Newron announces 2016 financial results and provides outlook for 2017
Board approves agenda for AGM on March 28, 2017

Milan, Italy, March 2, 2017 – 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, today announces its financial results for the year ended December 31, 2016, and reiterates material events with the outlook for 2017. In addition, Newron presents the approved agenda for the 2017 AGM.

Highlights

Xadago® (safinamide):

- Launched by Zambon for patients with Parkinson's disease in three additional top five territories in the EU (Italy, Spain, UK) as well as Belgium, Denmark, Sweden, Luxembourg, The Netherlands, Norway and Switzerland
- U.S. FDA considers the re-submitted NDA for Xadago® to be a complete, class 2 response to Complete Response Letter (CRL) of March 2016, and sets PDUFA date of March 21, 2017
- Seqirus and Zambon enter into a partnership for Xadago® in Australia and New Zealand (post period)

Evenamide (NW–3509):

- Phase IIa study design presented at 5th Biennial Schizophrenia International Research Society Conference in Florence, Italy
- Encouraging preliminary results of Phase IIa study with Evenamide (NW-3509) in patients with schizophrenia disclosed (post period)
- Detailed Phase IIa study results to be presented at 16th International Congress on Schizophrenia Research (ICOSR), March 24–28, 2017, San Diego, CA, USA

Sarizotan:

- IND approval for sarizotan for the treatment of Rett syndrome by the U.S. FDA
- STARS trial design presented at U.S. Rett Syndrome Symposium
- Initiation of STARS potentially pivotal study for patients with Rett syndrome
- Start of International burden of disease study in Rett syndrome

Corporate:

- Newron raised EUR 26.8 million in October 2016 via a private placement of new shares and an exercise in March 2016 of a 2015 option agreement with a U.S. institutional investor
- Dennis Dionne, Executive Director for Commercial Operations, appointed to Newron's Senior Management Team as Vice President Commercial Affairs

Xadago® launched in ten additional European countries

Following the 2015 European approval and the launch in Germany, 2016 saw the launch of Xadago® in ten further European markets by Newron's partner Zambon. The launch in, among others, Italy, Spain, the UK and Switzerland, means that a large and increasing number of patients across Europe can now be treated using Xadago®, the first New Chemical Entity in ten years to receive Marketing Authorization from the EU Commission for the treatment of Parkinson's disease. From the initial

launch of Xadago® in Germany in May 2015, Newron has generated cumulated royalty revenues of EUR 2.2 million on product sales by its partner Zambon. Post-period, Zambon and Seqirus announced that they have entered a partnership for the registration and commercialisation of Xadago® in Australia and New Zealand.

Following the news in March 2016 that the US Food and Drug Administration (FDA) had issued a CRL for Xadago®, Newron announced, in July 2016, alongside its partners U.S. WorldMeds and Zambon, that the FDA no longer required the Company to perform any studies to clinically evaluate the potential abuse liability or dependence/withdrawal effects of Xadago®, the key subject of the CRL. In October 2016, Newron welcomed the FDA's announcement that it considered the September 2016 re-submission of the U.S. NDA by the Company to be a complete Class 2 response.

"We are hopeful that Xadago® will be approved in the U.S. on or before its PDUFA date of March 21 and that it will become available to U.S. patients, in the near future," comments Ravi Anand, Newron's Chief Medical Officer.

Progress with Evenamide

In April 2016, Newron presented a poster at the 5th Biennial Schizophrenia International Research Society Conference titled "Evenamide (NW–3509), a Putative Antipsychotic, Targets Abnormal Electrical Activity and Glutamatergic Abnormalities in Improving Psychotic Symptoms in Patients with Schizophrenia in a Phase II, Placebo-controlled Trial". The encouraging results of this Phase IIa study were announced post period in January 2017. Evenamide met the study objectives of good tolerability, safety, and preliminary evidence of efficacy as an add-on therapy for the treatment of schizophrenia. Detailed results of the study will be presented at the 16th International Congress on Schizophrenia Research (ICOSR), in March, in San Diego (CA), USA.

Studies initiated with Sarizotan

In May 2016, the FDA approved Newron's Investigational New Drug (IND) application for the evaluation of sarizotan for the treatment of patients with Rett syndrome. Following this approval, in July the Company initiated its potentially pivotal clinical STARS study that will evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome suffering from respiratory symptoms. The initiation of the STARS study is an important milestone within the development program for sarizotan. As of December 31, 2016, the study is enrolling patients in both the USA and Europe.

As part of Newron's wider commitment to addressing the needs of Rett syndrome patients, the Company is currently sponsoring a study to evaluate the burden of disease experienced by patients with this debilitating condition and their families. The study will be comprised of two global surveys, one to be completed by at least 750 caregivers and the other by at least 210 healthcare providers(HCP). The surveys have been developed in accordance with regulatory guidance, with the final versions being used for data collection in the USA, the UK, Italy, Germany and the Netherlands.

Financial Highlights

- Total revenues have substantially increased to EUR 6.7 million from EUR 2.4 million (2015) in the reporting period; mostly due to
    - Increased license income, reflecting milestone payments received from Zambon (EUR 3.0 million in 2016 vs. EUR 1.8 million in 2015)
    - Royalties of EUR 1.7 million (EUR 0.5 million in 2015)
    - Other income, especially Italian R&D tax credits of EUR 2.0 million (EUR 0.1 million in 2015).

- Research and development expenses were EUR 12.4 million (2015: EUR 18.4 million), net of Italian R&D tax credits of EUR 4.9 million; investment was primarily made into the Evenamide Phase IIa study, the STARS potentially pivotal study in Rett syndrome patients, and the Burden of Disease study in Rett syndrome.

- Cash used in operations has increased to EUR 19.6 million (2015: EUR 12.9 million).

- In 2016, Newron, by placing new shares to investors, raised total funds of EUR 26.8 million, of which EUR 3.0 million related to the exercise, in March, of a purchase option for 209,364 shares by a shareholder under a 2015 subscription and option agreement, while the remaining EUR 23.8 million resulted from a private placement executed in October.

- Newron's liquidity, including available financial assets and cash and cash equivalents, was EUR 46.5 million, at year-end (2015: EUR 40.9 million)

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

	2016	**2015**
Licence income	3,039	1,800
Royalties	1,698	475
Other income	1,989	105
Revenues	**6,726**	**2.380**
Research and development expenses, net	12,398	18,449
Operating loss	**15,325**	**24,400**
Financial income	121	(583)
Net loss	**15,237**	**22,816**
Loss per share	1.04	1.66
Cash used in operating activities	19,583	12,862
Cash, cash equivalents, other short term fin. Assets	46,468	40,931
Total assets	56,591	44,380

Newron's 2016 Annual Report is available on http://www.newron.com/financial-report

Outlook for 2017
"We look forward to the decision on the forthcoming PDUFA date for Xadago® on or around March 21 and are confident that in 2017, we will see Xadago® become available to patients in the USA and additional European territories. We are highly encouraged by the potential of both sarizotan and Evenamide and we look forward to continuing the development of both in the ongoing year. Our innovative pipeline is progressing well and we will strengthen our position as a leading player in the CNS disease area. We started 2017 with funds totalling EUR 46.5 million, which we anticipate will take our Company towards the end of 2018, beyond expected key value inflexion points", comments Newron's Chief Executive Officer Stefan Weber.

AGM 2017 Agenda
Newron's Board of Directors has approved the agenda below for the March 28, 2017, 10:30 am CET, ordinary 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 or about March 2. The full invitation and supporting material will be made available on the Company's website on the same date. The agenda is as follows:

- Approval of the financial statements as at December 31, 2016. Related and consequent resolutions
- Appointment of the Board of Directors for the financial years 2017, 2018 and 2019 and, therefore, until the approval of the financial statements as of December 31, 2019, as follows:
  - Ulrich Köstlin in quality of Chairman of the Board and non-executive director
  - Stefan Weber, in quality of executive director
  - Patrick Langlois in quality of non-executive director
  - Bo Jesper Hansen in quality of non-executive director
  - Robert Leslie Holland in quality of non-executive director
  - Luca Benatti in quality of non-executive director and,
  - Donald de Bethizy in quality of non-executive director
  - Determination of the remuneration of the Board of Directors. Related and consequent resolutions

Dial-in to media/analyst conference on March 2, 2017, 9:15-10:15 am CET
The Newron management team will present the 2016 full year results and provide an update and guidance for 2017. The conference call can be accessed via the following dial-in numbers:

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

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

Next events

- Annual Shareholders' meeting March 28, 2017
- Half year report 2017 September 14, 2017

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, with a subsidiary in Morristown, NJ, U.S.A. Xadago® (safinamide) has received marketing authorization for the treatment of Parkinson's disease in the European Union and Switzerland and is commercialized by Newron's partner Zambon. US WorldMeds holds the commercialization rights in the US. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. In addition to Xadago® for Parkinson's disease, Newron has a strong pipeline of promising treatments for rare disease patients at various stages of clinical development, including sarizotan for patients with Rett syndrome and ralfinamide for patients with specific rare pain indications. Newron is also developing Evenamide as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. **www.newron.com**

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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