Ad hoc announcement pursuant to Art. 53 LR

Newron presents 2024 financial results and provides 2025 outlook

Milan, Italy, April 1, 2025, 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, 2024, and provided an outlook for 2025.

Highlights 2024:

Evenamide

Exceptional data from study 014/015 and study 008A:

- Demonstrated significant and increasing efficacy of evenamide as an add-on therapy on multiple measures of psychopathology in treatment-resistant schizophrenia (TRS) and chronic schizophrenia
- Confirmed evenamide's favorable safety and tolerability profile
- The data adds to the growing evidence that evenamide's glutamatergic inhibition mechanism of action offers an innovative therapeutic option to schizophrenia patients who are not benefiting from current antipsychotic treatments on the market

Strategic licensing and partnerships:

- In December 2024, the Company announced a licensing agreement with EA Pharma, a subsidiary of Eisai, to develop, manufacture and commercialize evenamide in Japan and other designated Asian territories. Under the terms of the agreement, Newron will receive up to a maximum total of EUR 117 million, including an upfront payment of EUR 44 million, financial contributions to its upcoming pivotal Phase III one-year study of evenamide, milestone payments, and tiered royalties up to a double-digit percentage of net sales for evenamide
- Post-period, in January 2025, the Company announced a further licensing agreement with Myung In Pharm to develop, manufacture and commercialize evenamide in South Korea. Under the terms of the agreement, Myung In Pharm will contribute 10% of the total patient population to be enrolled into Newron's upcoming Phase III trial and cover the costs related to this population

Upcoming milestones:

- Newron is planning to initiate a pivotal Phase III randomized, double-blind, one-year trial in Q2 2025 that will compare evenamide to placebo as an add-on treatment in patients with TRS
- The Company continues to pursue further development opportunities for evenamide in other territories

Corporate

- Post-period, in March 2025, the Board of Directors of Newron proposed Dr. Chris Martin for election as Independent, Non-Executive Director and Chairman of the Board of Directors, at the Company's upcoming Annual General Meeting, to be held on April 23, 2025. He is expected to succeed Dr. Ulrich Köstlin, who will end his twelve years of service on the Board of Newron following the completion of this year's shareholder meeting
- Newron's Board was strengthened in April 2024 through the appointment of Margarita Chavez as an Independent, Non-Executive Director and Chair of the Board's Business Development Committee, bringing more than 20 years of US and international dealmaking expertise and leadership in the pharmaceutical industry
- In March 2024, the Company signed 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, with total proceeds generated of EUR 15 million
- Also in March 2024, an agreement with the European Investment Bank was reached to extend the near-term tranche repayment dates of its 2018 financing agreement until the end of 2025 and into 2026

Stefan Weber, CEO of Newron, commented: *"The positive evenamide data and strong momentum from our partnering agreements have set the stage for our pivotal Phase III randomized, double-blind, one-year trial, that will compare evenamide to placebo as an add-on treatment in at least 600 patients with TRS. We expect to continue building on our progress in 2025 by initiating this clinical trial with the compound in Q2 2025, and pursuing further development opportunities for evenamide, in addition to the two licensing agreements announced to date. A key objective for 2025 will also be strengthening our institutional shareholder base, and the preparation of a potential registration of our shares in the USA, the key capital market for our industry.*

Newron's total available cash resources, along with the proceeds deriving from the two licensing agreements for evenamide – signed with EA Pharma/Eisai Group in late December 2024 and with Myung In Pharm in early January 2025 – will fund the Company's planned development programs and operations well through 2026."

"We encourage our shareholders to register for and participate in the upcoming Ordinary and Extraordinary shareholders' meeting on April 23, 2025, as the proposed resolutions will materially contribute to the success of our ambitions. At these meetings, we will also bid a heartfelt farewell to Ulrich Köstlin and thank him for his many years of service as Newron's Chairman", Stefan Weber added.

Evenamide – advancing schizophrenia treatment

2024 was marked by significant milestones for the evenamide development program, with Newron reporting two sets of exceptional data on the use of evenamide as an add-on treatment for patients with TRS and chronic schizophrenia, as well as announcing its first licensing agreement:

- In January, the Company reported the 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 TRS 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. Remarkably, 25% of patients achieved "remission", which represents the highest level of improvements that can be obtained in a patient with schizophrenia and has never been described before in TRS patients. Furthermore, approximately 50% of patients that completed one-year of treatment with evenamide no longer met the criteria used to diagnose treatment resistance; also, there were no patient relapses during the one-year treatment period.
- In April, Newron announced data from study 008A, a potentially pivotal four-week, randomized, double-blind and placebo-controlled Phase III study of evenamide as an add-on therapy in patients with chronic schizophrenia demonstrating inadequate benefit from their current second-generation antipsychotic. The study met its key safety and efficacy endpoints: 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 96% rate of study completion. Additionally, no new or specific concerns were raised in the study.

In May, further analysis of this data revealed significant multi-domain benefits in PANSS and Clinical Global Impression of Change (CGI-C) ratings, confirming a highly statistically significant improvement for evenamide irrespective of the population analyzed or the statistical methods used. In addition, the benefits noted on efficacy measures continued to increase up to day 29, indicating potentially larger and more enduring effects following long-term treatment with evenamide.

Together, the data from these studies reaffirmed evenamide's favorable safety and tolerability profile and demonstrated its efficacy on multiple measures of psychopathology in TRS and chronic schizophrenia. The readouts also add to the growing evidence that the glutamatergic inhibition mechanism of action offers an innovative therapeutic option to schizophrenia patients who do not benefit from current antipsychotic treatments.

Financial key takeaways 2024:

- In 2024, Newron reported, for the first time since its inception, a net profit of EUR 15.8 million, compared with a net loss of EUR 16.2 million in 2023
- License income in 2024 was EUR 44.5 million, predominantly resulting from the upfront payment due under the license agreement signed with EA Pharma/Eisai Group
- In addition, the Company received royalty payments for Xadago from Zambon of EUR 6.9 million (2023: EUR 6.7 million)
- Total revenues increased from EUR 9.1 million in 2023 to EUR 51.4 million in the reporting period
- Newron's R&D expenses increased to EUR 13.6 million (2024) from EUR 13.2 million in 2023
- G&A expenses increased from EUR 7.5 million in 2023 to EUR 11.5 million in 2024, mostly due to one-time transaction-related costs
- As the upfront payment was transferred in January 2025, only, the cash used in operating activities increased to EUR 17.6 million in 2024, from EUR 10.1 million in 2023
- Cash and other current financial assets as of December 31, 2024, were at EUR 9.8 million, compared to EUR 12.6 million at the beginning of the year. EUR 42 million of proceeds from the execution of the two licensing agreements with EA Pharma/Eisai Group and Myung In Pharm were collected net of withholding taxes, in January 2025.

Financial Summary (IFRS) 2024 and 2023:

In thousand EUR (except per share information)

	2024	2023
Licence income from contracts with customers	44,470	58
Royalties from contracts with customers	6,920	6,735
Other income from contracts with customers	0	2,264
Revenue	**51,390**	**9,057**
Research and development expenses	(13,642)	(13,152)
Operating Result	**26,173**	**(11,629)**
Financial result, net	(4,779)	(4,571)
Net gain/(loss)	**15,843**	**(16,224)**
Gain/(Loss) per share	0.85	(0.91)
Cash used in operating activities	(17,614)	(10,140)
Cash, cash equivalents and Other current financial assets	9,826	12,599
Total assets	63,908	25,866

Newron's Annual Report 2024 is available for download on the Company's website at:
www.newron.com/investors/reports-and-presentation/year/2024

Outlook 2025:

Newron's position has been strengthened in 2024 and early 2025 with licensing agreements and increased financial flexibility. Following a busy 2024 full of milestones for our evenamide development program, Newron expects to continue building on its progress in 2025 by initiating the pivotal Phase III clinical study of the compound in Q2 2025, and pursuing further development opportunities for evenamide in addition to the two licensing agreements announced to date.

Newron is delighted with the progress of evenamide so far and is excited about the clear benefits that the development compound can bring to patients who are underserved by the antipsychotics currently on the market, and who are in great need of new and innovative treatments. The Company looks forward to providing an update on evenamide, including any business development opportunities, in due course.

A key objective for 2025 will be strengthening the Company's institutional shareholder base and the preparation of a potential registration of its shares in the USA, the key capital market for the Life Sciences industry.

The Company's total available cash resources together with the proceeds deriving from the signature of the two licensing agreements for evenamide with EA Pharma/Eisai Group in late December 2024 and with Myung In Pharm in early January 2025 are expected to fund Newron's planned development programs and operations well through 2026.

Media/analyst/investor Conference Call today at 3 pm CET/2 pm UK/9 am ET

Newron's management team will today present the 2024 full-year results and provide an update and guidance for 2025. 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
- For additional available numbers, please see here

The presentation is available at www.newron.com/investors/reports-and-presentation/year/2024

2025 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the **April 23, 2025**, Shareholders' Ordinary and Extraordinary annual 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 April 1, 2025. All documents connected with the agendas as per applicable laws and regulations as well as the necessary information to register and attend these meetings 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. Review and approval of the annual financial statements and presentation of the consolidated financial statements as of December 31, 2024. Connected and consequent resolutions;
2. Appointment of a new member of the Board of Directors, until the approval of the financial statements as of December 31st, 2025, as follows:
   2.1 Proposal to appoint Chris Martin* in quality of new independent and non-executive director;
   2.2 Proposal to appoint Chris Martin in quality of new non-executive Chairman of the Board;
   2.3 Determination of the remuneration.

Connected and consequent resolutions:

3. Appointment of the auditing company for the three fiscal-year term 2025-2027; connected and consequent resolutions;
4. Appointment of the statutory auditors for the three fiscal-year term 2025-2027 and determination of their fees. Connected and consequent resolutions;

Extraordinary part

1. Proposal of attribution to the Board of Directors of powers, pursuant to art. 2443 of the Civil Code, to be executed during the next 5 years, to increase the share capital, in one or more times, for a maximum amount of nominal Euro 399,177.00, in addition to any premium, without option rights, pursuant to art. 2441, paragraph 4, second part of the Civil Code. Amendment of art. 6 of Newron By-law. Related and consequential resolutions;
2. Proposal of attribution to the Board of Directors of powers, pursuant to art. 2443 of the Civil Code, to be executed during the next 5 years, to increase the share capital, in one or more times, for a maximum amount of nominal Euro 119,753.00, 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. Amendment of art. 6 of Newron By-law. Related and consequential resolutions;
3. Proposal of attribution to the Board of Directors of powers, pursuant to art. 2443 and 2420-ter of the Civil Code, to be executed during the next 5 years, to increase the share capital, in one or more times, for a maximum amount of nominal Euro 1,397,120.00, in addition to any premium, by issuing shares and/or convertible bonds, with or without option rights, pursuant to art. 2441, paragraphs 4, first part, 5, 6 and/or 8 of the Civil Code, optionally cum warrant, optionally related to the listing of the shares or the other above mentioned instruments on NASDAQ and/or NYSE and/or on any other market. Amendment of art. 6 of Newron By-law. Related and consequential resolutions;
4. Creation of American Depositary Shares and listing them on the NASDAQ and/or NYSE and/or on any other market in the United States of America; connected and consequent resolutions

* Dr. Chris Martin is a recognized leader in the biopharma industry who has taken therapeutic technology from the lab bench through to regulatory approval and global market sales. Over his career, he has raised more than $1.4 billion on the capital markets to support the development of his companies. He was instrumental in co-founding ADC Therapeutics in 2012 and served as its CEO from its inception until 2022. Under his tenure, the Swiss-based ADC Therapeutics grew from a private biotech start-up to a New York Stock Exchange listed leader in the field of antibody-drug conjugates (ADC) with products marketed worldwide. He co-founded and was the CEO of Spirogen Ltd, an innovator of ADC payload technology, which was subsequently sold to AstraZeneca for a total of up to $440 million. Currently chairing the boards of MyricxBio, Tagworks, Tokamak Energy Ltd. and serving on the boards of Osivax SAS, Solcom Ltd. and Senya therapeutics (all private companies), Chris Martin holds a bachelor's degree in chemical engineering from Aston University, a DPhil in Engineering Science from the University of Oxford, and an MBA from IMD Business School. He is a British citizen and lives in Switzerland.

Financial calendar

- AGM and EGM 2025: April 23, 2025
- Half-year results and report 2025: September 16, 2025

About Newron Pharmaceuticals

Newron (SIX: NWRN, XETRA: NP5) is a biopharmaceutical company focused on developing novel therapies for patients with diseases of the central and peripheral nervous system.

Headquartered in Bresso, near Milan, Italy, Newron is advancing its lead compound, evenamide, a first-in-class glutamate modulator, which has the potential to be the first add-on therapy for treatment-resistant schizophrenia (TRS) and for poorly responding patients with schizophrenia. Evenamide is currently in Phase III development and clinical trial results to date demonstrate the benefits of this drug candidate in the TRS patient population, with significant improvements across key efficacy measures increasing over time, as well as a favourable safety profile, which is uncommon for available antipsychotic medications.

Newron has signed development and commercialization agreements for evenamide with EA Pharma (a subsidiary of Eisai) for Japan and other Asian territories, as well as Myung In Pharm for South Korea.

Newron has a proven track record in bringing CNS therapies to market. Its Parkinson's disease treatment, Xadago® (safinamide), is approved in over 20 markets, including the USA, UK, EU, Switzerland, and Japan, and commercialized in partnerships with Zambon and Meiji Seika.

For more information, please visit: www.newron.com

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