Ad hoc announcement pursuant to Art. 53 LR

Newron presents H1 2025 results and provides business update

Milan, Italy, September 16, 2025, 07:00 am CEST – 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, 2025, and provided a business update for 2025 and beyond.

Highlights H1 2025:

Evenamide

Clinical trials:

- In May, the Company announced regulatory approval for its pivotal Phase III ENIGMA-TRS program with evenamide as add-on therapy in patients with treatment-resistant schizophrenia (TRS). The program consists of two pivotal studies:
  - ENIGMA-TRS 1, an international, one-year, double-blind, placebo-controlled Phase III study in at least 600 patients. Following a successful screening period, patient enrolment began post-period, in August 2025, with 12-week study results expected in Q4 2026
  - ENIGMA-TRS 2, approved by the US Food and Drug Administration, to be performed at centers in the US and selected additional countries. This 12-week, double-blind, placebo-controlled Phase III study in at least 400 patients is expected to start by October 2025

Strategic licensing and partnerships:

- In January, the Company announced a 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 ENIGMA-TRS 1 study and will cover the costs related to this population
- Following the execution (in December 2024) of the licensing agreement with EA Pharma, a subsidiary of Eisai, to develop, manufacture and commercialize evenamide in Japan and other designated Asian territories, Newron in the reporting period received the upfront payment of EUR 44 million and invoiced the first milestone achievement
- Newron continues to actively explore additional partnership opportunities for the global development and commercialization of evenamide in other territories

Industry engagement and scientific exchange:

- In January, evenamide's exceptional results in study 014/015 and study 008A were published in the peer reviewed *International Journal of Neuropsychopharmacology*
- Post-period, in August 2025, new preclinical data from researchers at the University of Pittsburgh was published in the peer-reviewed journal *Neuropsychopharmacology*. The research suggests that evenamide ameliorates schizophrenia-related dysfunction, targeting the key site of schizophrenia pathology in the hippocampus, and so could be an ideal therapeutic agent for the treatment of schizophrenia

Corporate

- In April, Dr. Chris Martin was elected as the Chairman of Newron's Board of Directors, succeeding Dr. Ulrich Köstlin who served as Chairman of the Company from 2013

Stefan Weber, CEO of Newron, commented: *"Since the beginning of the year, Newron has continued to make exciting progress in the development of our novel drug candidate evenamide. Most notably, we announced the approval of our pivotal ENIGMA-TRS Phase III development program evaluating evenamide as an add-on therapy in patients with treatment-resistant schizophrenia (TRS) and recently we began enrolling patients into the first study from the program, ENIGMA-TRS 1. We're delighted to have achieved this crucial milestone on evenamide's clinical development journey and continue to believe that this new chemical entity has blockbuster potential and could bring enormous benefits to patients who are insufficiently served by the treatments currently available."*

Evenamide – advancing schizophrenia treatment

In January, Newron announced its licensing agreement with Myung In Pharm to develop, manufacture and commercialize evenamide as an add-on therapy for TRS and poorly responding patients with schizophrenia in South Korea. Under the terms of the agreement, Myung In Pharm, besides the usual financial terms for such agreement, will contribute 10% of the total patient population to be enrolled into Newron's pivotal ENIGMA-TRS 1 clinical trial and cover the costs related to this population.
There has also been strong progress from EA Pharma, who Newron has entered into a license agreement with to develop, manufacture and commercialize evenamide in Japan and other designated Asian territories. EA Pharma expects to initiate its clinical development program for evenamide in Japan. Also, the first milestone under the license agreement became due and was invoiced in the reporting period.

In May, Newron announced the regulatory approval of its pivotal Phase III ENIGMA-TRS program with evenamide as add-on therapy in patients with TRS. More than one third of schizophrenia patients suffer from TRS and are not responding to the existing second-generation antipsychotics on the market. Consequently, these patients are in great need of the development and approval of new therapeutic treatments. If approved, evenamide would be the first medication added to existing antipsychotics that improves the symptoms of TRS.

The ENIGMA-TRS Phase III development program consists of two pivotal studies, ENIGMA-TRS 1 and ENIGMA-TRS 2:

- **ENIGMA-TRS 1** is an 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 as an add-on treatment to current antipsychotics, compared to placebo. Patients on second-generation antipsychotics (SGAs), including clozapine, will meet Treatment Response and Resistance Psychosis (TRRIP) international consensus criteria for TRS. The study will enroll at least 600 patients at study centers in Europe, Asia, Latin America and Canada.
- 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 52-week time point. 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 12-week results from the study in Q4 2026.
- ENIGMA-TRS 1 is actively screening across all target continents. Post-period, in August 2025, Newron announced that the first patients have been successfully enrolled following the completion of a 42-day screening period. Newron's partner Myung In Pharm has also received the necessary approvals in South Korea to move towards enrolling patients in this region.
- **ENIGMA-TRS 2**, the second study in Newron's pivotal Phase III development program, has been approved by the US Food and Drug Administration (FDA), and will be performed at centers in the US and selected additional countries. 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 as an add-on treatment to current antipsychotics, compared to placebo.
- Patients will undergo the same screening as the ENIGMA-TRS 1 trial. The efficacy and safety analysis will be performed at the 12-week point following successful completion of the study. US investigational centers are expected to initiate the study by October 2025.

Shortly after the reporting period, in August 2025, new preclinical data from Dr. Anthony Grace and other researchers at the University of Pittsburgh was published in the peer-reviewed journal *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. Using the neurodevelopmental MAM model of schizophrenia, 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. Importantly, time-course analysis indicates effects of a single dose of evenamide last long after elimination of drug, suggesting effect on neuronal plasticity. 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.

Xadago®/safinamide – Parkinson's disease

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

Corporate

At the Annual General Meeting 2025, Dr. Chris Martin was elected as the new Chairman of the Board following his nomination by the Company. Chris Martin took over from Dr. Ulrich Köstlin, who served as Chairman of Newron's Board since 2013. Dr. 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. He co-founded ADC Therapeutics in 2012 and served as its CEO from its inception until 2022, growing the company from a private biotech start-up to a New York Stock Exchange listed leader in the field of antibody-drug conjugates with products marketed worldwide. Chris Martin also co-founded and was the CEO of Spirogen, an innovator of antibody-drug conjugate payload technology, which was subsequently sold to AstraZeneca for a total of up to $440 million.

Outlook

Following the approval of the pivotal Phase III ENIGMA-TRS program for evenamide and the subsequent initiation of the ENIGMA-TRS 1 study, Newron's key focus for the coming months is on progressing this study and initiating ENIGMA-TRS 2, initially in the US study centers.

In addition to its licensing agreements with Myung In Pharm and EA Pharma, Newron continues to be supported by one of world's leading full-service investment banking and capital markets firms in a structured process to secure the most attractive, value creating transactions for the Company's shareholders.

Furthermore, to comprehensively protect the future value of evenamide for shareholders and new investors, Newron is currently in the process of filing additional patent applications to further extend the Intellectual Property protection around evenamide as a novel treatment for schizophrenia. Additionally, the existing patent applications pertaining to evenamide continue to be granted within the European Union and the US.

Newron CEO Stefan Weber concluded: *"We are very excited about our continued achievements, and we are one step closer to potentially bringing enormous benefits to schizophrenia patients who are insufficiently served by the treatments currently available. The financial position of our Company remains strong – Newron's total available cash resources are expected to fund our planned development programs and operations well towards the end of the year 2026."*

Financial Summary (IFRS) H1 2025 and 2024:

In thousand EUR (except per share information)

	H1 2025	**H1 2024**
Licence income/Royalties/Other income	11,898	3,407
Research and development expenses	(6,081)	(6,453)
General and administrative expenses	(4,423)	(4,579)
Net loss	(73)	(9,557)
Loss per share	(0.00)	(0.51)
Cash generated/(used) in operating activities	33,353	(8,828)
	As of June 30, 2025	**As of December 31, 2024**
Cash and Other current financial assets	43,195	9,826
Total assets	61,394	63,908

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