Newron announces 2021 financial results and provides outlook for 2022

Ad hoc announcement pursuant to Art. 53 LR

Milan, Italy, March 15, 2022, 7 am CET – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN, XETRA: NP5), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system, today announced its financial results and operational highlights for the year ended December 31, 2021, and provided an outlook for 2022.

Highlights 2021:

Evenamide (Schizophrenia)

- Two short-term explanatory studies of evenamide both met their primary objectives of demonstrating absence of arrhythmia risk (TQT-Study 010) in healthy volunteers, and the absence of EEG/neurological abnormalities (EEG Study 008) in patients with schizophrenia
- Newron initiated:
  - an open-label study of evenamide as add-on to antipsychotics in patients with treatment resistant schizophrenia (TRS) and its extension (studies 014 and 015)
  - study 008A, the first randomized, placebo-controlled, adequate, well-controlled, potentially pivotal study of evenamide in patients with chronic schizophrenia not responding adequately to second-generation antipsychotics (non-TRS)
- Newron continues to evaluate strategic commercial and development partnering options for evenamide

Xadago®/safinamide (Parkinson's disease)

- Newron signed a partnership agreement with Zambon to initiate a potentially pivotal study with safinamide in Parkinson's disease patients with levodopa-induced dyskinesia (PD LID)
- Newron and its partners Zambon and Supernus continue to work to protect intellectual property rights associated with Xadago®/safinamide in the US, responding to Paragraph IV Notice Letters regarding Abbreviated New Drug Applications submitted from generic pharmaceutical manufacturers

Corporate

- Newron received the fourth and fifth tranches of funding from the European Investment Bank (EIB), each totaling EUR 7.5 million; total financing from the EIB since 2019 is now EUR 40 million, and has thus been fully drawn
- Newron continues to explore a number of potential opportunities to expand its pipeline in central nervous system diseases

Stefan Weber, CEO of Newron, commented:

"We are pleased to share the progress made by Newron throughout 2021, as well as to provide an update on what we hope to achieve as we move forward into 2022. Most significantly, our team has succeeded in initiating study 008A with evenamide, launching our Phase II/III program and representing the first potentially pivotal study in patients with schizophrenia who are inadequate responders to antipsychotics. Our team continues to explore a number of strategic opportunities and potential commercial partnerships to expand our pipeline in central nervous system diseases, including opportunities to in-licence."

Evenamide

In 2021, Newron announced the results from two short-term explanatory studies of evenamide, study 010 and study 008, which both met their primary objective of safety. Study 010 was a short-term safety study of the effects of two doses of evenamide (30mg and 60mg) in 56 healthy volunteers, and study 008 was a four-week Phase II study in 138 outpatients with chronic schizophrenia currently being treated with a second-generation atypical antipsychotic. The results showed that evenamide is safe at all doses investigated (with no systematic

pattern of adverse effects on the central nervous system), is devoid of any arrhythmic effect (a risk associated with antipsychotics) and can be safely taken with other antipsychotics. Following recent discussions with the U.S. Food and Drug Administration (FDA), Newron will address the remaining FDA issues once data from studies 014 and 008A studies are available.

After the encouraging results from study 008, Newron initiated study 008A, a four-week, randomized, double-blind placebo-controlled study to assess the efficacy, tolerability, and safety (including electroencephalogram effects) of the therapeutic BID dose of 30mg in patients with chronic schizophrenia currently being treated with a second-generation antipsychotic. This study represents the first part of Newron's Phase II/III clinical trial program that targets patients with schizophrenia experiencing worsening of psychosis who are inadequately responding to therapeutic doses of second-generation antipsychotics (non TRS). Study 008A involves treatment centers across twelve countries in Europe, Asia and Latin America, and results are expected around the end of 2022. Subject to positive results, study 008A would be the first randomized, placebo-controlled, adequate, well-controlled, potentially pivotal study of evenamide in schizophrenia patients who are inadequate responders to atypical anti-psychotic treatment.

In the second indication of its Phase II/III development plan for evenamide, treatment-resistant schizophrenia (TRS), Newron has initiated pilot study 014. This is a six-week, open-label, randomized, rater-blinded, multi-centre study with sites in Italy, India, Sri Lanka and Malaysia. The study was designed to evaluate the safety, tolerability, and preliminary efficacy of fixed doses of evenamide of 7.5 mg BID, 15 mg BID and 30 mg BID as add-on treatment in patients with moderate to severe TRS. Currently, 110 of the intended 150 patients have been enrolled to study 014. Completers are eligible to continue treatment with the randomized dose in an extension study (015) for up to 46 weeks. Newron intends to announce first results from study 014 in Q2 2022.

The pilot study in patients suffering from TRS would be followed by the second potentially pivotal study with evenamide in patients with treatment resistant schizophrenia on a second-generation antipsychotic. Importantly, if approved, evenamide would be the first add-on therapy for schizophrenia. Its glutamatergic inhibition mechanism of action represents an innovative alternative to common dopaminergic or serotonergic drugs, potentially offering a new therapeutic option for patients who are not or inadequately responding to existing second-generation antipsychotics.

Xadago®/safinamide

As Newron looks to further develop its marketed product, Xadago®/safinamide, in 2021 the company announced it had signed a partnership agreement with Zambon to begin a potentially pivotal study in patients with Parkinson's disease and levodopa-induced dyskinesia (PD LID). Under this partnership agreement, Newron will sponsor the study and be responsible for its development and execution, and lead on all regulatory interactions. Newron and Zambon will share the costs of the study evenly. The double-blind, placebo-controlled study is intended to be performed in the US, Europe and Asia/Australia, with the aim of a label extension for safinamide in key markets.

In May 2021, Newron announced that it had received several Paragraph IV Notice Letters regarding the submission by generic manufacturers of an Abbreviated New Drug Application to the FDA, seeking approval to engage in the commercial manufacture, use or sale of safinamide mesylate drug product in the US before expiration of certain US patents. Newron and its partners Zambon and Supernus have responded by filing an infringement suit against the generic manufacturers to secure a 30-month stay of the ANDAs approval, and thus to protect its intellectual property rights relating to Xadago®/safinamide tablets. Xadago® (safinamide) tablets are currently protected by three patents listed in the FDA's Approved Drugs Product List (Orange Book) that expire no earlier than 2027.

Financial Key takeaways 2021:

- In 2021, Newron reported a net loss of EUR 14.9 million, compared to EUR 21.0 million in 2020
- Cash used in operating activities has decreased to EUR 11.5 million from EUR 15.6 million in 2020
- Xadago® revenues from Zambon increased from EUR 5.3 million in 2020 to EUR 5.8 million in the reporting period.
- Newron's R&D expenses have fallen to EUR 10.7 million from EUR 14.9 million in 2020
- G&A expenses reached EUR 7.4 million in 2021 versus EUR 8.1 million in 2020
- Cash and Other current financial assets as at December 31, 2021 were at EUR 34.6 million, compared to EUR 31.3 million at the beginning of the year

Financial Summary (IFRS) 2021 and 2020:

In thousand EUR (except per share information)

	2021	**2020**
Licence income contracts with customers	34	23
Royalties from contracts with customers	5,728	5,235
Revenues	**5,762**	**5,258**
Research and development expenses, net	(10,725)	(14,853)
Operating Loss	**12,357**	**18,066**
Financial result, net	(2,527)	(1,552)
Net loss	**14,901**	**20,998**
Loss per share	0.84	1.18
Cash used in operating activities	(11,445)	(15,588)
Cash, cash equivalents and Other current financial assets	34,594	31,250
Total assets	50,486	51,198

Newron's Annual Report 2021 is available for download on the Company's website: www.newron.com/investors/reports-and-presentation/year/2021

Outlook 2022:

"We look forward to completing study 008A evaluating the efficacy of evenamide in patients with schizophrenia, with results expected towards the end of 2022. We look forward to results from our open-label study of evenamide as add-on to antipsychotics in patients with treatment resistant schizophrenia, and plan to follow up on this study by investigating evenamide in a Phase III study as a new therapeutic option for patients who are considered to have treatment-resistant schizophrenia. In 2022, we will also continue to progress towards initiating the label-extension study for safinamide in patients with Parkinson's disease and levodopa-induced dyskinesia with our partner Zambon. Newron's total available cash resources will fund the Company's planned development programs and operations into 2024," outlined Stefan Weber, CEO of Newron.

2022 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the April 5, 2022, Shareholders' meeting, which will take place at the Company's registered office (Via Antonio Meucci 3) in Bresso (Mi), Italy, starting at 10 am CET. The formal invitation to shareholders will be issued and disclosed in the statutory papers on or around March 15.

The full invitation and supporting material will be made available on the Company's website (www.newron.com/investors/shareholders-meeting) on the same date. The agenda is as follows:

1. Approval of the balance sheet as at 31 December 2021. Connected and consequent resolutions
2. Redefinition of the number of the Board members; connected and consequent resolutions
3. Appointment of the statutory auditors for the three fiscal-year time 2022-2024 and, therefore, until the approval of the balance sheet as at 31 December, 2024, and determination of their fees. Connected and consequent resolutions

4. Appointment of the auditing company; connected and consequent resolutions

Dial-in details to the media/analyst/investor conference on March 15, 2022, 3 pm CET

The Newron management team will present the 2021 full-year results and provide an update and guidance for 2022. 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 06 13
- United States: +1 (1)631 570 56 13

The slide deck is available at www.newron.com/investors/reports-and-presentation/year/2021

Upcoming events

- AGM 2022: April 5, 2022
- Half-year report 2022: September 15, 2022

About Newron Pharmaceuticals

Newron (SIX: NWRN, XETRA: NP5) 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, the UK, the USA, Australia, Canada, Latin America, Israel, the United Arab Emirates, Japan and South Korea, and is commercialized by Newron's Partner Zambon. Supernus Pharmaceuticals 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. 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, the timing of commencement of various clinical trials and receipt of data and current and future collaborations for the development and commercialization of its product candidates, (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's 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 difficulties in enrolling clinical trials, 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. Newron does not undertake any obligation to publicly update 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. This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron and no part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.