



Ad hoc announcement pursuant to Art. 53 LR

Newron presents 2025 financial results and provides 2026 outlook

Milan, Italy, and Morristown, NJ, USA – March 24, 2026, 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, 2025, and provided an outlook for 2026.

Highlights 2025:

Evenamide

Initiation of pivotal Phase III ENIGMA-TRS clinical program

- In May, the Company announced regulatory approval for its pivotal Phase III ENIGMA-TRS program with evenamide as an add-on therapy in patients with treatment-resistant schizophrenia (TRS). The program comprises two pivotal studies, ENIGMA-TRS 1 and ENIGMA-TRS 2.
- Post-period, in January 2026, Newron’s partner EA Pharma (Eisai Group), who has the rights to develop, manufacture and commercialize evenamide in Japan and other designated Asian territories, initiated its Phase III clinical trial with evenamide in Japan.

IP expansion

- Post-period, in January 2026, the European Patent Office issued the decision to grant the Company an additional substance (COM) patent with life until 2044 for evenamide extending its exclusivity runway. The patent covers crystalline forms of evenamide, processes for their preparation, and their uses.

Industry engagement and scientific exchange

- In January, evenamide’s impressive results in study 014/015 and study 008A were published in the “International Journal of Neuropsychopharmacology”.
- In August, new findings from the University of Pittsburgh were disclosed in the same publication.
- Throughout the reporting year, Newron presented exciting clinical data and new analyses from its evenamide studies 014/015 and 008A at key conferences worldwide.
- Additionally, post-period, in February 2026, peer-reviewed data was published in the journal “Therapeutic Advances in Psychopharmacology”.

Corporate

- In April, Dr. Chris Martin was elected as the Chairman of Newron’s Board, succeeding Dr. Ulrich Köstlin who served as Chairman of the Company from 2013.
- Sell-side coverage of Newron has been initiated by four new US and European analysts.
- Post-period, in March 2026, the Company announced that it would propose George Garibaldi and Paolo Zocchi as new, independent, non-executive Board members to the 2026 Annual General Meeting, as Patrick Langlois and Luca Benatti would step down after long-standing service.
- Post-period, in February 2026, the Company entered into an agreement for the subscription of newly issued shares for proceeds of up to EUR 38 million with a group of existing and new shareholders from Europe and Asia, strengthening the Company’s financial position as it advances the ENIGMA-TRS Phase III program.
- Post-period, in March 2026, the Company announced its agreement with the European Investment Bank (EIB) to extend the maturity date of all outstanding tranches under its 2018 Finance Contract to June 28, 2028, subject to the execution of definitive agreements.

Stefan Weber, CEO of Newron, commented: *“2025 was a landmark year for Newron, marked by significant headway across our evenamide development program. During this period, we achieved several important milestones, including strong clinical progress, the expansion of our intellectual property portfolio, and the extension of our cash runway. We are extremely proud of what we have accomplished and continue to believe that evenamide is a potential blockbuster, with the ability to deliver meaningful benefits to patients where currently available treatments on the market have failed.”*



“We encourage our shareholders to register for and participate in the upcoming Ordinary and Extraordinary shareholders’ meeting on April 23, 2026, as the proposed resolutions are expected to positively contribute to the success of our continuous ambitions, including the preparation of a potential NDA dossier for evenamide and the evaluation of its benefits in additional indications beyond schizophrenia, as well as a potential listing of our shares on a US stock exchange. At this meeting, we will also have the opportunity to thank our meritorious Board members, Patrick Langlois and Luca Benatti, for their dedicated support of our Company over many years. And George Garibaldi and Paolo Zocchi, two highly experienced industry and financial experts, are proposed for election as new, independent members of the Board of Directors”, added Stefan Weber.

Evenamide – advancing schizophrenia treatment

2025 was marked by significant milestones for the evenamide development program, with the approval of the pivotal ENIGMA-TRS Phase III development program evaluating evenamide as an add-on therapy in patients with TRS. This development program consists of two pivotal studies, ENIGMA-TRS 1 and ENIGMA-TRS 2:

- **ENIGMA-TRS 1** is an ongoing, international, 52-week, randomized, double-blind, placebo-controlled Phase III study evaluating the efficacy, tolerability, and safety of the 15mg BID and 30mg BID therapeutic doses of evenamide compared to placebo. Patients on second-generation antipsychotics, including clozapine, will meet Treatment Response and Resistance Psychosis international consensus criteria for TRS. The study will enroll at least 600 patients at study centers in Europe, Asia, Latin America and Canada. The first patients were successfully enrolled in August 2025, following the completion of a rigorous 42-day screening period. Patients are currently being enrolled across eight countries on all target continents.

The primary assessment of efficacy and safety of ENIGMA-TRS 1 will be performed 12 weeks after randomization to treatment. Following this initial period, the study will continue double-blind and placebo-controlled until the 26- and 52-week time points. The primary efficacy endpoint of the trial will be the change from baseline in the Positive and Negative Syndrome Scale (PANSS) scores at 12 weeks. Newron expects to announce results from the 12-week primary endpoint assessment in QIV 2026..

- **ENIGMA-TRS 2** is taking place at centers in the US and selected additional countries with the same screening procedure as the ENIGMA-TRS 1 trial. ENIGMA-TRS 2 will include at least 400 patients in a 12-week, randomized, double-blind, placebo-controlled Phase III study, designed to evaluate the efficacy, tolerability, and safety of the 15mg BID dose of evenamide compared to placebo. In December 2025, ENIGMA-TRS 2 was initiated in the US, following approvals from the US Food and Drug Administration (FDA) and the Institutional Review Board (IRB). The first sites to initiate were the Semel Translational Research Center for Neuropsychiatry at the University of California, Los Angeles (UCLA), and the Johns Hopkins University School of Medicine (Baltimore), with the three more sites in the US being fully approved and expected to start enrolling shortly. Regulatory submissions are currently being made in the other countries that are expected to participate in this trial in the coming months, with first approvals having been received. The efficacy and safety analysis will be performed at the 12-week point following successful completion of the study.

Post-period, in January 2026, Newron shared the announcement that its partner for Japan and other designated Asian territories, EA Pharma (Eisai Group), had initiated its Phase III clinical trial with evenamide in Japan.

In August, new data from Dr. Anthony Grace and other researchers at the University of Pittsburgh was published in the peer-reviewed journal “International Journal of Neuropsychopharmacology”. The data suggests that evenamide ameliorates schizophrenia-related dysfunction, and for the first time demonstrates that evenamide targets the key site of schizophrenia pathology in the hippocampus. Researchers demonstrated that evenamide could offer a novel therapeutic strategy capable of addressing the positive, cognitive, and negative symptoms of schizophrenia, a key advantage over existing antipsychotic drugs which only target positive symptoms. These findings help explain the robust and sustained symptom improvements observed in Newron’s Phase II and Phase III studies in patients with chronic schizophrenia, reinforcing evenamide’s potential as a transformative therapy for treatment-resistant and poorly responding patients, and offering a promising alternative to traditional dopamine D2-based antipsychotics.

Newron’s R&D team also used the reporting year to present and discuss data on the mechanism of action of evenamide in scientific publications, such as the “International Journal of Neuropsychopharmacology”. Post-period, in February 2026, peer-reviewed data co-authored by Newron’s Chief Medical Officer, Ravi Anand,



MD, and colleagues was also published in “Therapeutic Advances in Psychopharmacology”. The publication collated results from multiple randomized clinical trials and provided a scientific mechanistic rationale for the use of evenamide as a unique approach that targets disease mechanisms not addressed by existing antipsychotics. Furthermore, throughout 2025, Newron presented new analyses from its evenamide clinical development program at key conferences, including the 2025 World Congress of Biological Psychiatry in September and the 38th European College of Neuropsychopharmacology Congress in October.

To comprehensively protect the future value of evenamide for existing shareholders and new investors, Newron is filing additional patent applications to further extend the IP protection for evenamide as a novel treatment for schizophrenia. These additional patents would complement the existing patent applications pertaining to evenamide which continue to be granted within the European Union and the US. In January 2026, just after the end of the reporting period, the European Patent Office issued the decision to grant the Company an additional patent until 2044 for evenamide. The patent covers crystalline forms of evenamide, processes for their preparation, and their uses. This is an important milestone for Newron, and the decision is likely to extend evenamide’s exclusivity runway, helping to maximize its therapeutic and commercial potential.

In addition to its licensing agreements with Myung In Pharm and EA Pharma, the Company’s Board and Management are actively exploring additional global development and commercial opportunities for evenamide and will prioritize and negotiate any offers based on their potential to increase shareholder value.

Financial key takeaways 2025:

- In 2025, Newron reported a license income of EUR 8.6 million (2024: EUR 44.5 million), resulting from the upfront payment due under the license agreement signed with Myung In Pharm Co. Ltd. and milestones from both EA Pharma (Eisai Group) and Myung In.
- In addition, the Company received royalty payments for Xadago® from Zambon of EUR 7.8 million (2024: EUR 6.9 million) and booked Other revenues for a total of EUR 2.7 million.
- Newron’s R&D expenses increased to EUR 15.1 million (from EUR 13.6 million in 2024).
- As a result, in 2025 Newron reported a net loss of EUR 13.2 million, compared with a net profit of EUR 15.8 million in 2024 (due to the upfront payment received under the license agreement signed with EA Pharma in December 2024).
- As the EA Pharma (Eisai Group) upfront payment was received in January 2025, only, Operating activities generated EUR 32.3 million of cash, while in 2024 Operating activities used EUR 17.6 million.
- Cash and Other current financial assets as of December 31, 2025 were at EUR 28.9 million, compared to EUR 9.8 million at the beginning of the year.

Financial Summary (IFRS) 2025 and 2024

In thousand EUR (except per share information)

	2025	2024
Licence income from contracts with customers	8,628	44,470
Royalties from contracts with customers	7,770	6,920
Other revenues	2,728	0
Revenues	19,126	51,390
Research and development expenses	(15,119)	(13,642)
Operating Result	(4,697)	26,173
Financial result, net	(7,657)	(4,779)
Net profit/(loss)	(13,239)	15,843
Gain/(Loss) per share	(0.66)	0.85
Cash generated from operating activities	32,349	(17,614)
Cash, cash equivalents and Other current financial assets	28,876	9,826
Total assets	40,055	63,908

Newron’s Annual Report 2025 is available for download on the Company’s website at: www.newron.com/investors/reports-and-presentation/year/2025



Outlook 2026

Newron's and evenamide's progress in 2025 was highly encouraging, and the Company is well-positioned to build on this momentum in 2026, as the pivotal ENIGMA-TRS 1 and 2 trials advance, with initial pivotal data readout expected later this year. Progressing the evenamide clinical development program is the key priority for 2026, and Newron remains resolutely committed to delivering meaningful benefits to patients who urgently need innovative treatment options that address gaps in current therapeutic approaches.

The Company maintains a strong financial position, strengthened by the agreement for the subscription of newly issued shares in February 2026, which enables Newron to continue operating as a sustainable business. Newron's total available cash resources together with the EUR 15 million of proceeds from shares newly issued in February 2026, plus an additional EUR 11 million expected under the financing agreement before the end of 2026, should fund the Company's planned development programs and operations well through 2027.

Media/analyst/investor Conference Call today at 2:30 pm CET/1:30 pm UK/9:30 am EDT

Newron's management team will today present the 2025 full-year results and provide an update and guidance for 2026. 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/2025

2026 Shareholders' Meeting Agenda

Newron's Board of Directors has approved the below agenda for the **April 23, 2026**, 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 March 24, 2026. All documents connected with the agendas, as per applicable laws and regulations, as well as the necessary information to register and attend these meetings, are available on the Company's website via www.newron.com/investors/shareholders-meeting.

The agenda is as follows:

Ordinary part

1. Review and approval of the annual financial statements and presentation of the consolidated financial statements as at 31 December 2025; connected and consequent resolutions.
2. Appointment of the members of the Board of Directors for the financial years 2026, 2027 and 2028 and, consequently, until the approval of the financial statements as at 31 December 2028:
 - 2.1 determination of the relevant number;
 - 2.2 proposal to appoint the following persons:
 - A. Christopher John Martin: as Chairman of the Board and non-executive director;
 - B. Stefan Weber: as executive director;
 - C. George Garibaldi: as a non-executive director;
 - D. Gillian Dines: as a non-executive director;
 - E. Margarita Chavez: as a non-executive director;
 - F. Paolo Zocchi: as a non-executive director.
 - 2.3 Determination of the relevant remuneration.
Connected and consequent resolutions.

Extraordinary Part

1. Amendment of the Newron By-laws with particular reference to Articles 6 (*Share Capital*), 9 (*Convening*), 10 (*Admission – Proxy*), 13 (*Extraordinary General Meeting*) and 25 (*Obligations arising from listing*). Connected and consequent resolutions.
2. Granting of powers to the Board of Directors, pursuant to Article 2443 of the Civil Code, to be exercised no later than five years from the date of such grant, to increase the share capital, in one or more times, for a maximum



nominal amount of Euro 208,057.80, in addition to any premium, without option rights, pursuant to Article 2441, paragraphs 5, 6 and/or 8 of the Civil Code, to serve one or more incentive plans. Amendment of Article 6 of the Newron By-laws. Connected and consequent resolutions.

3. Granting of powers to the Board of Directors, pursuant to Articles 2443 and 2420-ter of the Civil Code, to be exercised no later than five years from the date of such grant, to increase the share capital, in one or more times, for a maximum nominal amount of Euro 624,173.80, in addition to any premium, by issuing shares and/or convertible bonds, with or without option rights pursuant to Article 2441, paragraphs 4, first part, 5 and 6 of the Civil Code, possibly combined with warrants or in service of warrants to be issued, including where this may be necessary for the listing of the Company's ordinary shares (or other financial instruments) on the NYSE, NASDAQ and/or any other market (or trading system) within the United States of America. Amendment of Article 6 of the Newron By-laws. Connected and consequent resolutions.
4. Creation of *American Depository Shares* and listing them, and/or listing of Newron shares, on the NYSE, NASDAQ, and/or on any other market (or trading system), including *over-the-counter* (OTC), within the United States of America. Connected and consequent resolutions.

Pursuant to Article 10 of the current Newron By-laws, in order to attend the meeting, the prior notice sent by the intermediary admitted to the centralised management system is required, confirming the ownership of the shares and of the voting right. The notification must reach the registered office no later than one working day before the date on which the meeting is scheduled.

For the purpose of appointing the members of the Board of Directors referred to in item 2 on the agenda, the shareholders' meeting will be called upon to vote in favor of or against the appointment of each candidate. The documentation relating to the items on the agenda, as required by current legislation, will be available to the public at the registered office in Bresso (MI), Via Antonio Meucci no. 3, Italy, during the 15 days prior to the date of the meeting.

Financial calendar

- AGM and EGM 2026: April 23, 2026
- Half-year results and report 2026: September 22, 2026

About Newron Pharmaceuticals

Newron (SIX: NWRN, XETRA: NP5) is a biopharmaceutical company focused on the development of innovative therapies for patients with diseases of the central and peripheral nervous system. Headquartered in Bresso near Milan, Italy, the Company has a strong track record of advancing neuroscience-based treatments from discovery to market. Newron's lead compound, evenamide, is a first-in-class glutamate modulator and 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 developed in the global pivotal ENIGMA-TRS Phase III development program. Clinical trial results to date demonstrate the benefits of this drug candidate in the TRS as well as poorly responding patient population, with significant improvements across key efficacy measures increasing over time, as well as a favorable 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's first marketed product, 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. The product is commercialized by Newron's partner Zambon, with Supernus Pharmaceuticals holding marketing rights in the U.S., and Meiji Seika responsible for development and commercialization in Japan and other key Asian territories. 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.