



## **NEWRON PHARMACEUTICALS REPORTS 2007 RESULTS**

- **PROGRESS IN DEVELOPMENT OF R&D PIPELINE**
  - **SOLID CASH POSITION**

**Milan, Italy– March 27, 2008** - 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 2007.

### **Highlights**

- Ralfinamide in clinical development for the treatment of neuropathic and inflammatory pain:
  - Commercial settlement with Purdue – option on Purdue patents
  - Positive phase II data in neuropathic pain
- Safinamide (cooperation with Merck Serono) in phase III clinical trials for the treatment of patients with Parkinson’s disease (PD):
  - Long-term safety and efficacy data in PD
  - Extension of patent protection: EPO intention-to-grant letter received post end of reporting period
- Pre-clinical IND-enabling studies of NW-3509 initiated
- Opening of clinical development facility in Basel
- Lower net loss and solid cash position

In addition, in February 2008 Newron announced its intention to acquire Hunter-Fleming Ltd., a private UK bio-pharmaceutical company developing new medicines to treat neurodegenerative and inflammatory disorders.

Luca Benatti, Newron’s CEO, commented: “2007 was a year of excellent progress in our development programs. The achievements with safinamide in Parkinson’s disease and ralfinamide in neuropathic pain further increase the value of these two important assets. In addition, the recently announced acquisition of Hunter-Fleming will further expand Newron’s pipeline. The company’s fundamentals are stronger than ever and we look forward to the upcoming significant milestones in 2008.”

## Financial Highlights

Licence income in 2007 increased to EUR 4.0m from EUR 1.2m in 2006. Under IFRS Newron recognises the upfront payment from Merck Serono on a straight-line basis until end of September 2009. Research and development expenses were lower than in 2006, down to EUR 8.2m from EUR 11.5m. All costs related to the development of ralfinamide were reimbursed by Merck Serono. Thus, in 2007 all development costs were related to two ongoing phase II studies with ralfinamide and work on NW-3509. Financial income increased to EUR 2.6m due to the interest on cash in hand. Net loss was significantly lowered to EUR 11.1m from EUR 16.4m. Cash and cash equivalents totalled EUR 63.2m at year-end.

Cash used in operating activities in 2008 is expected to be approximately EUR 25m, assuming the completion of the acquisition of Hunter-Fleming Ltd. and R&D expenses which are expected to be significantly higher due to the increased clinical development activity on ralfinamide and other compounds.

## Financial Summary (IFRS)

In EUR m (except per share information)

|                                    | 2007 Group** | 2006 Newron |
|------------------------------------|--------------|-------------|
| Licence income                     | 4,024        | 1,191       |
| Research and development expenses* | 8,197        | 11,488      |
| Operating loss                     | 13,681       | 16,752      |
| Financial income                   | 2,593        | 0,351       |
| Net loss                           | 11,089       | 16,401      |
| Loss per share                     | 1.90         | 4.33        |
| Cash and cash equivalents          | 63,157       | 74,765      |
| Total assets                       | 70,368       | 86,157      |

\* Net of safinamide development cost reimbursed by Merck Serono

\*\* Newron Group is composed of Newron Pharmaceuticals S.p.A., Bresso (Italy) and Newron Suisse SA, Basle (Switzerland), which was incorporated during 2007

## R&D Highlights 2007

Ralfinamide is a unique new chemical entity that is believed to mediate analgesic and anti-inflammatory effects through the modulation of ion channels implicated in pain and the inhibition of substance P. In early 2007, Newron reached a settlement in an ongoing patent dispute with Purdue Neuroscience. The agreement, giving Newron an option on certain Purdue patents, allows Newron to focus on the further expansion of ralfinamide's clinical development program.

In July, Newron presented the results of a phase II study with ralfinamide in neuropathic pain. The study showed that ralfinamide was well tolerated and safe, with reported side effects comparable to placebo. More importantly, the compound showed clear evidence of efficacy in the treatment of peripheral neuropathic pain. In October 2007, Newron initiated phase II development of ralfina-

mide in post-surgical dental pain. The study is designed to determine the safety, tolerability and preliminary evidence of preventive analgesic efficacy of orally administered ralfinamide, compared to placebo, in patients with third molar, post-extraction, dental pain. The trial design is based on a pre-clinical study that demonstrated that pre and/or post-operative treatment with ralfinamide provides long-lasting suppression of spontaneous post-surgical neuropathic pain-related behaviour.

Newron's most advanced compound, safinamide, is in phase III trials for the treatment of 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. In 2007, phase III studies with safinamide as add-on treatment to either dopamine agonist therapy in early Parkinson's patients or to levodopa therapy in mid-to-late stage patients, were ongoing:

- In August 2007, Newron and Merck Serono announced preliminary results of a 12-month extension study of the first 6-month phase III trial of safinamide as an add-on treatment to dopamine agonist therapy in patients with early-stage Parkinson's disease. The 18-month study showed a favorable safety profile and, at a dose of 50 to 100 mg/day, benefit on motor symptoms and quality of life and a potential to reduce the number of patients experiencing interventions.
- In January 2007, a second phase III study was initiated in mid-to late stage Parkinson's disease. The study is designed to determine the efficacy and safety of safinamide in comparison to placebo in patients who are receiving stable doses of L-dopa with or without additional treatment with dopamine agonists and/or anticholinergic drugs. This trial is proceeding with completion of enrolment expected shortly.
- In November 2007, Merck Serono initiated the second add-on-to dopamine agonist therapy study (MOTION: SafinaMide add-On To dopamine agonist for early Idiopathic Parkinson's disease). This study will evaluate the efficacy and safety of two dose regimens of safinamide as add-on therapy to a stable dose of a single dopamine agonist, compared with dopamine agonist monotherapy.

NW-3509, a potent and highly specific sodium channel blocker, entered into IND-enabling studies in December 2007.

## Outlook

Upcoming milestones include:

- Ralfinamide phase II data in post surgical (dental) pain
- Presentation of ralfinamide phase II data in neuropathic pain subtypes at AAN (Chicago, April 15, 2008)
- Start of ralfinamide phase IIb/III study in neuropathic pain
- Safinamide phase III data in add-on study to L-dopa
- Start of phase I of HF1020 in Trident Special Purpose Vehicle
- Start of phase II trial with HF0220 in Rheumatoid Arthritis
- Completion of phase II safety and tolerability study with HF0220 in Alzheimer's Disease

Also expected is the closing of the acquisition of Hunter-Fleming Ltd., announced in February 2008.

## Media/analyst conference and conference call on 27 March 2008, 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 27 March 2008, 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 Gaap Financial Statements are available for download at: [www.newron.com](http://www.newron.com)

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Newron Pharmaceuticals S.p.A. extraordinary and ordinary shareholders' meeting will be held at the Park Hyatt Hotel, Beethoven-Strasse 21 in Zurich on 24 April 2008 at 14:00 CET. For more information, please go to [www.newron.com](http://www.newron.com)

## Next events

|                        |                        |
|------------------------|------------------------|
| Annual General Meeting | April 24, 2008, Zurich |
| 1HY2008 Results        | September 19, 2008     |

## About Newron Pharmaceuticals

Newron Pharmaceuticals S.p.A. ([www.newron.com](http://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 is conducting phase II trials with ralfinamide for the treatment of neuropathic and post surgical (dental) pain. In February 2008, Newron signed an agreement providing for the acquisition of 100% of the issued share capital of 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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