Ad hoc announcement pursuant to Art. 53 LR

Newron presents H1 2026 results and provides corporate update

Milan, Italy, and Morristown, NJ, USA – September 22, 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 first half of 2026, and provided a corporate update.

Highlights H1 2026:

Evenamide

- ENIGMA-TRS 1: Screening for enrollment completed post-period in September. Target enrollment of at least 600 patients expected around mid-October, Topline 12-week results in Q1 2027
- ENIGMA-TRS 2: Following a constructive Type A meeting with the FDA in July, Newron expects US enrollment to resume in the near future. Ongoing enrollment outside the US
- IP: European Patent Office decision to grant an additional Composition of Matter patent extending protection for evenamide to 2044
- Japan: Partner EA Pharma (Eisai Group) announced initiation of its Phase 3 clinical trial with evenamide in Japan

Corporate

- A financing agreement for proceeds of up to EUR 38 million was signed, strengthening Newron's financial position and supporting the evenamide Phase 3 program
- Extended maturity of all outstanding European Investment Bank financing tranches to June 2028.
- Post-period, Newron received a further EUR 5.5 million milestone payment from EA Pharma/Eisai
- George Garibaldi and Paolo Zocchi were elected as new, independent non-executive Board members at the AGM

Stefan Weber, CEO of Newron, commented: *"During the first half of 2026, we made significant progress advancing evenamide and our pivotal Phase 3 ENIGMA-TRS program. We are very pleased with the continued progress of ENIGMA-TRS 1, with the last patient having completed screening and enrollment expected to reach its target shortly. Following our constructive Type A meeting with the FDA, we also remain confident that enrollment in the US component of ENIGMA-TRS 2 will resume in the near future. Together, these developments bring us closer to potentially delivering a much-needed new treatment option for patients with treatment-resistant schizophrenia. With our strengthened financial position and intellectual property portfolio, Newron is well positioned to advance evenamide towards key ENIGMA-TRS clinical readouts in 2027."*

Evenamide – advancing schizophrenia treatment

Newron continued to make substantial progress with its pivotal ENIGMA-TRS Phase 3 development program during the first half of 2026. The program evaluates evenamide as an add-on therapy in patients with treatment-resistant schizophrenia (TRS), a population that remains underserved by currently available treatments.

ENIGMA-TRS 1 is an international, 52-week, randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy, tolerability and safety of the 15mg BID and 30mg BID doses of evenamide compared with placebo. The study is designed to enroll at least 600 patients at centers across Europe, Asia, Latin America and Canada.

Post-period, in September 2026, the last of 996 patients entered screening for enrollment. Newron expects target enrollment of at least 600 patients to be reached around mid-October 2026.

The primary efficacy endpoint is the change from baseline in the Positive and Negative Syndrome Scale (PANSS) score at 12 weeks. Newron expects to announce Topline 12-week results in Q1 2027. The study will continue under double-blind, placebo-controlled conditions through 52 weeks.

ENIGMA-TRS 2 is a 12-week, randomized, double-blind, placebo-controlled Phase 3 study designed to enroll at least 400 patients and evaluate the efficacy, tolerability and safety of the 15mg BID dose of evenamide.

Enrollment started in the US in December 2025, followed by regulatory approvals in study centers in Asia and Latin America. In April 2026, Newron announced a pause in enrollment at US study centers following notification to the FDA of the sudden death of a study participant at a clinical site outside the US, in accordance with standard practice.

Following a constructive Type A meeting with the FDA in July, Newron is implementing changes discussed with the FDA and expects U.S. enrollment to resume following FDA clearance. Study centers outside the US are not affected by the pause.

In January 2026, Newron's partner EA Pharma (part of the Eisai Group), announced initiation of its Phase 3 clinical trial with evenamide in Japan.

Intellectual property and scientific engagement

In January 2026, the European Patent Office issued a decision to grant Newron an additional Composition of Matter patent providing protection for evenamide through 2044. The patent covers crystalline forms of evenamide, processes for their preparation and their uses, further strengthening the Company's intellectual property position.

In February, peer-reviewed data was published in *Therapeutic Advances in Psychopharmacology*. The publication brought together findings from multiple randomized clinical trials and provided further scientific and mechanistic support for evenamide as a novel treatment approach for patients with schizophrenia who have an inadequate response to existing treatments, including those with TRS.

Newron also continued to engage with the scientific and investment communities at key industry and investor conferences during the reporting period.

Xadago®/safinamide – Parkinson's disease

In partnership with Zambon and Supernus, Newron continues to further develop and market Xadago®/safinamide.

In the US, generic versions of safinamide mesylate are not permitted to launch earlier than December 2027. In the European Union, Newron expects Supplementary Protection Certificates in key markets following completion of ongoing procedures.

Corporate developments

In February, Newron entered into an agreement with existing and new shareholders from Europe and Asia for the subscription of newly issued shares for proceeds of up to EUR 38 million. To date, EUR 20.5 million has been subscribed under the agreement, including a EUR 5.5 million tranche completed post-period in September. The financing further strengthens the Company's financial position and supports continued execution of the ENIGMA-TRS Phase 3 program.

A further EUR 5.5 million tranche from these investors is expected no later than November 30, 2026, with an additional EUR 12 million expected following disclosure of the ENIGMA-TRS results, conditional upon such results being positive.

In March, Newron announced an agreement with the European Investment Bank extending the maturity date of all outstanding tranches under its 2018 Finance Contract to June 28, 2028.

Post-period, Newron also received a further EUR 5.5 million milestone payment from EA Pharma (Eisai Group), reflecting continued progress in the development of evenamide.

At the Annual General Meeting in April, George Garibaldi and Paolo Zocchi were elected as new independent non-executive Board members, succeeding Patrick Langlois and Luca Benatti.

Financial key takeaways H1 2026

- For the first six months of 2026, Newron reported revenues of EUR 3.2 million, compared to EUR 11.9 million in the same period of 2025. H1 2025 revenues reflect the achievement of the first milestone under the license agreement with EA Pharma (Eisai Group) and the upfront payment received from Myung In Pharm.
- Newron's R&D expenses increased to EUR 14.6 million in H1 2026, up from EUR 6.1 million in H1 2025.
- This resulted in a net loss of EUR 16.4 million, compared to EUR 0.1 million in the same period in 2025.
- Operating activities absorbed EUR 10.8 million while as of June 2025 they generated EUR 33.4 million of cash.
- Cash and Other current financial assets as at June 30, 2026, were at EUR 32.9 million, compared to EUR 28.9 million as at December 31, 2025. Post period, in September, the cash balance was positively impacted by the milestone payment and the call for the second tranche of financing, by a total of about EUR 11.0 million.

Financial Summary (IFRS) H1 2026 and H1 2025

In thousand EUR (except per share information), unaudited

	H1 2026	**H1 2025**
Licence income from contracts with customers	125	7,772
Royalties from contracts with customers	3,064	3,780
Other income from contracts with customers	0	346
Revenues	**3,189**	**11,898**
Research and development expenses	(14,552)	(6,081)
Operating Result	**(16,600)**	**1,345**
Financial result	235	(1,402)
Net result	**(16,372)**	**(73)**
Result per share	(0.798)	(0.004)
	June 30, 2026	**Dec. 31, 2025**
Cash and cash equivalents, other current financial assets	32,890	28,876
Total assets	40,291	40,055

Newron's Half-Year 2026 is available for download on the Company's website at:
www.newron.com/investors/reports-and-presentation/year/2026

Outlook

Newron is well positioned to continue advancing the clinical development of evenamide through the remainder of 2026 and into 2027.

The Company's key priority remains the successful execution of the pivotal ENIGMA-TRS Phase 3 program. With ENIGMA-TRS 1 approaching target enrollment and US enrollment in ENIGMA-TRS 2 expected to resume in the near future, Newron remains focused on achieving important clinical milestones and expects topline results from both studies in 2027.

Newron also continues to explore development and commercial opportunities for evenamide and to strengthen its intellectual property position.

The Company's total available cash resources are expected to fund planned development programs and operations throughout most of 2027, including beyond the expected disclosure of the 12-week results from the ENIGMA-TRS program.

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 3 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: https://www.newron.com and connect with us on LinkedIn.

For more information:

Newron
Stefan Weber – CEO; pr@newron.com

UK/Europe
Simon Conway / Ciara Martin / Natalie Garland-Collins, FTI Consulting; +44 20 3727 1000, SCnewron@fticonsulting.com

Switzerland
Valentin Handschin, IRF; +41 43 244 81 54, handschin@irf-reputation.ch

Germany/Europe
Anne Hennecke / Maximilian Schur, MC Services; +49 211 52925227, newron@mc-services.eu

USA
John Fraunces, LifeSci Advisors, +1 917 355 2395, jfraunces@lifesciadvisors.com

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