



Newron Pharmaceuticals reports 2009 results

Milan, Italy – March 3, 2010 - 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 2009.

Highlights

- Safinamide has demonstrated significant improvement of motor function in patients with advanced Parkinson's disease (PD) in a phase III pivotal trial
- Ralfinamide has significantly advanced in the first potentially pivotal phase IIb/III study in patients with Neuropathic Low Back Pain (NLBP)
- NW-3509 progressing as a potential novel treatment for schizophrenia
- CHF7.9 million raised in a private placement in December 2009.

Luca Benatti, CEO, said: "2009 was a good year for Newron. Our focus was on our two lead development programmes, safinamide and ralfinamide, and we have been extremely encouraged with the progress made in both. In our collaboration on safinamide with Merck Serono, a division of Merck KGaA, Darmstadt, Germany, we presented data from the 016 study in 669 patients with advanced PD that showed statistically significant improvement in motor function. Motor fluctuations and dyskinesias represent major unmet medical need for advanced PD patients, depriving them of their independence and quality of life."

Newron's results showed that safinamide as add-on to levodopa met its primary endpoint by significantly increasing daily on time* by 1.3 hours compared to 0.7 hours for patients in the placebo group. While currently available add-on medications to levodopa improve on time but worsen troublesome dyskinesia, safinamide showed no worsening of dyskinesia. Additionally, it was shown that safinamide at 50 or 100 mg/day improved many secondary endpoints including UPDRS III (motor symptoms) and UPDRS IV (motor complications). GRID-HAMD (depressive symptoms) and PDQ-39 (quality of life) were improved in patients taking 100 mg/day. Two additional phase III studies in early PD (MOTION) and advanced PD (SETTLE) are ongoing and together with the completed studies will constitute the package for regulatory approval as add-on treatment in PD. The adverse event profile from phase II/early phase III studies supports further investigation of safety and efficacy of safinamide.

In early 2010, Newron announced that recruitment into ralfinamide's SERENA study was completed. This first phase IIb/III six month study of ralfinamide in patients with NLBP evaluates the safety and efficacy of two dose regimens of ralfinamide compared to placebo. It could be one of the two pivotal studies required for approval in NLBP, an indication experienced by about 55 million patients in the US, Europe and Japan and for which there are currently no approved treatments.



Luca Benatti, CEO, added: "Whilst we must remain open-minded about the outcome of this trial, we are encouraged that industry experts consider ralfinamide to have the "greatest potential of all late-stage neuropathic agents examined".* *

Financial Highlights

Licence income in 2009 was EUR 0.9 million (2008: EUR 2,6 million), referring to the 2006 upfront payment from Merck Serono for the licensing of safinamide, which is recognised as revenue on a straight line basis. Other income largely consisted of R&D grants from the Italian government as well as R&D tax credits from the Italian and UK governments, covering periods prior to 2009. Research and development expenses increased to EUR 18.5 million (2008: EUR 12.9 million), mostly as a result of the pursuit of the phase IIb/III trial for ralfinamide. This amount is net of (i) safinamide development costs of EUR 5.3 million (2008: EUR 9.5 million) incurred by Newron and fully reimbursed by Merck Serono (ii) R&D costs of EUR 2.1 million (2008: EUR 0) covered by ongoing R&D grant programs and tax credits. The net loss rose to EUR 23.5 million from EUR 16.4 million in 2008, mostly due to advancing R&D and its related costs.

Newron raised CHF 7.9 million in a private placement with leading international institutional investors and strengthened its balance sheet in order to pursue the longer-term clinical development of its key product candidates as they near commercialisation. Cash, cash equivalents and other short term financial assets were EUR 24.3 million at year-end. To further conserve costs, Newron upon integrating the acquired Hunter-Fleming projects into its development operations, has terminated Hunter-Fleming's operations in the UK.

Financial Summary (IFRS)

In EUR m (except per share information)

| | 2009 | 2008 |
|--|--------|--------|
| Licence income | 946 | 2,635 |
| Other income | 1,596 | 1,298 |
| Research and development expenses* | 18,544 | 12,881 |
| Operating loss | 24,556 | 18,319 |
| Financial income | 205 | 1,963 |
| Net loss | 23,481 | 16,364 |
| Loss per share | 3.86 | 2.74 |
| Cash, cash equivalents, other short term fin. assets | 24,294 | 41,267 |
| Total assets | 41,678 | 60,540 |
| Net cash used in operating activities | 23,056 | 19,932 |

* Net of safinamide development cost reimbursed by Merck Serono and R&D grants/tax credits



R&D Highlights

Newron and its partner Merck Serono presented results from the first phase III clinical trial of safinamide in advanced Parkinson's disease at the Movement Disorder Society's 13th International Congress in Paris (June) and the XVIII WFN World Congress on Parkinson's disease and Related Disorders in Miami (December). Merck Serono also initiated the SETTLE study, which is the second phase III clinical trial of safinamide in advanced PD. The study is a six month trial involving over 450 patients to evaluate the efficacy and safety of a dose range of safinamide (50-100 mg once daily) as add-on therapy to a stable dose of levodopa compared to levodopa treatment.

Ralfinamide is currently being developed in Neuropathic Low Back Pain (NLBP). For patients with moderate NLBP, the first potentially pivotal phase IIb/III study is being pursued to evaluate the safety and efficacy of two dose regimens of ralfinamide compared to placebo. Early this year, Newon announced that enrolment in this SERENA study (**S**afety and **E**fficacy of **R**alfinamide in **n**europathic low back **p**ain **p**atients) was completed. EMEA has approved plans for the NLBP indication, study design, diagnostic criteria, outcome measures, and statistical analysis.

In central pain, unique statistically significant analgesic effects of ralfinamide in an experimental model of central pain were presented at the Sixth International Congress of the European Federation of IASP Chapters (EFIC), Lisbon in September.

NW-3509, a pre-clinical compound, was positioned as potentially the first selective sodium channel blocker being specifically developed for schizophrenia therapy, as an adjunctive treatment for patients who receive inadequate benefit from their current antipsychotic treatment. In pre IND and CTA meetings, regulatory authorities have accepted the pharmacological, toxicological and pharmaceutical information collected in IND enabling studies to date, as well as the proposed clinical development plan for phases I and II, as reported in January 2010.

Outlook

Upcoming milestones include:

- Top line results for ralfinamide in Neuropathic Low Back Pain, phase IIb/III SERENA study, expected in QII 2010
- Top line long term results for safinamide as add-on treatment to levodopa in patients with advanced PD (18 months' extension of study 016)
- Start of phase I clinical development with NW-3509
- Further development of HF0220, with promising prospects for the treatment of neurodegenerative conditions.



Media/analyst conference and conference call on 3 March 2010, 11.00-12.00am CET
Luca Benatti, CEO, Ravi Anand, CMO, 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 3 March 2010, 11.00-12.00 am CET. The conference call can be accessed via the following dial-in numbers:

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

The presentation and the Annual Report, including 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 Shareholders' meeting Milan, 1 April 2010 (first call)
Half year report 2010 10 September 2010

* On time represents periods when Parkinson's patients experience their best levels of motor function

* * Datamonitor, Forecast Insight : Neuropathic Pain
Brighter future for pipeline drugs while current brands downgraded
DMHC2567, Publication Date 4 December 2009

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 is in the process of completing a potentially pivotal study (SERENA) with ralfinamide in patients with Neuropathic Low Back Pain (NLBP). Newron's additional projects are in development at various stages of preclinical and clinical development, including HF0220 for neuroprotection and NW-3509 for the treatment of schizophrenia. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.



For more information, contact:

| Media | Investors and analysts |
|---|--|
| <p>Italy Luca Benatti - CEO Phone: +39 02 6103 4 626 E-mail: pr@newron.com</p> <p>UK/Global media Julia Phillips Financial Dynamics Phone: +44 (0) 20 7269 7187</p> <p>Switzerland Martin Meier-Pfister IRF Communications Phone: +41 43 244 81 40</p> | <p>Stefan Weber - CFO Phone: +39 02 6103 46 30 E-mail: ir@newron.com</p> |

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