Ad hoc announcement pursuant to Art. 53 LR

Newron presents 2023 financial results and provides 2024 outlook

Milan, Italy, March 19, 2024, 07:00 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, 2023, and provided an outlook for 2024.

Highlights 2023:

Evenamide (Schizophrenia)

- Compelling efficacy results across multiple investigation timepoints up to and including one-year from study 014/015 evaluating evenamide as an add-on therapy to a single antipsychotic in patients with treatment-resistant schizophrenia (TRS)
- Presentation of data to the medical community at several international scientific conferences, highlighting the clinically meaningful response to evenamide in TRS patients, across various timepoints
- Publication of data from study 014 and results from first 100 patients of study 015 in peer-reviewed journal, the *International Journal of Neuropsychopharmacology*, outlining the continued improvement in symptoms of psychosis in TRS patients treated with evenamide
- The findings from study 014/015 support the initiation of a potentially pivotal, Phase III, randomized, double-blind, placebo-controlled study with evenamide as an add-on treatment in patients with TRS
- Study 008A, a potentially pivotal study of evenamide (30 mg bid) in patients with chronic schizophrenia demonstrating inadequate benefit to their current second-generation antipsychotic, completed patient enrollment; top-line results are expected in April 2024

Xadago®/safinamide (Parkinson's disease)

- Newron and its partners reached agreement with generic pharmaceutical manufacturers who submitted Paragraph IV Notice Letters regarding Abbreviated New Drug Applications in the US
- In Europe, Supplementary Protection Certificates (SPCs) have been approved in most territories of relevance

Corporate

- Newron's senior management team strengthened by two key promotions: Laura Faravelli, previously Director Business Development at Newron, was promoted to Vice President Business Development; Roberto Galli, Vice President Finance since 2012, was promoted to Chief Financial Officer
- Gillian Dines appointed as Non-Executive Director to the Board of Newron at the AGM 2023
- Margarita Chavez appointed as advisor to the Board of Newron; she is nominated for election as Non-Executive Director to the Board at the next Ordinary AGM on April 17, 2024
- Post-period, Newron entered into an agreement for the subscription of up to 2.05 million newly issued shares with an institutional investor focused on investing in high-growth firms across sectors including biotech and healthcare, to finance the Company's operations beyond the current key inflection points in its pipeline
- Post-period, agreement with European Investment Bank (EIB) to extend the near-term tranche repayment dates of Newron's 2018 financing agreement

Stefan Weber, CEO of Newron, commented: "Against a backdrop of challenging global biotechnology market conditions, we have continued to make huge strides in advancing our evenamide development program for treatment-resistant schizophrenia (TRS) through the clinic. We have reported multiple data sets across three different study timepoints, each showing compelling evidence of the benefit of evenamide in schizophrenia patients no longer responding to their first- or second-generation antipsychotic treatments. Post-period, we also optimized our financing structure by agreeing with the EIB to extend the near-term tranche repayment dates of our financing agreement. And we welcomed an institutional investor that signed a subscription agreement for new shares to finance our operations beyond the current key inflection points in the pipeline. We thank our shareholders for their ongoing support and for sharing our vision to improve the lives of patients suffering from diseases of the CNS, by now for 25 years, since Newron was founded."

Evenamide

Newron made substantial progress across its evenamide development program over the reporting year and into early 2024. The published compelling data is demonstrating the benefit of the Company's new chemical entity for patients with TRS:

- In Q1 2023, Newron disclosed interim analyses of study 014, a Phase II, international, randomized, open label, rater-blinded trial evaluating evenamide (7.5, 15 or 30 mg bid) as an add-on to a single antipsychotic (excluding clozapine) in patients with moderate to severe TRS, not responding to their current antipsychotic medication, and study 015, its extension to one year of treatment. Results from the first 100 patients to complete six months (30 weeks) of treatment with evenamide were reported in January, followed by results in February 2023 from the same 100-person cohort at the one-year (52 weeks) timepoint. The results at the six-week, six-month and one-year timepoints demonstrated a clinically important and sustained improvement in symptoms, and importantly, a substantially greater benefit at one-year than at the six-week and six-month datapoints.
- Topline data from all 161 patients at the six-week primary endpoint were reported in March. Although the primary objective of the study was safety and tolerability of evenamide, efficacy over baseline was also assessed. The mean Positive and Negative Syndrome Scale (PANSS) total score, Clinical Global Impression of Severity (CGI-S) rating, and the Strauss-Carpenter Level of Functioning (LOF) total score significantly improved compared to baseline ($p<0.001$). The results from the complete study population of 161 patients were fully consistent with the findings from the first 100 patients at this timepoint. Notably, evenamide was safe and well-tolerated at all doses, with almost all (95%) patients completing six weeks of treatment. The incidence of treatment-emergent adverse events was very low, and more than 90% of the completers chose to continue with evenamide treatment into the long-term extension study (study 015).
- In the beginning of Q4, Newron provided data from the full study population in the extension study (study 015) at the 36th ECNP Congress in Barcelona, Spain, demonstrating the positive effect of evenamide at six months of treatment. Results showed that benefits continued to accrue over time, and many patients who did not respond early achieved clinically important benefits later on in the study. Remarkably, following treatment with evenamide, approximately 40% of patients at six months no longer met the protocol severity criteria used to diagnose TRS.
- These data were further strengthened, post-period in January 2024, with the final results from study 015 reviewing all study participants after one year of treatment. The data showed that treatment with evenamide was associated with sustained, clinically significant benefit that increased throughout the one-year course of treatment. Gradual and sustained improvement was demonstrated across all efficacy scales used. More than 70% of patients experienced clinically important reduction in disease severity. Review of the efficacy data indicated that treatment with evenamide resulted in approximately 50% of patients at one-year no longer meeting any of the protocol severity criteria used to diagnose treatment resistance. Significantly 25% of all patients achieved "remission" (no/minimal symptoms for at least six months), never described before in TRS patients. Moreover, in contrast to common clinical experience, no patient relapsed during the one-year treatment period.

The durability and longevity of these clinical benefits is unprecedented in this indication and suggest that the glutamate modulating effect of evenamide could lead to a progressive and long-standing alteration in brain processes, synergizing with the effect of the antipsychotic to which the patient had become resistant. The next R&D activities will be:

- In their totality, the results from study 014/015 support the initiation of a potentially pivotal Phase III, randomized, double-blind, placebo-controlled study of evenamide as an add-on treatment in patients with TRS, which will hopefully confirm the benefit of evenamide seen so far. If approved, the compound would be the first add-on drug that improves the symptoms of TRS, offering a much-needed new therapeutic option for those who are not responding to existing antipsychotics.
- Newron is also investigating evenamide in a potentially pivotal study (study 008A) in a separate indication, in patients with chronic schizophrenia currently being treated with a second-generation antipsychotic, but who demonstrate an inadequate response to that treatment. Study 008A is a four-week, randomized, double-blind and placebo-controlled study assessing the efficacy, tolerability, and safety of evenamide (30 mg bid). Patient enrollment has completed and results from this study are expected in April 2024.

Xadago®/safinamide

In partnership with Zambon and Supernus, Newron continued 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 some generic manufacturers of an Abbreviated New Drug Application ANDA 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 the three US patents listed in the FDA Orange Book for Xadago®, Newron and its partners Zambon and Supernus have reached settlement agreement with said generic manufacturers, thus resolving the legal action. All three patents remain valid and in force. Under the agreement, the generic manufacturers will be allowed to enter the US market with a safinamide mesylate drug product no earlier than December 1, 2027. In the EU, Supplementary Protection Certificates (SPCs) have already been approved in most territories of relevance; Newron and Zambon are confident that upon completion of the still ongoing procedures and targeted activities, the SPCs will be granted in all key territories.

ESG reporting

The Annual Report 2023 provides further transparency on Newron's corporate ESG commitments. The relevant section covers information on the following topics: employee aspects, environmental aspects including climate, social aspects, human rights, and anti-corruption as well as cyber security – given their relevance to Newron and its stakeholders and given the Company's ability as a company to have a positive impact on the listed areas. Newron's 2023 ESG Report follows the most recent edition of the Directive on Information relating to Corporate Governance (Annex 7) of SIX Exchange Regulation (SER).

Financial key takeaways 2023:

- In 2023, Newron reported a net loss of EUR 16.2 million, slightly lower compared to EUR 17.5 million in 2022
- Cash used in operating activities has decreased to EUR 10.1 million from EUR 11.1 million in 2022
- Xadago® revenues from Zambon increased from EUR 6.0 million in 2022 to EUR 9.0 million in the reporting year
- Newron's R&D expenses have risen to EUR 13.2 million from EUR 12.0 million in 2022
- G&A expenses slightly increased from EUR 7.4 million in 2022 to EUR 7.5 million
- Cash and Other current financial assets as of December 31, 2023 were at EUR 12.6 million, compared to EUR 22.8 million at the beginning of the year

Post-period, in March 2024, Newron announced it has entered into an agreement for the subscription of up to 2.05 million shares with an institutional investor focused on investing in high-growth firms across sectors including biotech and healthcare, raising gross proceeds of up to EUR 15.0 million (at current exchange rate CHF-EUR). Under the agreement, the fund subscribes to an initial 750,000 newly issued shares at a subscription price of EUR 7.33 per share, which corresponds to gross proceeds of approximately EUR 5.5 million. In addition, the fund has a right to subscribe to an additional up to 1,300,000 newly issued shares until no later than January 31, 2025, at a subscription price to be calculated pursuant to an agreed formula. The share subscriptions are governed by the capital increase authorised by Newron's shareholders in 2018 and approved and empowered by the Company's Board of Directors in 2023. Newron intends to use the net proceeds of the fundraise for general corporate purposes, including the financing of its operations and research programs and for the development of current and future pipeline products. Newron also continues to seek opportunistic additions to its pipeline portfolio.

Post-period, and also in March 2024, Newron announced that the Company has agreed with the European Investment Bank (EIB) to extend the near-term tranche repayment dates of its loan agreement. Under the amendment to certain terms of the financing agreement with the EIB, the repayment of tranches one to three (out of a total of five) has been shifted substantially, with tranche one now scheduled for repayment by 25 November 2025, tranche two by April 2026 and tranche three by June 2026. The EIB qualifies now for certain performance-based remuneration. Newron appreciates the support of the EIB in helping the Company to align its contractual obligations with the potential timing of certain upcoming inflection points from its pipeline.

Financial Summary (IFRS) 2023 and 2022:

In thousand EUR (except per share information)

	2023	2022
Licence income from contracts with customers	58	14
Royalties from contracts with customers	6,735	5,936
Other income from contracts with customers	2,264	144
Revenue	**9,057**	**6,094**
Research and development expenses, net	(13,152)	(12,005)
Operating Result	**(11,629)**	**(13,302)**
Financial result, net	(4,571)	(4,170)
Net loss	**(16,224)**	**(17,493)**
Loss per share	(0.91)	(0.98)
Cash used in operating activities	(10,140)	(11,092)
Cash, cash equivalents and Other current financial assets	12,599	22,774
Total assets	25,866	37,195

Newron's Annual Report 2023 is available for download on the Company's website at: www.newron.com/investors/reports-and-presentation/year/2023

Outlook 2024:

Following the remarkable evenamide data to date, Newron plans to initiate a potentially pivotal trial evaluating evenamide in TRS, once preparations are completed and a partner has been identified. If this trial replicates the data published in study 014/015, the Company believes there will be substantial improvements in the treatment paradigm and outlook for TRS patients. Newron is also primed to report data from study 008A, a potentially pivotal study assessing evenamide in schizophrenia patients not deemed to be treatment resistant. If positive, this would be the first well-controlled study to demonstrate the clinical utility of evenamide in schizophrenia patients who show an inadequate response to treatment with atypical antipsychotics.

Newron is continuing to have a productive dialogue with industry players around potential future collaboration opportunities for evenamide. The Company also continues to review the CNS landscape for opportunities to expand its drug development pipeline.

Newron's total available cash resources together with the initial proceeds deriving from the subscription agreement signed post-period, will fund the Company's planned development programs and operations well into 2025 and well beyond the current key value inflection points in our pipeline.

Media/analyst/investor Conference Call today at 3 pm CET

Newron's management team will present today the 2023 full-year results and provide an update and guidance for 2024. 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

The presentation is available at www.newron.com/investors/reports-and-presentation/year/2023

2024 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the **April 17, 2024**, Shareholders' Ordinary and Extraordinary 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 26, 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 day.

The agenda is as follows:

Ordinary part

1. Approval of the financial statements as at 31 December 2023. Update – as per art. 2447 Civil Code - regarding the freezing of 2022 Newron' standalone losses. Connected and consequent resolutions;
2. Appointment of a new members of the Board of Directors, for the financial years 2024 and 2025 and, therefore, until the approval of the financial statements as of December 31st, 2025, as follows:
   a. determination of the relevant number,
   b. proposal to appoint Margarita Chavez*, in quality of new non-executive director
   c. Determination of the remuneration

   Connected and consequent resolutions.

Extraordinary part

1. Proposal to amend Art 14 of the by-laws. Related and consequential resolutions;
2. Proposal of attribution to the Board of Directors of powers, pursuant to art. 2443 of the Civil Code, exercisable during the next 5 years, to increase the share capital, in one or more times, for a maximum amount of Euro 357.636,00, in addition to any premium, with or without option rights, pursuant to art. 2441, paragraphs 1 and/or 4, first and second part, and/or 5, 6 of the Civil Code. Related and consequential resolutions;
3. Proposal of attribution to the Board of Directors of powers, pursuant to art. 2443 of the Civil Code, exercisable during the next 5 years, to increase the share capital, in one or more times, for a maximum amount of Euro 107.291,00, in addition to any premium, with exclusion of the option rights, pursuant to art. 2441, paragraphs 5, 6 and/or 8 of the Civil Code, for one or more stock option plans. Related and consequential resolutions;

* Margarita Chavez brings to Newron over 20 years of dealmaking expertise and leadership in the pharmaceutical industry. Most recently, she was Managing Director of AbbVie Ventures, where she led investments and built biotech companies across the US and Europe. Ms. Chavez also served as a board member for several biotech companies across the US and Europe. As a Director in Abbott's Global Pharmaceutical Licensing & Acquisitions Division, she was involved in the successful in-licensing of Elagolix and the acquisitions of Solvay, ImmuVen and the Lupron franchise. Before joining Abbott, Ms. Chavez practiced as a corporate and securities lawyer in the Silicon Valley, advising tech and biotech companies on strategic transactions including IPOs and mergers and acquisitions. She received her bachelor's degree from Santa Clara University and her juris doctor from Santa Clara University School of Law (both California). Ms. Chavez is currently a Venture Partner at Wellington Partners and has been acting as advisor to Newron's board since October 1, 2023.

Financial calendar

- AGM and EGM 2024: April 17, 2024
- Half-year report 2024: September 19, 2024

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:

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