - Significant milestones and royalties, dev cost covered by MS

Safinamide: add-on to DA in early PD



- No drug approved as add-on to dopamine agonist (DA)
- DA are very effective in early PD
- When efficacy fades L-dopa is introduced
- Long-term use of L-dopa is associated with significant side effects: motor fluctuations and dyskinesia
- Recent competitor's results further support our strategy
 - Mixed results with rasagiline (ADAGIO trial)
 - Failure of stalevo in early PD

Safinamide: add-on to L-Dopa in advanced PD



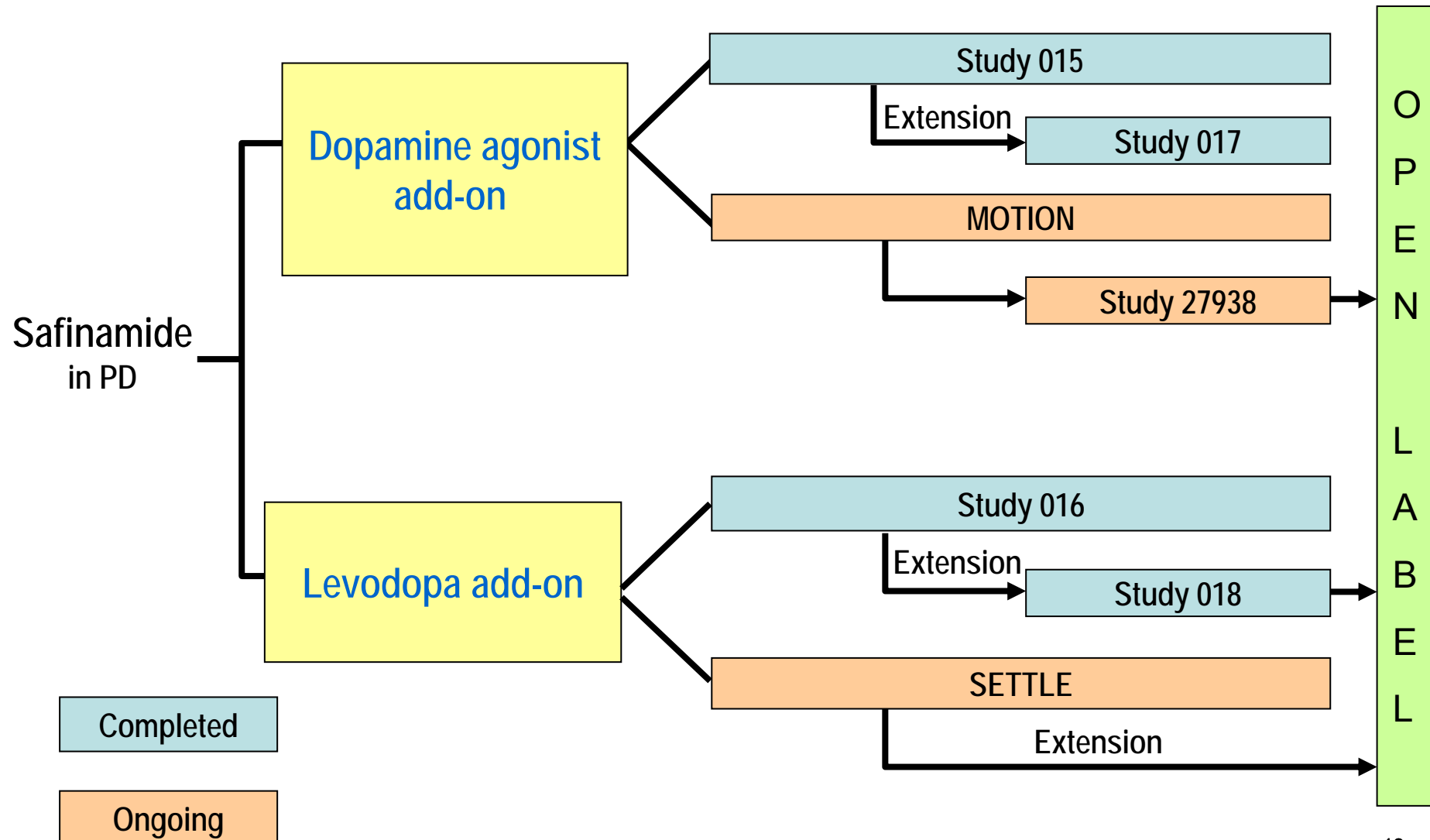
- Levodopa-induced motor complications
 - Wearing off / on-off response
 - Dyskinesia
- Unmet need
 - All adjunctive therapies to L-dopa worsen dyskinesia
 - No drugs have demonstrated maintenance of benefits in improving motor fluctuations during long term treatment
 - Depression is a significant co-morbidity in advanced PD

Safinamide in PD – Differentiation (Phase II and III clinical studies' outcome)



- **First add-on treatment to any dopamine agonist in early PD**
 - Maintenance of long term benefits on motor symptoms
 - Reduction in use of levodopa/interventions by 50 %
- **First add-on to levodopa in advanced PD showing long term (24 months) maintenance of effect**
 - NO increase in troublesome dyskinesia
 - Trend towards improvement of dyskinesia (add. analysis to be presented at AAN)
 - Only add-on to levodopa showing benefit in motor fluctuations, motor symptoms, activities of daily living, depression, quality of life
- **Potential for cognitive improvement**

Safinamide Clinical Development Plan





Ralfinamide

Ralfinamide Overview

- Oral use, small molecule, new chemical class
- Ion channel blocker and NMDA modulator originated from in-house ION channel program
- Efficacy demonstrated in multiple models of neuropathic, visceral and central pain and mania
- No titration required in patients (very well tolerated)
- Demonstrated efficacy in
 - Placebo-controlled trial in patients with peripheral neuropathic pain
 - Post-hoc analysis indicated strong effect in patients with NLBP (no drug approved, large market opportunity)
- Phase III program in NLBP agreed to with Health Authorities

Phase IIb/III SERENA trial in NLBP



- Double-blind placebo controlled, parallel-group, multinational trial
- Treatments:
 - Placebo and 2 doses of ralfinamide (160mg and 320 mg daily)
- Randomisation: Equally to all three groups
- Study Duration: 12 weeks
 - Patients who complete 12 weeks of treatment will be eligible to enter a double-blind 40 week extension
 - Patients will continue on the same dose of study medication they were receiving at the end of the 12 week treatment period
- Number of Patients: approx 411
- Excellent tolerability
- Primary efficacy endpoint (likert pain): drug did not separate from placebo

Ralfinamide summary and next steps



- Top line results in patients with NLBP did not confirm compelling post hoc Phase II analysis
- US pain expert panel recommended continued development in other NP indications
 - Mechanism of action, strong pharmacology, positive Phase II in NP patients, excellent safety (>600 patients)
- Recent exciting pharmacological results support ralfinamide development in non pain indications
- Newron is currently reviewing development plan for the compound



Sarizotan & Pruvanserin

Leaveraging Newron's reprofiling capabilities

Saritozan and Pruvanserin



News

- License agreement announced March 31, 2011
- Newron receives development license for the two clinical stage compounds
- Buy-back option for Merck upon PoC
- If Merck exercises buy-back option, Newron has co-development option
- No financial details disclosed

Characteristics

- Highly selective compounds for specific serotonin or dopamine receptors
- Modulating the activity of such neurotransmitters in the brain
- Both compounds exhibit pharmacological properties and have clinical data that support further evaluation and development

Next steps

- Additional preclinical experiments
- PoC studies in diseases of the CNS



NW-3509

A novel approach for the treatment
of psychiatric disorders

NW-3509



- Innovative compound from Newron's ion channel program
- Addressing unmet needs in schizophrenia
- Large market opportunity (anti-psychotic market >\$23bn)
- Rapid onset of action; high availability in the brain
- Positive pre IND and CTA meetings on planned development as **add-on to antipsychotics for patients with psychosis**
- IND filing 2q2011
- Phase I development to be started 2011

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



- **Add-on with antipsychotics**
 - NW-3509 increase efficacy of antipsychotics decreasing their dosage and associated side effects
- **Potential to alleviate symptoms not benefited by current treatment**
 - NW-3509 acting by different mechanism of current antipsychotics may be effective against negative symptoms, mood disorders and suicidal
- **Cognitive symptoms**
 - NW-3509 is active in models of short and long-term memory impairment. Most anti-psychotics have no or even detrimental effect on cognition
- **Co-morbidities**
 - NW-3509 is active in models of anxiety and depression, suggesting to be able to address important co-morbidities in schizophrenia

HF0220

In the search of new medicines
for inflammatory and degenerative diseases

HF0220



- HF0220 is the 7- β -hydroxyl derivative of epiandrosterone (EPIA)
- It showed potent anti-inflammatory effect in experimental models of RA as well as strong neuroprotective and pro-cognitive properties
- TRIOLEX, a similar but much less potent compound from Harbor BioSciences is currently undergoing Phase II trial in obese type 2 diabetes mellitus patients
- Phase II safety of HF0220 in AD patients showed high tolerability of the drug
- POC study initiation subject to funding/partnership

Key newsflow



- Safinamide MOTION results
- Safinamide SETTLE results
- Safinamide regulatory filing and milestone payments
- Safinamide POC in LID
- Safinamide POC in Cognition in PD
- NW-3509 Phase I start
- HF1020 Phase I results
- Ralfinamide POC in new indication