Newron Pharmaceuticals reports 2015 financial results
Board approves agenda for AGM on March 22, 2016

Milan, Italy – March 1, 2016 - Newron Pharmaceuticals S.p.A. ("Newron"), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system (CNS) and pain, announces its financial results for the year-ended December 31, 2015, reiterates material events and presents the outlook for 2016.

Key facts and events

- EU Commission approves Xadago® (safinamide) for mid-to-late-stage Parkinson's disease in February
- A late-cycle review meeting with the U.S. Food and Drug Administration (FDA) was held in September 2015 for the New Drug Application. The PDUFA date is set for 29 March, 2016
- Zambon launches Xadago® in Germany in May
- Meiji Seika Pharma initiates Phase II/III confirmatory and Phase III long-term trials with safinamide as add-on therapy to levodopa in patients with Parkinson's disease in Japan in October
- Swissmedic approves Xadago® for use in Parkinson's disease patients in Switzerland in November
- Orphan Drug Designation for sarizotan for the treatment of patients with Rett syndrome received from EU Commission and from U.S. FDA in the summer
- Planned pivotal international trial with sarizotan in patients with Rett syndrome; study expected to start in Q2 2016
- U.S. Phase II study initiation with NW-3509 as add-on treatment in patients with schizophrenia in December, following positive Phase I data reported in January 2015
- sNN0031 and sNN0029 development programs terminated following early-stage pipeline prioritization in October
- Completion of EUR 28.4 million private placements with leading EU and U.S. investors in April and November
- Zambon launches Xadago® in Switzerland, Spain and Italy in the beginning of 2016 (post-period events)

Stefan Weber, CEO of Newron, said: "It is very rewarding to see Xadago® now available to patients suffering from Parkinson's disease. Xadago® has been approved and launched in several territories across Europe and is continuing to progress towards approval in both the U.S. and Japan. We are delighted to have made such major achievements in 2015."

Ravi Anand, Newron's CMO, added: "While Xadago® remained the main focus of 2015, sarizotan has made significant progress, too. In summer, both the European Commission and the U.S. FDA granted Orphan Drug Designation for sarizotan for the treatment of patients with Rett syndrome. We have carried out advanced and extensive discussions with regulatory authorities in Europe, the U.S. and Canada, and we are planning a pivotal, 24-week, double-blind, placebo-controlled efficacy study to start in Q2 2016. Previous studies indicate that sarizotan has the potential to reduce apneas and hyperventilation episodes significantly, therefore having the potential to improve the quality of life of patients with Rett syndrome and their carers. If approved, sarizotan is likely to be the first product approved for this devastating disease and the first product that Newron commercializes on its own."

Xadago® (safinamide) launched in Germany
Early in the year, the European Commission approved the use of Xadago® for patients with mid-to-late-stage Parkinson's disease. Xadago® was approved as add-on therapy to levodopa alone or in combination with other Parkinson's disease treatments, making it the first new chemical entity in 10 years to receive approval for this indication. Most importantly, the label clearly lists the unique features of the product. In May, Newron's partner Zambon launched Xadago® in Germany and, following November's Swissmedic approval of Xadago® for use in Parkinson's disease patients in Switzerland, Zambon and Newron announced in early 2016 that Xadago® has been launched in Switzerland, Spain and Italy. The reception in Germany has been positive.

Further to this, in September the U.S. FDA New Drug Application late-cycle review meeting for Xadago® was completed with a PDUFA date of March 29, 2016. In October, the Japanese partner, Meiji Seika Pharma initiated Phase II/III confirmatory and Phase III long-term trials of safinamide as add-on therapy to levodopa for patients with Parkinson's disease in Japan who are experiencing the "wearing-off" phenomenon of their standard therapies. Xadago® has thus been approved and launched in several territories across Europe and is continuing to progress towards approval in both the U.S. and Japan.

Progress with sarizotan
This new chemical entity is being developed for the treatment of Rett syndrome, a rare neurodevelopmental disorder. Mid-year, the Committee for Orphan Medicinal Products (COMP) adopted a positive opinion, recommending sarizotan as an orphan medicinal product to the European Commission for the treatment of patients with Rett syndrome. This was followed by both the European Commission and the U.S. FDA granting Orphan Drug Designation to sarizotan for the indication. Newron believes sarizotan has the ability to reduce apneas and hyperventilation episodes significantly, therefore having the potential to improve the quality of life of patients with Rett syndrome and, by reducing secondary cardio-respiratory complications, to extend the lives of girls and women with Rett syndrome. Following advanced discussions with regulatory authorities in Europe, the U.S. and Canada a pivotal, 24-week, double-blind, placebo-controlled efficacy study for sarizotan is currently being planned.

Secured financing of pipeline projects
Newron's shareholders have been supportive and approved capital increases of up to 1.3 million additional shares to raise funds for developing the Company's pipeline assets. In April, institutional investors from Europe and the U.S. demonstrated their confidence in Newron by subscribing to 843,072 newly issued shares raising gross proceeds of EUR 23.4 million. Further to this, in November, Newron completed a private placement of 209,364 shares with a leading U.S. biotechnology and healthcare specialist fund, raising gross proceeds of EUR 4.9 million. These funds will be used to accelerate the development of the innovative product pipeline, namely the lead clinical programs, sarizotan in Rett syndrome and NW-3509, a novel add-on therapy for schizophrenia.

Financial Highlights
- License income, amounting to EUR 1.8 million (2014: EUR 1.3 million), is related to the non-refundable milestone payment from Zambon S.p.A. upon approval of Xadago® (safinamide) for the treatment of idiopathic Parkinson's disease; royalties of EUR 0.5 million were paid by Zambon based on net sales in Germany of Xadago® occurred in the period from May 15 to December 31

- Research and development expenses, net, increased to EUR 18.4 million (2014: EUR 6.0 million), primarily due to the progress made in the development of sarizotan and NW-3509, as well as the cost of terminating development, impairing sNN0031 and sNN0029, and restructuring the operations. R&D expenses related to Xadago® (safinamide) of EUR 3.2 (2014: EUR 6.4) have been reimbursed by Zambon. R&D expenses of EUR 1.7 million (2014: 2.1 million) have been covered by grants.
- Cash used in operations has increased to EUR 12.9 million (2014: EUR 9.9 million), mostly due to the increased investment in to R&D projects.

Group's liquidity, including available for sale financial assets and cash and cash equivalents, was EUR 41 million at year-end.

Financial Summary (IFRS)
In thousand EUR (except per share information)

	2015	**2014**
Licence income	1,800	1,300
Royalties	475	0
Other income	105	257
Revenue	**2.380**	**1.557**
Research and development expenses, net	18,449	6,017
Operating loss	**24,400**	**11,215**
Financial income	(583)	492
Net loss	**22,816**	**10,095**
Loss per share	1.66	0.80
Cash used in operating activities	12,862	9,998
Cash, cash equivalents, other short term fin. Assets	40,931	25,702
Total assets	44,380	37,074

Newron's full annual report 2015 is available on http://www.newron.com/financial-report

Outlook
Xadago® is now commercially available in Germany, Spain, Italy and Switzerland. The FDA has given a PDUFA date for Xadago® of March 29, 2016. The key pipeline projects sarizotan and NW-3509 are progressing well. The pivotal efficacy study with sarizotan is expected to start in Q2 2016 and results from the Phase II study of NW-3509 are anticipated in Q4 2016. On the basis of higher expected royalties on net sales of Xadago® in various European territories over the full-year period 2016 plus additional milestone payments and potential income from further licensing of Safinamide due from Zambon, 2016 revenue is expected to notably increase over 2015. R&D expenses will be higher compared to 2015, due to clinical development cost for the efficacy studies for sarizotan and NW-3509. The Group's liquidity will take Newron well into 2017, beyond expected key value inflexion points.

AGM/EGM 2016 Agenda
Newron's Board of Directors has approved the below agenda for the March 22, 2016, 10:30 am 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 1. The full invitation and supporting material will be made available on the Company's website on the same date.

1. Approval of the balance sheet as at 31 December 2015
2. Appointment of the statutory auditors for the three year time 2016-2018 and, therefore, until the approval of the balance sheet as at 31 December 2018, and determination of their fees
3. Appointment of the auditing company for the period 2016-2018
4. Granting to the Board of Directors of the powers, pursuant to article 2443 of the Civil Code, to increase, in one or more time, the share capital, severally (*in via scindibile*), even with the exclusion of the option right pursuant to article 2441, parts 4, first section, 5, 6 and/or 8 of the Civil Code, provided that in the whole the increases in the share capital under points 4, 5 and 6 of this shareholders' meeting can be executed for a maximum par value not higher than Euro 711.177,20 and therefore for a maximum of n. 3.555.886 Newron Pharmaceuticals S.p.A. ordinary shares
5. Granting to the Board of Directors of the powers, pursuant to article 2420-ter of the Civil Code, to issue convertible bonds and to increase, in one or more time, the share capital, severally (*in via scindibile*), and to increase, in one or more time, the share capital, severally (*in via scindibile*), even with the exclusion of the option right pursuant to article 2441, part 5 and 6 of the Civil Code, provided that in the whole the increases in the share capital under points 4, 5 and 6 of this shareholders' meeting can be executed for a maximum par value not higher than Euro 711.177,20 and therefore for a maximum of n. 3.555.886 Newron Pharmaceuticals S.p.A. ordinary shares
6. Increase in the share capital, severally (*in via scindibile*), for payment, with the exclusion of the option right, within the limit of 10% of the share capital pursuant to article 2441, part 4, second section, of the Civil Code, provided that in the whole the increases in the share capital under points 4, 5 and 6 of this shareholders' meeting can be executed for a maximum par value not higher than Euro 711.177,20 and therefore for a maximum of n. 3.555.886 Newon Pharmaceuticals S.p.A. ordinary shares
7. Subject to approval and execution of resolutions under points 4, 5 and 6 above, revocation:
   (i) of the resolution adopted on 27 March 2014, drafted by Notary Public Filippo Zabban of Milan, rep. 66.143/11.351 granting to the Board of Directors, pursuant to article 2443 of the Civil Code, the power, within 27 March 2019, to increase the share capital for payment, severally (*in via scindibile*), in one or more time, up to a maximum par value of Euro 375,844.00 and therefore up to maximum no. 1,879,220 Newron Pharmaceuticals S.p.A. ordinary shares having the same characteristics of the already issued ones, with exclusion of the option right pursuant to Article 2441, part 5, of the Civil Code;
   (ii) of the resolution adopted on 2 April 2010, minuted by Notary Public Stefano Rampolla of Milan, rep. 34893/8887, upon the several (in via scindibile) share capital increase in option up to a maximum par value of Euro 375,844.00 through the issuance of maximum no. 1,879,220 ordinary Newron Pharmaceuticals S.p.A. shares.

Dial-in to media / analyst conference on 1 March 2016, 9:15 - 10:15 am 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.:	+1 631 570 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	22 March 2016
Half year report 2016	15 September 2016

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) for the treatment of Parkinson's disease was granted by the EU Commission in February 2015, followed by Swissmedic's marketing authorization for Switzerland in November 2015. The drug has been launched by Newron's partner Zambon in the first key EU countries Germany, Spain and Italy, as well as in Switzerland. The New Drug Application (NDA) has been accepted for review by the FDA, PDUFA date March 29, 2016. Zambon has the rights to develop and 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. They include Sarizotan for patients with Rett Syndrome, for which Newron received Orphan Drug Designation in both the US and the EU, ralfinamide for patients with specific rare pain indications, and NW-3509 as potentially the 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.

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