Newron Pharmaceuticals

US trial pause should not obscure progress

Clinical update

Healthcare

5 May 2026

Newron Pharmaceuticals has announced that the FDA has placed a hold on the enrolment of new patients at US sites in the Phase III ENIGMA-TRS 2 trial. This was due to the sudden death of a participant at a non-US clinical site; however, it is important to highlight that the investigator assessed the event as unrelated to the study treatment (evenamide), while the independent international safety monitoring board reviewed the event and recommended that the ENIGMA-TRS programme continue as designed. As such, the pause is limited to US sites in ENIGMA-TRS 2 only. The registrational ENIGMA-TRS 1 trial continues across 21 countries, with more than 400 patients enrolled, while ENIGMA-TRS 2 has approvals in Argentina and India, with Colombia and Malaysia in the final stages. We view the pause as a manageable regulatory process, rather than a change to the underlying evenamide investment case.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/24	51.4	21.7	0.87	0.00	17.4	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	12.7	N/A

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

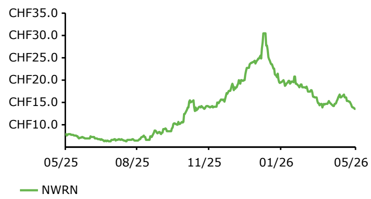
Management has communicated that it is working closely with the FDA and that it intends to provide the requested information to support a resolution of the hold, with the aim of resuming enrolment at US sites as soon as it is appropriate to do so. While any safety related regulatory action naturally warrants investor attention, the company has provided several key contextual points that we believe are worth highlighting. Importantly, the death was judged unrelated to treatment by the investigator and has been reviewed by the independent monitoring board overseeing the overall ENIGMA-TRS programme and recommended that the studies continue as designed. Newron also stated that, to date, there has been no increased mortality risk between patients treated with evenamide and patients treated with placebo based on treatment duration.

The broader programme continues to advance, with over 400 participants already enrolled on the way to randomisation of a total 600. ENIGMA-TRS 1 is a global, 52-week, randomised, double-blind, placebo-controlled trial assessing evenamide 15mg and 30mg twice daily as an add-on to antipsychotics, including clozapine (the only therapy specifically approved for treatment-resistant schizophrenia, TRS). The key 12-week efficacy and safety assessment (primary endpoint: PANSS total score change from baseline) is expected in Q426, representing a potentially significant upcoming catalyst.

Evenamide remains Newron's central value driver and is being developed as a potential first add-on therapy for TRS, a patient group with limited current options. Prior clinical data showed encouraging improvements in TRS, including more than 70% of patients achieving a clinically meaningful reduction in condition severity, c 50% of patients no longer meeting the protocol severity criteria for a diagnosis of TRS, and 25% of patients described as achieving clinical remission (a phenomenon that has not been previously observed in TRS, to our knowledge). For a more detailed discussion of Newron's current activities and financial position, we direct readers to our recent update note.

Price	CHF13.80
Market cap	CHF287m
	€1.08/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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