Newron Pharmaceuticals reports half-year results 2014

Milan, Italy – 16 September 2014 – Newron Pharmaceuticals S.p.A. ("Newron", SIX: NWRN), a research and development company focused on the development of therapies for patients with Central Nervous System (CNS) and pain disorders, today announces its financial results for the half year ended June 30, 2014.

Half-Year 2014 Highlights

- Application for Authorization of safinamide submitted to Swissmedic by Zambon as the Authorization holder
- New results with NW-3509, demonstrating potential of unique mechanism to benefit poor responders to antipsychotics in patients with schizophrenia, presented at the 4th Biennial Schizophrenia International Research Society (SIRS) Conference
- CHF 22.2 million raised in private placements to existing and new institutional shareholders in Europe and the US
- Safinamide New Drug Application (NDA) submitted to the US Food and Drug Administration (FDA)

In May, Newron achieved a key milestone by submitting safinamide to the US FDA for the indications "safinamide as add-on therapy to a stable dose of a single dopamine agonist" in early Parkinson's disease patients and "safinamide as add-on therapy to levodopa alone or in combination with other Parkinson's disease treatments" in mid-to late stage Parkinson's disease patients. Upon preliminary review, the FDA identified some organization and navigation problems, relating to the hyperlinking of tables, folders and the organization of the table of contents in the submission, as well as the conformation of the Package Insert to FDA guidelines. The Refusal to File (RTF) letter received on July 28, 2014, does not relate to the acceptability of the clinical data, and no judgment is made on the efficacy or safety of safinamide.

Following on from the submission in December 2013 of the Marketing Authorization Application (MAA) for safinamide to the European Medicines Agency, in April Newron reported Zambon's submission to Swissmedic for approval in Switzerland. These submissions cover the indications "safinamide as add-on therapy to a stable dose of a single dopamine agonist" in early Parkinson's disease patients and "safinamide as add-on therapy to levodopa alone or in combination with other Parkinson's disease treatments" in mid-to late stage Parkinson's disease patients.

Progress in R&D pipeline – with new funding

New mechanistic and behavioral studies with Newron's compound NW-3509 confirmed its potential for use in patients with schizophrenia. These studies, together with preliminary results from an ongoing US Phase I study were presented at the 4th Biennial Schizophrenia International Research Society (SIRS) Conference in April in Florence, Italy. The results confirmed NW-3509's selectivity to block voltage gated sodium channels (VGSCs) based on the evaluation of over 130 targets including receptors, channels, transporters and enzymes. By end of the current year, Newron plans to initiate a placebo-controlled safety and efficacy trial in schizophrenic patients who are poor responders to current treatment.

In April, Newron completed a capital increase resulting in gross proceeds of CHF 18.6 million, following the subscription by institutional investors of 1,183,597 newly issued shares. The

fundraising was supported by current institutional shareholders and institutional investors joining from Europe and the US, including J.P. Morgan Asset Management, Aviva, Investor AB and Swisscanto. In January, Newron had announced the placement of 211,473 shares left from a prior capital increase with J.P. Morgan Asset Management, resulting in proceeds of CHF 3.6 million. The net proceeds from the fundraisings will be primarily used to accelerate the development of the pipeline of innovative CNS therapeutics, including three Phase II compounds for orphan indications; sarizotan for patients suffering from Rett Syndrome, sNN0031 for patients with Parkinson's disease no longer responding to oral therapy, sNN0029 for patients with Amyotrophic Lateral Sclerosis (ALS), as well as NW-3509, in development as an add-on therapy for patients with positive symptoms in schizophrenia.

Stefan Weber, CEO of Newron, commented: "In the first six months of this year, our focus has been to work with our partner Zambon in completing the application dossiers for safinamide to the authorities in both Europe and the US. These have been submitted, although outside of this period, we have received a RTF letter from the US FDA. Whilst this is disappointing, based on the recent meeting we had with the FDA, we confirm our confidence that we can speedily resolve the organization and navigation problems the FDA has with the submission documentation, and refile the dossier as soon as reasonably practicable." Mr. Weber continued: "In the EU, the process towards the potential approval of safinamide is fully on track and we are confident that a decision on the submission will be received within the 12 months' review period, around the 2014 year-end."

Interim financial statements

In the first six months of 2014, Newron has invested EUR 6.5 million into drug development and preparations for regulatory submission of safinamide, up from EUR 4.4 million in 2013. Of these, EUR 3.8 million have been covered by our safinamide partner Zambon as well as by grants. Therefore, for the first six months of the year, net R&D expenses are EUR 2.6 million, up from 2013 expenses of EUR 0.8 million. G&A expenses reached EUR 3.5 million in the first six months of 2014, down from EUR 3.7 million in 2013. Revenues for the first half of 2014 were EUR 1.4 million, stemming from recognition of a 2012 license down-payment over the period of collaboration with partner Zambon, as well as the US submission milestone. The net loss for the first six months of 2014 amounts to EUR 4.6 million, compared to EUR 2.4 million in 2013. With EUR 31.4 million cash and short term investments, Newron has a healthy cash position, which should take the Company well into 2016, beyond expected key value inflexion points.

Financial Summary (IFRS)

In EUR thousand (except per share information)

	HY1 2014	**HY1 2013**
Licence income	1,300	1,799
Other income	100	353
Research and development expenses*	2,620	837
General and administration expenses	3,498	3,710
Net loss	4,596	2,446
Loss per share	0.37	0.21
	30/6/2014	**30/06/2013**
Cash, cash equivalents, other short term fin. assets	31,390	21,766
Total assets	44,626	37,102
Net cash used in operating activities	4,443	7,299

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

For further details see the Half-Year Report 2014 which is available for download at:
http://www.newron.com/financial-report

About Newron Pharmaceuticals
Newron (SIX: NWRN) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the Central Nervous System (CNS) and pain. The Company is headquartered in Bresso near Milan, Italy. Following the submission of the Marketing Authorization Application (MAA) for safinamide for the treatment of Parkinson's disease to the European Medicines Agency (EMA) in December 2013, to Swissmedic in March, 2014 as well as the New Drug Application NDA to the US FDA, Newron is working towards global approval of the compound, together with its partners. Zambon Group has the rights to commercialize safinamide globally, excluding Japan and other key Asian territories where Meiji Seika has the rights to develop and commercialize the compound. Newron's additional projects are based on highly promising treatments for rare disease patients and are at various stages of clinical development, including sarizotan for patients with Rett syndrome, sNN0031 for patients with Parkinson's disease, non-responsive to oral drug treatments, sNN0029 for patients with ALS and ralfinamide for patients with specific rare pain indications. Newron is also developing NW-3509 as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. www.newron.com

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