Newron Pharmaceuticals reports 2014 financial results
Board approves agenda for AGM on March 24, 2015

Milan, Italy – March 4, 2015 - Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel Central Nervous System (CNS) and pain therapies, announces its financial results for the year ended December 31, 2014, reiterates material events so far and presents the outlook for 2015.

Key facts and events

- Marketing approval for Xadago® (safinamide) by the EU Commission in February 2015 to treat Parkinson's disease based on the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) in December 2014
- Early March Newron informed that Xadago® (safinamide) New Drug Application (NDA) was accepted for filing by the US Food and Drug Administration FDA, after re-submission in December 2014
- Application for Authorization of Xadago® (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
- Newron US operations established: Newron Pharmaceuticals US, Inc., located in Morristown, New Jersey
- Newron shares included into the SXI Life Sciences® and the SXI Bio+Medtech® indices

Stefan Weber, CEO of Newron, said: "We are delighted to have made such major achievements in 2014. We are excited that the CHMP gave a positive opinion on safinamide to treat Parkinson´s disease, leading to the Marketing Authorization for Xadago® by the EU Commission, and eagerly await the start of commercialization of our first approved compound by our partner Zambon."

Ravi Anand, Newron's CMO, added: "Although Xadago® (safinamide) has been the main focus of 2014, our pipeline has also been progressing well. Results from mechanistic and behavioural studies with voltage-gated sodium channel (VGSC) blocker NW-3509 confirmed its potential for use in patients with schizophrenia. We have prepared the next studies for our promising treatments for patients with rare diseases – Rett Syndrome, ALS and Parkinson's disease, non-responsive to oral drug treatments – and have initiated these studies in early 2015 or will initiate them during 2015."

Xadago® (safinamide) at the forefront

In Europe, Newron was delighted to hear that the CHMP has recommended approval of Xadago® (safinamide) to treat Parkinson´s disease in the European Union, followed by the Marketing Authorization received from the EU Commission in February 2015. The approval covers the indication "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.

This is the first New Chemical Entity (NCE) in 10 years to receive a Marketing Authorization from the EU Commission for the treatment of Parkinson's disease and Newron believes it could offer significant improvement to the quality of life of those living with this condition.

In July, Newron received a refusal to file (RTF) letter from the US FDA for the use of Xadago® (safinamide) as add-on therapy for patients with Parkinson's disease. The RTF letter did not relate to the acceptability of the clinical data, and no judgment was made on the efficacy or safety of Xadago® (safinamide). Newron has since then worked closely with the FDA to resolve the organization and navigation problems with the application and has resubmitted the New Drug Application (NDA) to the FDA in December 2014. It is with great satisfaction that the Company has announced on March 2, 2015 the acceptance for filing of the NDA by the FDA.

Financial Highlights

- Licence income, amounting to EUR 1.3 million (2013: EUR 3.2 million) is related to the milestone payment received from Zambon S.p.A. upon submission of the NDA for Xadago® (safinamide) in the US and the 2012 upfront payment obtained from Zambon as part of the exclusivity and collaboration agreements related to Xadago® (safinamide).
- Research and development expenses were EUR 6.0 million (2013: EUR 4.5 million). R&D expenses related to Xadago® (safinamide) have been reimbursed by Zambon. R&D expenses include an impairment charge on HF0220. Gross R&D expense prior to reimbursement by Newron's partners and grants received was EUR 14.5 million (2013: EUR 11.9 million).
- The net loss was EUR 10.1 million (2013: EUR 7.1 million) due to lower license income and increased investment into R&D projects.

With EUR 25.7 million of cash in the bank and short term investments and approximately EUR 2.0 million committed funds by third parties, Newron is funded well into 2016, beyond key expected value inflexion points and related success payments.

Financial Summary (IFRS)

In thousand EUR (except per share information)

	2014	**2013**
Licence income	1,300	3,213
Other income	257	326
Research and development expenses, net	6,017	4,537
Operating loss	11,215	7,776
Financial income	492	63
Net loss	10,095	7,098
Loss per share	0.80	0.62
Cash, cash equivalents, other short term fin. Assets	25,702	18,426
Total assets	37,074	31,618

Newron's full annual report 2014 is available on http://www.newron.com/financial-report

Outlook

In 2014 and early 2015, Newron has succeeded in bringing Parkinson's disease patients a step closer to a potentially life changing therapeutic. The company is now looking forward to supporting the path towards the approval of Xadago® (safinamide) in the US and Switzerland. Looking ahead, Newron is continuing to develop its pipeline of novel CNS therapies and looking forward to progressing and expanding its portfolio in 2015.

AGM 2015 Agenda

Newron's Board of Directors has approved the below agenda for the March 24, 2015, 10:30am CET, ordinary and extraordinary Shareholders' meeting, which will take place at the Company's registered office in Bresso (Mi), Italy. The formal invitation to shareholders will be issued and disclosed in the statutory papers on March 4. The full invitation and supporting material will be made available on the Company's website on the same date.

1. Approval of the financial statements as at December 31, 2014
2. Share capital increase for payment, severable, with exclusion of the option right, for maximum nominal Euro 260,850, and therefore, for maximum n. 1,304,250 Newron Pharmaceuticals S.p.A. ordinary shares and, in any event, within the limits of the 10% of the share capital in accordance with article 2441, paragraph fourth, second part, of the Italian Civil Code and with article 6 of Company's By-Laws.
3. Share capital increase for payment, severable, with exclusion of the option right, in accordance with article 2441, paragraphs 5 and 8, of the Italian Civil Code, for maximum nominal Euro 80,000, and therefore, for maximum n. 400,000 Newron Pharmaceuticals S.p.A. ordinary shares, nominal value Euro 0.20 each, to serve one or more stock incentive plans.

Dial-in to media / analyst conference on 4 March 2015, 9:15-10:15am CET

The Newron management team will present the full year results and provide an update and guidance for the development of Newron's R&D pipeline.

The conference call can be accessed via the following dial-in numbers:

Continental Europe:	+41 (0) 58 310 50 00
UK:	+44 (0) 203 059 58 62
U.S.A.:	+1 (1) 631 570 56 13
Italy:	+39 02 30 46 48 58

The slide deck used in the presentation is available at http://www.newron.com/downloads

Next events

Annual Shareholders' meeting	24 March 2015
Half year report 2015	15 September 2015

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. Marketing authorization in the EU for Xadago® (safinamide) was granted by the EU Commission in February 2015, following the recommendation by the Committee for Medicinal Products for Human Use (CHMP) to approve the compound in the EU on Dec. 19, 2014. The New Drug Application (NDA) to the U.S. FDA, as informed in early March, has been accepted for filing, after being re-submitted by Newron on Dec. 26, 2014. In March 2014, Zambon Group, a partner of Newron, submitted a MAA to Swissmedic. Zambon 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.

For more information

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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. By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions. Newron may not actually achieve the plans, intentions or expectations disclosed in forward-looking statements and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron's research programmes, development activities, commercialisation plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions.

Newron does not undertake any obligation to publicly up-date or revise forward looking statements except as may be required by applicable regulations of the SIX Swiss Exchange where the shares of Newron are listed.

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