Newron Pharmaceuticals

Constructive FDA meeting

Regulatory update

Healthcare

3 July 2026

Newron has announced a constructive Type A meeting with the FDA regarding the enrolment hold affecting US sites in the Phase III ENIGMA-TRS 2 study. The discussion focused on information previously submitted by the company and the changes required by the FDA before it will consider allowing enrolment to resume. Importantly, management indicated that both parties discussed potential actions towards resolving the outstanding issues, with Newron now planning to propose protocol changes agreed with the agency. While the timing of US enrolment resumption remains uncertain, we view this update as encouraging, as it shows continued regulatory engagement, and provides a clearer pathway towards resolving the hold. Meanwhile, the broader ENIGMA-TRS programme is progressing, with ENIGMA-TRS 1 actively enrolling patients globally ahead of its planned Q426 primary endpoint readout.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/24	51.4	21.7	0.87	0.00	15.6	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	11.3	N/A

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

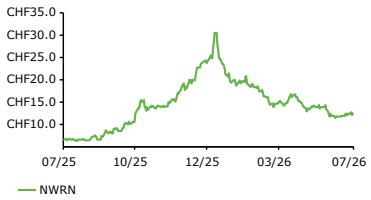
The FDA placed a hold on enrolment at US sites in ENIGMA-TRS 2 in April 2026 following the sudden death of a participant at a non-US clinical site. The investigator concluded that the event was unrelated to evenamide treatment, and the independent international safety monitoring board reviewed the case and recommended that both ENIGMA-TRS studies continue as designed. The latest announcement suggests that discussions have now progressed from information gathering, towards identifying specific actions that could enable the FDA to lift the hold.

We highlight that these events have not affected ENIGMA-TRS 1, which remains the lead international registrational study. The trial is currently enrolling patients across 15 countries and remains on track to report its primary 12-week efficacy and safety assessment in Q426. ENIGMA-TRS 2 includes sites outside the US, supporting Newron's strategy of advancing a global Phase III programme for evenamide in treatment-resistant schizophrenia.

Overall, we believe the announcement should be viewed as an incremental but positive regulatory update. Although there is still no definitive timeline for restarting US enrolment in ENIGMA-TRS 2, the constructive nature of the meeting and Newron's agreement with the FDA on the next steps suggest that the review process is progressing. In our view, the key investment focus remains the continued execution of ENIGMA-TRS 1 and the anticipated Q426 readout, which represents the most significant near-term catalyst for the programme.

Price	**CHF12.40**
Market cap	**CHF258m**
	€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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