Newron announces 2017 financial results and provides outlook for 2018

Milan, Italy, March 1, 2018 – Newron Pharmaceuticals S.p.A. ("Newron"), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system, today announces its financial results and operational highlights for the year ended December 31, 2017, and provides an outlook for 2018. Additionally, Newron announces the approved agenda for the Company's 2018 shareholders' meeting.

Highlights:

Xadago® (safinamide)

- Xadago available in the US for the treatment of Parkinson's disease as add-on therapy to levodopa/carbidopa, following US FDA approval
- Newron received EUR 11.3 million milestone payment for US approval of Xadago
- Zambon launched Xadago in Portugal, Austria and Finland for patients with mid- to late-stage Parkinson's disease; Xadago now available in 14 European countries
- Zambon entered into partnerships and collaborations for Australian/New Zealand, Canadian and Israeli markets
- Dossiers for marketing authorization currently under review in Australia, Brazil, Canada and Colombia
- Meji Seika entered into a collaboration with Eisai for the development and commercialization in Japan and key territories in Asia; the partners announced that the primary endpoint was met in Ph II/III clinical study with safinamide as add-on to levodopa (post-period)

Evenamide

- Evenamide met Phase IIa study objectives of good tolerability, safety, and preliminary evidence of efficacy as an add-on therapy for the treatment of patients with chronic schizophrenia
- Encouraging results presented at International Congress on Schizophrenia Research and at the European College of Neuropsychopharmacology Congress
- Meetings with a number of health authorities confirmed the acceptance of preliminary evidence of efficacy and of the design of two potentially pivotal studies, which are key components of the Phase III development program that is expected to commence towards the end of 2018

Sarizotan

- Newron amended its "Sarizotan Treatment of Apneas in Rett Syndrome" (STARS) study to include Rett syndrome patients under 13 years of age, following FDA approval of the extension
- STARS study launched at trial sites in Italy, Australia, the UK and India
- Poster presented at 22nd Annual International Meeting of the International Society for Pharmaeconomics and Outcome Research on the largest and most comprehensive qualitative study to examine burden of Rett syndrome
- Burden of Disease Advisory Board Meeting and Thought Leadership Roundtable at European Rett Congress

Corporate

- Newron raised CHF 27.0 Million in a private placement of new shares
- Coverage of Newron stock initiated by Bank Vontobel and Kempen (post end of reporting period)

Stefan Weber, Newron's Chief Executive Officer, commented:
"We are delighted by the progress that has been made both with our commercial product, Xadago and with our pipeline products during 2017. In 2018, we hope Xadago will be made available to patients in additional countries and territories. We are excited by the potential of both sarizotan and Evenamide and we look forward to their continued development. We believe their progression has the potential to strengthen our position as a leader in the CNS disease area. With a strong balance sheet, we anticipate our funding will take us to 2020,

beyond expected key value inflection points. Newron also continues to evaluate non-dilutive funding opportunities".

Xadago®: Launch in the US and additional study to confirm benefits in LID

In 2017, Xadago (safinamide) received FDA approval and was launched in the United States (US). It is the first New Chemical Entity approved in more than a decade for the treatment of Parkinson's disease (as an add-on therapy for patients currently taking levodopa/carbidopa and experiencing so-called "OFF" episodes) and an important milestone for the Company. As a result of the approval by the FDA, Newron received a EUR 11.3 million milestone payment from its partner Zambon. In addition to the product's launch in the US, Xadago was also made available by Zambon in Portugal, Austria and Finland, in 2017. Dossiers for marketing authorization of Xadago in Brazil and Colombia have been submitted by Zambon, and are under review by the relevant authorities.

Furthermore, Zambon announced partnerships for Xadago with Seqirus in Australia and New Zealand, with Valeo Pharma in Canada, and, post period, informed Newron of its partnership with Medison Pharma in Israel. Seqirus has filed for marketing authorization in Australia and will undertake the commercialization of Xadago in Australia and New Zealand. Valeo Pharma has filed for marketing authorization in Canada and will be responsible for all further regulatory, sales and marketing, quality, and distribution activities in Canada.

In addition, Newron's partner in Asia, Meiji Seika, entered into a collaboration with Eisai for the development and commercialization of Xadago in Japan and key territories in Asia. Post-period, both announced that the primary endpoint was met in a Phase II/III clinical study with safinamide as an add-on to levodopa in patients with Parkinson's disease. Consequently, Meiji plans to file for marketing authorization of safinamide with the Japanese Pharmaceutical and Medical Device Agency (PMDA) during 2018.

A study to demonstrate the anti-dyskinetic effect of Xadago in Parkinson's disease patients with Levodopa Induced Dyskinesia (LID) is scheduled to start in the second half of 2018 and is being planned together with the Company's partner Zambon.

Newron's CEO Stefan Weber commented: "We are confident that the prior evidence of Xadago's benefits in Parkinson's disease patients with Levodopa Induced Dyskinesia will be confirmed, providing a treatment option for more patients and an enhanced commercial opportunity."

Evenamide: Design of two potentially pivotal studies underway

Newron has also made strong progress with Evenamide, the Company's innovative drug candidate with a novel mechanism of action, offering a new treatment option for patients suffering from schizophrenia. In 2017, a Phase IIa study demonstrated evidence of efficacy in significantly improving symptoms of psychosis compared with placebo, when added to two of the most commonly prescribed atypical antipsychotics in patients with chronic schizophrenia. It also indicated that Evenamide is a highly selective sodium channel antagonist, and does not interact with any of the neurotransmitters, enzymes, or transporters affected by most antipsychotics. Ravi Anand, Newron's Chief Medical Officer, commented: "These results, together with earlier preclinical results, which indicated inhibition of stimulated release of glutamate by Evenamide, have been discussed with a number of health authorities; meetings with the EMA's CHMP and the FDA are being scheduled for Q2 2018."

Newron intends to finalize the design of two potentially pivotal efficacy studies within the Phase III development program, which is expected to commence towards the end of 2018, after receiving CHMP and FDA input. The first study will enroll patients with schizophrenia experiencing worsening of psychosis on atypical antipsychotics, and the second study will be performed in treatment-resistant schizophrenia patients not responding to the antipsychotic drug clozapine. It is estimated that this latter cohort consists of approximately 20,000-35,000 patients in the US and potentially provides a separate indication for Evenamide that Newron may commercialize on its own.

Sarizotan: Expanded STARS study and poster presentation

The development of Newron's Rett syndrome candidate sarizotan has been advancing in 2017. The ongoing "Sarizotan Treatment of Apneas in Rett Syndrome" (STARS) study was expanded, with patients as young as six years now included in the trial. This expansion was approved by the US FDA and health authorities in Italy, Australia, the UK and India. Currently, patients are recruited in 15 centers in the US, the UK, Italy, India and Australia.

In addition to the clinical development of sarizotan, Newron continues to advance its partnership with the Rett community. Newron initiated the first qualitative study to examine the burden of Rett syndrome on individuals and their caregivers with the help of an international panel of experts. A poster entitled "Burden of Disease in Rett Syndrome: A Qualitative Analysis" was presented at the 22nd Annual International Meeting of the International Society for Pharmacoeconomics and Outcome Research, showing the results of a targeted literature search and preliminary findings from a qualitative interview study aimed at describing the burden of Rett syndrome on individuals and their families.

Initiative for standardized methodology to assess the value of orphan drugs

In November 2017, at the European Rett Syndrome Congress in Berlin, Newron held a Burden of Disease Advisory Board Meeting, at which the questions for inclusion in a survey that will be distributed internationally to caregivers and allied healthcare professionals were agreed. Alongside the Congress, the Company hosted a thought leadership roundtable discussion to discuss the need for a standardized methodology to assess the health economic value of orphan drugs treating rare diseases that impact multiple organ systems. Although, by definition, only a small number of patients suffer from each rare disease, collectively they present significant medical and socio-economic issues. "We believe that improved methods for assessing the value of orphan drugs will enable better development of drugs to treat these diseases. Improving these methods is an area of research and interest, which Newron will be pursuing further in 2018", emphasizes Newron's VP Commercial Affairs Dennis Dionne.

Financial Highlights:

- Total revenues substantially increased to EUR 13.4 million from EUR 6.7 million (2016) in the reporting period; largely due to
  - Increased license income, reflecting milestone payments received from Zambon (EUR 10.4 million in 2017 vs. EUR 3.0 million in 2016)
  - Royalties of EUR 2.9 million (EUR 1.7 million in 2016)
- Research and development expenses were significantly lower than in 2016, at EUR 8.6 million (2016: EUR 12.4 million), net of Italian R&D tax credits of EUR 4.5 million;
- Cash used in operations decreased to EUR 8.4 million (2016: EUR 19.6 million).
- In 2017, Newron, by a private placement of new shares to investors, raised CHF 27.0 million.
- Newron's cash position, including available financial assets and cash and cash equivalents, was EUR 60.1 million, at year-end (2016: EUR 46.5 million)

Financial Summary (IFRS):

In thousand EUR (except per share information)

	2017	**2016**
Licence income	10,430	3,039
Royalties	2,855	1,698
Other income	143	1,989
Revenues	**13,428**	**6,726**
Research and development expenses, net	8,596	12,398
Operating loss	**4,346**	**15,325**
Financial result, net	(955)	121
Net loss	**5,282**	**15,237**
Loss per share	0.32	1.04
Cash used in operating activities	8,404	19,583

Cash, cash equivalents, other short-term fin. assets	60,081	46,468
Total assets	73,024	56,591

Newron's full 2017 Annual Report is available on www.newron.com/financial-report-2017

Outlook for 2018:

"We look forward to Xadago becoming available to patients in additional countries and territories. The Company is highly encouraged by the potential of both sarizotan and Evenamide and looks forward to continuing the development of both in the ongoing year. We started 2018 with funds totalling EUR 60.1 million, which we anticipate will take the Company to 2020, beyond expected key value inflection points. We also continue to evaluate non-dilutive funding opportunities", commented Newron's VP Finance Roberto Galli.

2018 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the March 27, 2018, 10:00 am CET, 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 around March 1. The full invitation and supporting material will be made available on the Company's website on the same date. The agenda is as follows:

1. Approval of the financial statements as at December 31, 2017. Related and consequent resolutions.
2. Granting to the Board of Directors of the powers, pursuant to articles 2443 and 2420-ter of the Italian Civil Code, to issue shares and/or convertible bonds, up to Euro 1,426,987.60 even with the exclusion of option rights pursuant to article 2441, parts 4, first section, 5, 6 and/or 8 of the Italian Civil Code, eventually cum warrant. Amendment of article 6 of the By-Laws. Connected and consequent resolutions.
3. Powers to create American Depositary Shares and to list them on the Nasdaq or on any other market in the United States of America; connected and consequent resolutions.

Dial-in details to the media/analyst conference on March 1, 2018, 9:15-10:15 am CET

The Newron management team will present the 2017 full year results and provide an update and guidance for 2018. The conference call can be accessed via the following dial-in numbers:

Switzerland/Europe: +41 (0) 58 310 50 00
United Kingdom: +44 (0) 207 107 0613
United States: +1 (1) 631 570 5613
Italy: +39 02 805 88 20

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

Upcoming events:

- Annual Shareholders' meeting March 27, 2018
- Half year report 2018 September 13, 2018

About Newron Pharmaceuticals

Newron (SIX: NWRN) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system. The Company is headquartered in Bresso near Milan, Italy. Xadago® (safinamide) has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland and the USA, and is commercialized by Newron's Partner Zambon. US WorldMeds holds the commercialization rights in the USA. 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. For more information, please visit: **www.newron.com**

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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 commercialization 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 programs, development activities, commercialization 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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