



Newron Pharmaceuticals reports 2008 results

- **Key compounds reach significant R&D milestones in Parkinson's disease and Neuropathic Low Back Pain**
- **Solid cash position**

Milan, Italy – April 2, 2009 - Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel CNS and pain therapies, announces its financial results for the year ended 31 December 2008.

Highlights

- Acquisition and integration of Hunter-Fleming Ltd
- Safinamide: completion of patient enrolment in phase III clinical trial in mid-to-late stage Parkinson's disease (PD), positive top-line results reported for this trial early 2009
- Ralfinamide: phase II study in peripheral neuropathic pain completed, initiation of phase IIb/III study of ralfinamide in patients with Neuropathic Low Back Pain (NLBP)
- Positive phase II safety and tolerability results reported for HF0220 in patients with mild to moderate Alzheimer's disease
- CHF 30 million long term standby equity line secured with Yorkville Global Investments, L.P.
- EUR 5 million awarded by the Italian government for R&D and training support

Luca Benatti, CEO, said: "In 2008 Newron has achieved some major milestones on its path to becoming a leading CNS and pain biopharmaceutical company. We are very encouraged by the trial results for both safinamide and ralfinamide, our two key development compounds. The Hunter-Fleming team and drug portfolio have been fully integrated and we look forward to progressing our expanded pipeline during 2009."

In May, Newron completed the acquisition of Hunter-Fleming, a privately-owned UK company focused on the development of medicines to treat neurodegenerative and inflammatory disorders. Bringing the two companies together has created an enlarged clinical pipeline and strengthened the Newron team with additional expertise in the area of neuro-inflammation.

Financial Highlights

Licence income in 2008 was EUR 2.6m, referring to the 2006 upfront payment from Merck Serono for the licensing of safinamide, which is recognized as revenue on a straight line basis. Other income mostly consisted of R&D tax credits from the Italian and UK governments. Research and development expenses increased to EUR 12.9m



(2007: EUR 8.5m) as a result of the initiation of the phase IIb/III trial for ralfinamide and the additional Hunter-Fleming programmes. Costs of EUR 9.5m (2007: EUR 9.5m) incurred by Newron for the development of safinamide were fully reimbursed by Merck Serono and R&D expenses are therefore shown net of these amounts. Financial income mostly results from interest income on funds from the IPO and decreased to EUR 2.0m from EUR 2.6 in the previous year. The net loss rose to EUR 16.4m from EUR 11.1m, mostly due to the increase in R&D expenses and a one-time restructuring cost of Hunter-Fleming (EUR 1.3m) during integration of the company. Cash and cash equivalents were EUR 41.3m at year-end.

In December, Newron secured a CHF 30m long-term standby equity line with US-based YA Global Investments, L.P. (YA Global) which provides Newron with financial flexibility in the current market environment. Newron has the option to take up YA Global's commitment to subscribe and pay for newly issued Newron shares to a total value of up to CHF 30 million over a period of 36 months at the sole and exclusive discretion of Newron.

Financial Summary (IFRS)

In EUR m (except per share information)

	2008	2007
Licence income	2,635	4,024
Other income	1,298	70
Research and development expenses*	12,881	8,474
Operating loss	18,319	13,681
Financial income	1,963	2,593
Net loss	16,364	11,089
Loss per share	2,74	1.90
Cash and cash equivalents	41,267	63,157
Total assets	60,540	70,368

* Net of safinamide development cost reimbursed by Merck Serono

R&D Highlights

For its lead drug, safinamide, Newron and its partner Merck Serono announced in February 2009 that the first phase III trial of safinamide as adjunctive therapy to levodopa (study O16) met its primary endpoint by increasing daily "ON" time in mid-to late-stage Parkinson's disease patients with motor fluctuations by 1.3 hours. "ON" time represents periods when Parkinson's patients experience their best level of motor functioning. Secondary efficacy endpoints of this study were also met, including decrease in daily "OFF" time, decrease in mean "OFF" time following first morning dose of levodopa, mean change from baseline in the Unified Parkinson's Disease Rating Scale (UPDRS) Section III (motor) score during "ON" time and mean change in Clinical Global Impression of severity of disease and change from baseline (CGI). The incidence of dropouts, serious adverse events or clinically notable events among the



three groups of the study were comparable. Full study results after completion of ongoing analyses will be submitted for presentation at upcoming scientific meetings.

Having received the approval to initiate the first phase IIb/III study of ralfinamide in patients with moderate NLBP prior to year end 2008, Newron announced randomization of the first patients in that study in March 2009. The SERENA study (**S**afety and **E**fficacy of **R**alfinamide in **nE**uropathic low back **paiN** **pA**tients) will evaluate the safety and efficacy of two dose regimens of ralfinamide compared to placebo. It is potentially one of the two pivotal studies required for an approval in NLBP, an indication with a prevalence of about 8% of the general population (US, Europe and Japan). The program was discussed with the EMEA, who approved the plans for the NLBP indication, the study design, diagnostic criteria, outcome measures and statistical analysis plan. The decision to pursue development in this indication was made after data announced in April 2008 showed a statistically significant and clinically relevant improvement in patients with neuropathic pain as a result of Nerve Compression/Nerve Entrapment (NCET). There are currently no treatments for NLBP, a very sizeable market.

HF0220, Hunter-Fleming's lead compound, was undergoing a phase II safety and tolerability trial in Alzheimer's disease when Newron acquired the company. In October, Newron announced positive results in patients with mild to moderate disease and is now evaluating the next steps in the compound's development.

Significant progress was achieved in the development of NW-3509, which is undergoing IND-enabling studies and shows promising efficacy in models of schizophrenia and mania. The compound has the potential to reduce relapse and improve mood as well as cognition in schizophrenia patients who show inadequate benefit of their current treatment.

Outlook

Upcoming milestones include:

- Start and completion of additional trials to allow regulatory filing of safinamide in PD
- Safinamide in mid-to-late stage PD: presentation of full study results at upcoming scientific meetings
- Filing of IND for NW-3509
- Initiation of PoC trial of HF0220 as neuroprotectant
- Phase IIb/III results of ralfinamide in NLBP

Net cash used in operating activities in 2009 is expected to be below EUR 25m.



Media/analyst conference and conference call on 2 April 2009, 10.30-11.45am CET

Luca Benatti, CEO, and Stefan Weber, CFO, will present the full year results and provide an update on the development of Newron's R&D pipeline at a media/analyst conference to be held in Haus zum Rüden, Limmatquai 42, Zurich, on 2 April 2009, 10:30-11:45am CET. Participation is also possible via conference call, dial-in numbers:

+41 91 610 5600 Continental Europe
+44 207 107 0611 UK

The presentation and the IFRS Consolidated Financial Statements as well as the Italian statutory financial statements are available for download at: <http://www.newron.com/presentationandfactsheet.asp>

Next events

Annual General Meeting 27 April 2009, Milan
1HY2009 Results 10 September 2009

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About Newron Pharmaceuticals

Newron Pharmaceuticals S.p.A. (www.newron.com) is a biopharmaceutical company focused on novel therapies for diseases of the Central Nervous System and pain. Newron is undertaking phase III trials with safinamide for the treatment of Parkinson's disease (PD) in conjunction with its partner, Merck Serono, which has exclusive worldwide rights to develop, manufacture and commercialize the compound in PD, Alzheimer's disease, and other therapeutic applications. Newron recently initiated a phase IIb/III study with ralfinamide in patients with Neuropathic Low Back Pain (NLBP). There are no approved drugs for the treatment of NLBP, an indication experienced by about 55 m patients in the USA, Europe and Japan.

Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.



Important Notices

This document contains forward-looking statements, including (without limitation) about (1) Newron's ability to develop and expand its business, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates and reduce costs (including staff costs), (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's anticipated future revenues, capital expenditures and financial resources, and (4) assumptions underlying any such statements. In some cases these statements and assumptions can be identified by the fact that they use words such as "will", "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron's strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements.

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