Ad hoc announcement pursuant to Art. 53 LR

Newron presents H1 2024 results and provides business update

Milan, Italy, September 19, 2024, 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 half year ended June 30, 2024, and provided an update on its business activities.

Highlights H1 2024:

Evenamide

- Reported positive final one-year results from study 014/015, a Phase II open label trial evaluating evenamide as an add-on therapy to a single antipsychotic in patients with treatment-resistant schizophrenia (TRS):
    - The study demonstrated significant, clinically important, progressive, sustained, and long-lasting improvement on Positive and Negative Syndrome Scale (PANSS) Total, Clinical Global Impression of Severity (CGI-S), the mean rating of change for the Clinical Global Impression of Change (CGI-C) and Level of Functioning (LOF)
    - More than 70% of patients experienced a clinically important reduction in disease severity
    - 25% of all patients achieved "remission," never described before in TRS patients

- Reported compelling results from study 008A, a potentially pivotal, four-week randomized, double-blind and placebo-controlled study of evenamide as an add-on therapy in patients with chronic schizophrenia demonstrating inadequate benefit to their current second-generation antipsychotic:
    - Study analysis revealed statistically significant multi-domain benefits in PANSS and Clinical Global Impression of Change (CGI-C) ratings
    - Benefit on efficacy measures increased over time, suggesting larger and enduring patient effects to be expected during long-term treatment

- Together, these studies:
    - Confirm evenamide's favorable safety and tolerability profile
    - Demonstrate evenamide's efficacy on multiple measures of psychopathology in TRS and chronic schizophrenia
    - Add to the growing evidence that the glutamatergic inhibition mechanism of action offers an innovative therapeutic option to schizophrenia patients not benefitting from current antipsychotic treatments

- Company is working towards the initiation of a potentially pivotal, multinational, randomized, double-blind, one-year, placebo-controlled study, assessing the efficacy, safety, and tolerability of evenamide as an add-on treatment in patients with TRS

- Company is currently running a structured process of securing the most attractive, value creating transaction around evenamide, and several indications of interest have been received. Board and Management are prioritizing and negotiating offers according to their potential to increase shareholder value, with the expectation of closing a transaction in the coming months

Corporate

- Company entered into an agreement for the subscription of up to 2.05 million newly issued shares, up to a value of EUR 15 million, with an institutional investor focused on investing in high-growth firms across sectors including biotech and healthcare
- An agreement was entered into with the European Investment Bank to extend the near-term tranche repayment dates of its 2018 financing agreement until the end of 2025 and into 2026, after potentially significant milestones
- Chairman and CEO increased their holdings in Newron, underlining their commitment to the Company

Stefan Weber, CEO of Newron, commented:

"It has been a busy and exciting six months for Newron where we have delivered two positive clinical milestones in the development of our novel drug evenamide. We reported exceptional data demonstrating positive clinical results from both study 014/15 and study 008A, which evaluated evenamide as an add-on treatment for patients with treatment-resistant schizophrenia (TRS) and chronic schizophrenia, respectively. We were also delighted to host a successful Investor Day in June in New York City, featuring presentations from leading KOLs on the unmet medical needs for patients with schizophrenia, underscoring the potentially pivotal role of evenamide for these patients. We believe our new chemical entity has blockbuster potential and could bring enormous benefits to patients who are insufficiently served by the existing treatments available. Newron, with the help of a leading healthcare investment bank, is currently exploring potential partnership agreements and opportunities for collaboration that will enable us to progress evenamide into Phase III clinical development for the potential treatment of patients with TRS and create value for our shareholders."

Evenamide (Schizophrenia)

During Q1 2024, Newron reported final one-year results from study 014/015, a Phase II open label trial evaluating evenamide as an add-on therapy to a single antipsychotic in treatment-resistant patients. The data demonstrated that evenamide as an add-on treatment for patients with TRS was associated with sustained, clinically significant benefits that increased throughout the one-year course of treatment, with more than 70% of patients experiencing a clinically important reduction in disease severity.

Overall, data from study 014 has demonstrated that evenamide was safe and well-tolerated at all doses, with 97% of 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 Q2, the Company announced two sets of data from study 008A, a potentially pivotal four-week randomized, double-blind and placebo-controlled study of evenamide as an add-on therapy in patients with chronic schizophrenia demonstrating inadequate benefit to their current second-generation antipsychotic. Topline data announced in April confirmed evenamide's favorable safety and tolerability profile, followed by compelling data from additional analyses reported in May.

The study met the primary endpoint (improvement of the Positive and Negative Syndrome Scale (PANSS) Total Score) and key secondary endpoint (improvement of the Clinical Global Impression of Severity (CGI-S)), with a high rate of study completion (96%). No new or specific concerns were raised in the study; only 25% of the patients in the study experienced at least one adverse event (evenamide 25% versus placebo 25.8%).

Newron will be presenting the results of study 008A at the upcoming 37th ECNP Congress (September 21-24, 2024) in Milan, Italy.

The totality of these results validated evenamide as the first glutamate modulator to demonstrate efficacy in inadequately responding patients with schizophrenia in a placebo-controlled study.

Following results from both study 008A and study 014/015, Newron's key focus is now on initiating a Phase III randomized, double-blind, one-year clinical trial. The trial is expected to start in the first half of 2025 and will compare evenamide to placebo as an add-on treatment in at least 400 patients with TRS. Participants will be evaluated at three timepoints, 12 weeks, 26 weeks, and one year, to assess the long-term safety, tolerability, and efficacy of evenamide. The study design has received regulatory approval in all relevant territories, final discussion is ongoing with the US Food and Drug Administration (FDA) on the dosing regimen.

Several indications of interest were received in a structured process of securing the most attractive, value creating transaction for Newron's shareholders, be it a regional or global license or an M&A transaction; with the process supported by one of the world's leading full-service investment banking and capital markets firms. The Board and Management will prioritize and negotiate the offers according to their potential to increase shareholder value, with the expectation to close a transaction in the coming months, enabling progression of the Phase III clinical development of evenamide in TRS patients.

Xadago®/safinamide (Parkinson's disease)

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 some generic manufacturers of an Abbreviated New Drug Application ANDA to the US 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 agreements 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.

Corporate

In April, Margarita Chavez, US-based, was elected as a Non-Executive Director to the Board of Newron following the 2024 Annual General Meeting. Margarita Chavez has been an advisor to Newron's Board since October 2023, and the Company continues to benefit from her more than 20 years of strategic transaction expertise in the US and internationally and her leadership in the pharmaceutical industry. She is heading the Business Development Committee of Newron's Board of Directors.

During the first half of 2024, Newron announced an agreement with the European Investment Bank to extend the near-term tranche repayment dates of the 2018 financing agreement until the end of 2025 and into 2026, after potentially significant milestones.

Furthermore, the Company 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. Under the agreement, the fund subscribed 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 and had the right to subscribe to an additional up to 1,300,000 newly issued shares until no later than January 31, 2025. The funds raised enable Newron to focus its attention on progressing evenamide into Phase III clinical development in TRS patients and support activities beyond immediate inflection points. At the time of this report, 1,350,000 newly issued shares have been subscribed to by the investor, under the rules of the agreement, generating proceeds of EUR 9.9 million. For further detail, please refer to https://www.ser-ag.com/en/resources/notifications-market-participants/significant-shareholders.html#/ .

In June 2024, Dr. Ulrich Köstlin, Chairman of Newron's Board of Directors, and Stefan Weber, CEO demonstrated their commitment to Newron and its future by buying shares via the SIX Swiss Exchange and Xetra.

ESG commitment and reporting

The Company has worked diligently to further implement its Environment, Social and Governance (ESG) strategy and reporting framework as disclosed in the Annual Report 2023. The ESG goals and projects for 2024 are well on track and management hopes that this will ensure Newron operates as a sustainable and conscious employer, business, and provider of innovative therapeutics. The Company will provide a further update in our 2024 Annual Report.

Financial Summary (IFRS) H1 2024 and H1 2023

In thousand EUR (except per share information)

	H1 2024	**H1 2023**
Licence income/Royalties/Other income	3,407	5,494*
Research and development expenses	(6,453)	(5,685)
General and administrative expenses	(4,579)	(4,062)
Net loss	(9,557)	(6,950)
Loss per share	(0.51)	(0.39)
Cash used in operating activities	(8,828)	(5,603)
	As of June 30, 2024	**As of December 31, 2023**
Cash and Other current financial assets	12,188	12,599
Total assets	24,937	25,866

* Including one-time payments of EUR 2,284

Outlook

Following positive results from the pivotal study 008A and unprecedented results from study 014/015, Newron expects to enter into a value-creating transaction around evenamide in the coming months, enabling progression of the Phase III clinical development of the compound. The Company is convinced about the blockbuster potential of evenamide and the benefits it can bring to patients who are currently underserved by the current treatments on the market. Newron also continues to assess the market for opportunities to expand its CNS pipeline. The Company looks forward to providing an

update on its evenamide partnership discussions and any pipeline developments as they may occur. Newron's total available cash resources will fund the Company's planned development programs and operations well into 2025.

Newron's Half-Report 2024 is available for download on https://www.newron.com/investors/reports-and-presentation/year/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

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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 or the Dusseldorf Stock 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.