EDISON

Newron Pharmaceuticals

Pivotal readout moves firmly into view

Clinical trial update

Healthcare

2 September 2026

Newron has announced the completion of screening for its pivotal Phase III ENIGMA-TRS 1 study of evenamide in treatment-resistant schizophrenia (TRS), marking an important milestone. A total of 996 patients have entered screening, with 411 already randomised and 352 still progressing through the 42-day screening assessment. Based on current eligibility rates, Newron expects at least another 200 patients to be randomised, taking the study beyond its protocol target of 600 patients from mid-October. Top-line results from the primary 12-week treatment period are anticipated in Q127, a slight adjustment from prior guidance of Q426. We do not view this modest timing shift as materially changing the investment case. The completion of screening provides increased visibility on delivery of the required study population and brings the first pivotal efficacy readout for evenamide into view. The Q127 readout represents a key potential upcoming catalyst.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/24	51.4	21.7	0.87	0.00	15.1	N/A
12/25	19.1	(12.1)	(0.65)	0.00	N/A	N/A
12/26e	7.8	(46.4)	(2.23)	0.00	N/A	N/A
12/27e	66.6	32.5	1.19	0.00	11.0	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

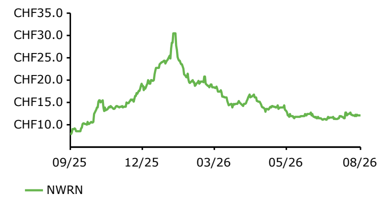
According to the announcement, screening for enrolment in ENIGMA-TRS 1 has been completed, providing greater clarity on overall trial timelines. Before randomisation, patients are required to complete 42 days of screening, including confirmation of their treatment-resistant diagnosis, checks of background antipsychotic drug levels and review against protocol criteria by an independent committee of three leaders in the field of schizophrenia. This is intended to ensure that the participants represent a typical TRS population, supporting the interpretability of the pivotal dataset. With 996 patients having entered screening and 411 already randomised, the remaining screening pool appears sufficient to take enrolment above the required 600 participants.

ENIGMA-TRS 1 is a one-year, randomised, double-blind, placebo-controlled trial testing evenamide as an add-on to existing antipsychotics, including clozapine (the only drug approved for TRS, though its use has safety and monitoring limitations). The primary endpoint uses the Positive and Negative Syndrome Scale (PANSS) score at 12 weeks, the gold standard in this indication. The study continues to 26 and 52 weeks, providing evidence on durability, safety and tolerability. Importantly, ENIGMA-TRS 1 has not been affected by the enrolment hold at US sites in the separate ENIGMA-TRS 2 trial, and remains Newron's most imminent inflection point.

Evenamide is designed to modulate excessive glutamate release via selective blockade of voltage-gated sodium channels, providing a novel approach versus available antipsychotics, which mainly act through dopamine pathways. Evenamide enters the pivotal programme with a substantial clinical evidence base. Study 014/015 demonstrated durable and clinically meaningful improvements in patients with TRS, while the international, double-blind, placebo-controlled Phase IIb/III study 008A in 291 poorly responding schizophrenia patients met both its primary and secondary efficacy endpoints with statistical significance. In study 008A, evenamide achieved a significantly greater improvement in PANSS score than placebo at day 29, alongside a tolerability profile similar to placebo. The key question is whether these strong findings can be confirmed in Phase III in the target TRS population.

Price	**CHF12.34**
Market cap	**CHF257m**
	€1.06/CHF
Pro forma net cash/(debt) at 31 December 2025	€5.8m
Shares in issue	20.8m
Free float	95.0%
Code	NWRN
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



Business description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease is sold in Europe, Japan and the United States. Evenamide, a novel schizophrenia add-on therapy, is involved in a Phase III trial programme targeting treatment-resistant schizophrenia.

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