



Newron reports half-year results 2008

Milan, Italy – September 19, 2008 - Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel CNS and pain therapies, today announced its financial results for the half year ended June 30, 2008.

Highlights

- Exciting phase II results with ralfinamide in Neuropathic Low Back Pain (NLBP)
 - significant and clinically relevant improvement in VAS/Likert scales: mean change and responder rates / Patient rated Activities of Daily Living / Disruption of Sleep
 - NLBP: prevalence of almost 8%; accounts for about 60% of all neuropathic pain diagnoses - no drugs approved to date
 - future development plans discussed with major health authorities
- Safinamide patent protection: EPO grant patent extending the use of safinamide plus levodopa therapy in Parkinson's disease until 2024 in Europe
- Completion of patient enrolment in phase III clinical trial with safinamide in mid-to-late stage Parkinson's disease
- Acquisition of Hunter-Fleming Ltd.
 - Data Safety and Monitoring Board recommends continuation of phase II study for HF0220 in patients with Alzheimer's disease
- Appointment of senior industry experts as non-executive Members of the Board of Directors
- Inclusion into SWX Swiss Performance Index
- Inclusion into SWX SXI indices*

* post end of reporting period

Ralfinamide – focus on Neuropathic Low Back Pain, indication with no approved drugs offering blockbuster potential

On April 15, 2008, Newron presented the results from the detailed analyses of the Phase II trial of ralfinamide in patients with neuropathic pain at the AAN** 60th Annual Meeting in Chicago. In the overall study population ralfinamide was well tolerated and safe, with reported side effects comparable to placebo. More importantly, the compound showed statistically significant superiority compared with placebo on the mean change in the patient-rated Visual Analog Scale (VAS) and Likert Scale – measures of the severity of pain. Responder rates were significantly increased compared to placebo and patients experienced a significant improvement in the quality of sleep and their performance of daily activities.

** American Academy of Neurology

A recent review of the trial population indicated that the largest group, 96 out of 272 patients included, was experiencing neuropathic pain due to Nerve Compression/ Nerve Entrapment (NCET). In these patients, treatment with ralfinamide compared to placebo was demonstrated to be highly efficacious as judged by the reduction in the intensity of pain (VAS/Likert), the responder rates, quality of sleep, daily activities and type of pain. As a large number of these patients experience low back pain due to a neuropathic component, the benefits demonstrated suggest that ralfinamide may provide a unique therapeutic benefit for patients with Neuropathic Low Back Pain (NLBP). The company is preparing to start a phase IIb/III trial of three months' treatment duration in 2008 in patients with NLBP, which could potentially become one of two pivotal trials required for approval in this indication. Currently, no such drugs are approved by



health authorities for use in NLBP, an indication with a prevalence of almost 8% of the population, accounting for about 60% of all neuropathic pain diagnoses.

Safinamide – patent position strengthened by granting of patent on combination therapy; first phase III study in mid-to-late stage PD to evaluate efficacy and safety completed enrollment

Newron is developing safinamide in conjunction with Merck Serono, which has exclusive worldwide rights to develop, manufacture and commercialize the compound in Parkinson's disease (PD), Alzheimers' disease (AD) and other therapeutic applications.

A patent application for the use of safinamide and levodopa in the treatment of PD has been granted by the European Patent Office. This patent will extend protection in Europe to 2024. The same patent was filed in the US.

The safinamide phase III development program was significantly advanced, with Newron announcing in May that patient enrollment was completed in the first phase III clinical trial that will evaluate the efficacy and safety of safinamide as add-on therapy to a stable dose of levodopa for the treatment of patients with mid- to late-stage PD. Topline results of the study should be reported during first quarter 2009.

Newron and Merck Serono plan to start the second phase III study in mid-to-late stage PD patients early next year and to see recruitment of patients in the second Phase III study in early PD patients accelerate.

Hunter-Fleming acquisition – execution of corporate strategy

In May 2008, Newron completed the acquisition of Hunter-Fleming Ltd., a private UK biopharmaceutical company developing new medicines to treat neurodegenerative and inflammatory disorders. Consistent with Newron's growth strategy, the acquisition broadens the clinical-stage pipeline, particularly in the area of neuro-inflammation. Upon closing, Hunter-Fleming shareholders in their totality received about 3.1% new Newron shares from a capital increase, with additional milestones of no more than EUR 17 m in new Newron shares, potentially adding to that in the next years. Milestones are strictly linked to development and commercialization success mostly of Hunter-Fleming 0220, the lead compound, currently being developed in Alzheimer's disease. In the meantime, the integration of the Hunter-Fleming operations has been successfully completed and the remaining team at the Bristol site, together with their counterparts in Basel and Bresso, are evaluating the detailed development plans for all of Newron's development compounds.

Hunter-Fleming's lead compound, HF0220, has been shown to reduce amyloid levels in AD transgenic mice, and to be protective in stroke models as well as in murine CIA models. The ongoing phase II safety and tolerability study is exploring biological markers in patients with Alzheimer's disease.

Luca Benatti, Newron's CEO, said: "We are excited by the huge potential that ralfinamide offers in Neuropathic Low Back Pain and look forward to seeing the value of the compound increase further in the next months with the start of a phase IIb/III trial and the potential for a licensing transaction. We expect first phase III data of safinamide in mid-to-late stage PD patients and further development steps being implemented. By taking over and integrating



Hunter-Fleming, Newron has significantly broadened its clinical pipeline with three new, promising clinical compounds and has acquired further expertise in the area of neuroprotection and inflammation."

Financial Highlights (IFRS)

For the first time, this year's 6 month financial statements include the results of Newron Suisse SA, a clinical development fully owned subsidiary based in Basel established in autumn 2007, and Hunter Fleming Limited, which has been acquired in May 2008.

Newron's half-year results show a net loss of EUR 7.3 m, (EUR 4.0 m in 2007), and net cash used in operating activities of EUR -12.7 m, resulting in a cash and cash equivalent position of EUR 47.6 m per June 30, 2008.

Licence income of EUR 1.3 m (2007: EUR 2.2 m) is due to the down-payment received from Merck Serono in October 2006 which is being recognized as revenue over the estimated period required to finalize the development of safinamide. The other income recorded in the first 6 months consists mainly of a research and development tax credit.

Newron has significantly increased its development costs for ralfinamide, NW3509 as well as the new HF compounds, fully in line with the guidance previously given to the financial markets. The development costs increased from EUR 2.8 m from the previous period to EUR 5.1 m in the current period, both net of safinamide development cost as reimbursed by Newron's partner Merck Serono of EUR 5.6 m (2007) and EUR 5.3 m (current period). In addition, 2008 R&D expense has been reduced by an R&D tax credit of EUR 0.4 m. Therefore, the current period's gross R&D expense increased to EUR 10.8 m, compared to EUR 8.4 m in 2007, reflecting the broadening of the pipeline and the further development of compounds. Due to the restructuring of Hunter-Fleming, post acquisition, a one-time expense of about EUR 1.3 m has impacted G&A expenses.



Financial Summary (IFRS)

In EUR thousand (except per share information)

	1 HY 2008	1HY 2007
License income	1,310	2,152
Other income	737	33
Research and development expenses	5,108	2,811
General and administrative expenses	5,297	4,503
Net loss	7,292	3,975
Loss per share	1.24	0.68
	30/06/2008	31/12/2007
Intangible assets	11,991	32
Receivables and prepayments	8,866	5,836
Cash and cash equivalents	47,637	63,157
Total assets	70,764	70,368

Due to the acquisition of Hunter Fleming, intangible assets increased significantly from close to zero by year end to EUR 12.0 m at the end of June 2008. Cash and cash equivalents were at EUR 47,6 m at the end of the reporting period, impacted by two items: Repayment of a significant part of HF debt post acquisition of the company and the late payment by a development partner of EUR 2.9 m, due in June, but arriving at Newron's bank accounts only in early July.

The cash burn guidance for 2008 of EUR 25,0 m is confirmed. Newron's cash position fully supports ongoing operations into 2010.

Outlook

- Start of ralfinamide phase IIb/III study in NLBP
- Safinamide phase III safety and efficacy data in mid-to-late stage PD
- HF0220 phase II safety and tolerability data in AD
- Management confirms the expenditure guidance for 2008

For further details see the full First-Half-Year Report of 2008 which is available at www.newron.com



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 reported excellent results for its compound ralfinamide in patients with Nerve Compression and Entrapment conditions, of which neuropathic low back pain (NLBP) represents the most common indication. There are no approved drugs for the treatment of NLBP. The Company expects to commence a phase IIb/III in NLBP later in 2008. In May 2008, Newron acquired Hunter-Fleming, a private UK bio-pharmaceutical company developing new medicines to treat neurodegenerative and inflammatory disorders. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SWX Swiss Exchange, trading symbol NWRN.

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