Newron announces 2022 financial results and provides outlook for 2023

Ad hoc announcement pursuant to Art. 53 LR

Milan, Italy, March 14, 2023, 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 business year ended December 31, 2022, and provided an outlook for 2023.

Highlights 2022:

Evenamide (Schizophrenia)

- Striking interim efficacy and safety results from world-first Phase II clinical trial evaluating evenamide as add-on therapy for patients with treatment-resistant schizophrenia (TRS), after six weeks and, post-period, six months and one year
- Enrolment of patients in study 014 completed, with 161 subjects randomized (post-period); full results from the study after six weeks of treatment expected in March 2023
- Following the interim data in patients suffering from TRS, study 003, a potentially pivotal, multinational, randomized, double-blind, ten-week, placebo-controlled study assessing the efficacy, safety and tolerability of 15 and 30 mg bid of evenamide as an add-on treatment in patients with TRS, is expected to commence in 2023
- Patient recruitment in potentially pivotal study 008A to evaluate evenamide in patients with chronic schizophrenia who are not classed as treatment resistant is ongoing, results from the study are expected in 2023

Xadago®/safinamide (Parkinson's disease)

- 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 continues its dialogue with industry partners around potential future collaboration opportunities for the development of evenamide. The company also continues to explore a number of potential opportunities to expand its pipeline in central nervous system diseases
- Gillian Dines proposed for election as new member to the Board of Directors at the AGM on April 18, 2023
- Development of ESG strategy completed, with focus areas and objectives for 2023 – Reporting will be based on 10 out of the 17 Sustainable Development Goals, as defined by the UN

Stefan Weber, CEO of Newron, commented:

"The last twelve months have been an exciting period for our Company, particularly given the announcement of three sets of compelling interim efficacy results from our ongoing Phase II clinical study 014/015 with evenamide in patients with treatment-resistant schizophrenia (TRS). We have also made significant progress with the Phase III study of evenamide (study 008A) in another indication – patients with chronic schizophrenia currently being treated with a second-generation antipsychotic, but who are not classed as having TRS – and have strengthened both our management team and our Environment, Social and Governance (ESG) efforts".

Evenamide

In June 2022, Newron was excited to share the first set of data from its Phase II study with evenamide, a new chemical entity being developed for the treatment of patients with schizophrenia. The results showed that the addition of evenamide improved symptoms of psychosis in patients with TRS. This was reflected by an approximately 12% reduction in the Positive and Negative Syndrome Scale (PANSS) score, Clinical Global Impression – Severity of illness (CGI-S) improvement of 0.7, and Clinical Global Impression – Change from baseline (CGI-C) ratings indicating that 77% of patients responded to the treatment.

Post-period, in Q1 2023, Newron was able to announce interim data from study 014 as well as its extension arm, study 015, showing results in the first 100 patients in the study after six months (30 weeks) and one year (52 weeks) of treatment with evenamide:

- In January 2023, Newron announced six-month interim data which demonstrated a continued improvement in TRS symptoms following treatment with evenamide, as well as a substantially greater proportion of patients experiencing a meaningful improvement when compared to six weeks of treatment.
- Closely following, in February 2023, the Company disclosed one-year interim data from study 014/015. Results provided further striking new evidence of the sustained efficacy of the addition of evenamide to antipsychotics in TRS patients by demonstrating substantially greater benefit at one year than noted at the six-week and six-month datapoints.

These results after six months and one year were highly compelling, statistically significant (paired t-test), and clinically meaningful, as not only was evenamide well tolerated with few adverse effects, but there was a sustained and continued improvement at all doses. Newron was particularly struck by data suggesting there is a continued improvement over time in these measures. While recognizing that this study has no control arm, clinically meaningful improvements over baseline in key efficacy measures after one year are, to the Company's knowledge, unprecedented in patients with diagnosed TRS.

The enrolment of study 014 has now been completed with 161 subjects. The Company expects to announce the full results from this study still in March 2023, which will include six-week data from all 161 patients enrolled into the study. One-year data from all 161 patients in extension study 015 is expected by Q1 2024.

Study 003 is planned to be a potentially pivotal, multinational, randomized, placebo-controlled, ten-week global study to assess the efficacy, safety and tolerability of evenamide (15/30 mg bid) as an add-on treatment in outpatients with treatment-resistant schizophrenia (TRS) not responding adequately to their monotherapy treatment with atypical antipsychotics (including clozapine). Positive data from this study would confirm the potential of evenamide as the first medication that could be added to an antipsychotic and improve symptoms of TRS in patients. Newron plans to initiate this study in 2023.

Alongside the R&D-work with evenamide in TRS, the Company is also conducting study 008A, a four-week, randomised, double-blind and placebo-controlled study assessing the efficacy, tolerability, and safety (including electroencephalogram effects) of evenamide (30 mg bid) in patients with chronic schizophrenia currently being treated with a second-generation antipsychotic, but who demonstrate an inadequate response to that treatment. Recruitment at treatment centers in Europe, Asia and Latin America is ongoing and results are expected in 2023. If results from the study are positive, it would represent the first well-controlled, potentially pivotal study of evenamide in schizophrenia patients who demonstrate an inadequate response to treatment with atypical antipsychotics.

Xadago®/safinamide

In partnership with Zambon and Supernus, Newron continues to further develop and market its product, Xadago®/safinamide.

In reference to the receipt of several Paragraph IV Notice Letters in May 2021 regarding the submission by generic manufacturers of an Abbreviated New Drug Application to the US Food and Drug Administration (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 filed an infringement case against these manufacturers to secure its intellectual property rights. Newron continues to challenge these submissions and note that its patents on Xadago® (safinamide) tablets remain protected by three patents in the FDA Approved Drugs Product List (Orange Book) until at least 2027.

Newron and Zambon have reached an agreement to discontinue their plans to initiate a clinical study with safinamide in Parkinson's disease patients with levodopa-induced dyskinesia (PD LID). As a matter of settlement, Zambon will advance an undisclosed fee to Newron.

ESG commitment and reporting

Sustainability is one of the most crucial current challenges, for every company, regardless of size or industry. Newron has already issued several policies and procedures and taken some specific actions that are part of ESG best practices, but in 2022 the strategic process started formally with a materiality analysis in close dialogue with internal and external stakeholders to best understand how each one of them could relate with relevance of all the possible areas to Newron's ESG efforts. An ESG strategy based on a key materiality review has been developed, and Sustainable Development Goals that the Company can contribute to have been identified. ESG focus areas and objectives for 2023 have been defined and Newron's Annual ESG reporting efforts commence with the Annual Report 2022 published today.

Financial Key takeaways 2022:

- In 2022, Newron reported a net loss of EUR 17.5 million, compared to EUR 14.9 million in 2021
- Cash used in operating activities has decreased to EUR 11.1 million from EUR 11.4 million in 2021
- Xadago® revenues from Zambon increased from EUR 5.8 million in 2021 to EUR 6.0 million in the reporting period
- Newron's R&D expenses have risen to EUR 12.0 million from EUR 10.7 million in 2021
- G&A expenses were stable at EUR 7.4 million
- Cash and Other current financial assets as at December 31, 2022, were at EUR 22.8 million, compared to EUR 34.6 million at the beginning of the year

Financial Summary (IFRS) 2022 and 2021:

In thousand EUR (except per share information)

	2022	**2021**
Licence income from contracts with customers	14	34
Royalties from contracts with customers	5,936	5,728
Revenue	**6,094**	**5,762**
Research and development expenses, net	(12,005)	(10,725)
Operating Result	**(13,302)**	**(12,357)**
Financial result, net	(4,170)	(2,527)
Net loss	**(17,493)**	**(14,901)**
Loss per share	(0.98)	(0.84)
Cash used in operating activities	(11,092)	(11,445)
Cash, cash equivalents and Other current financial assets	22,774	34,594
Total assets	37,195	50,486

Newron's Annual Report 2022 is available for download on the Company's website: www.newron.com/investors/reports-and-presentation/year/2022

Outlook 2023:

The Company anticipates that 2023 will be another exciting year, with further clinical updates from its evenamide program. Following the striking six-month and one-year results in TRS, Newron is continuing its dialogue with industry partners around potential future collaboration opportunities for the development of evenamide and to potentially expand its pipeline of CNS drugs.

Newron looks forward to presenting the full results from study 014 with evenamide in March 2023 and one-year results from extension study 015 in all patients by Q1 2024. The Company also remains on track to commence study 003 in 2023, the first potentially pivotal study of evenamide in TRS. In patients with chronic schizophrenia currently being treated with a second-generation antipsychotic, but who are not classed as having TRS, Newron looks forward to reporting data from study 008A in the second half of 2023.

Newron's total available cash resources will fund the Company's planned development programs and operations well into 2024.

2023 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the April 18, 2023, 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 14, 2023.

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 2022. Connected and consequent resolutions;
2. Appointment of the members of the Board of Directors, for the financial years 2023, 2024 and 2025 and, therefore, until the approval of the financial statements as of December 31st, 2025, as follows:

   2.1. determination of the relevant number,

   2.2. proposal to appoint:

   - 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;
   - Luca Benatti in quality of non-executive director; and,
   - Gillian Dines in quality of non-executive director*.

   2.3. Determination of the remuneration of the Board of Directors. Connected and consequent resolutions.

*** Gillian Dines - introduction as new candidate for non-executive director position:**

Gillian Dines is the Senior Vice President and Head of Research and Early Development at Jazz Pharmaceuticals. Prior to that she was SVP R&D Operations at GW Pharmaceuticals and VP, Head of R&D Strategic Planning at UCB. One of her key roles in 2008 was Company Director and Chief Development Officer at RespiVert, a UK based biotech that delivered clinical phase assets from start-up to acquisition by global pharma player in only 18 months, with a budget of £20M. Her previous experience covers various leadership roles at GlaxoSmithKline. In her career she led 20+ novel medicines and devices through successful IND and clinical submissions in areas of respiratory, immunology, rare disease, anti-infective and neurology therapy areas. She has a MSc in Toxicology from the University of Surrey and a BSc from University of Leeds in Biochemistry and Genetics. She is English.

Dial-in details to the media/analyst/investor conference call on March 14, 2023, 3 pm CET
Newron's management team will present the 2022 full-year results and provide an update and guidance for 2023.

Please dial in five to ten minutes prior to the beginning of the call using one of the following telephone numbers:

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

or connect to the webcast

Participants' Link: https://media.choruscall.eu/mediaframe/webcast.html?webcastid=hMiCgav4

The investor presentation is available on 14 March as of 7 am CET at www.newron.com/investors/reports-and-presentation/year/2022

Financial calendar

- AGM 2023: April 18, 2023
- Half-year report 2023: September 14, 2023

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 symptoms of schizophrenia. For more information, please visit: www.newron.com

For more information, please contact:

Newron
Stefan Weber – CEO, +39 02 6103 46 26, pr@newron.com

UK/Europe
Simon Conway / Ciara Martin / Natalie Garland-Collins, FTI Consulting, +44 20 3727 1000, SCnewron@fticonsulting.com

Switzerland
Valentin Handschin, IRF , +41 43 244 81 54, handschin@irf-reputation.ch

Germany/Europe
Anne Hennecke / Caroline Bergmann, MC Services, +49 211 52925222, newron@mc-services.eu

USA
Paul Sagan, LaVoieHealthScience, +1 617 374 8800, Ext. 112, psagan@lavoiehealthscience.com

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