

Newron Pharmaceuticals

Next stage unlocked for evenamide

Clinical update

Healthcare

13 May 2025

Newron has announced receipt of **regulatory clearance** to conduct its Phase III programme for evenamide (ENIGMA-TRS), taking it one step closer to the market. It will comprise two separate trials: ENIGMA-TRS 1, a 600-patient international study with enrolment set to start imminently; and ENIGMA-TRS 2, a 400-patient US-focused study with enrolment due to commence within the next three months. Note that the decision to conduct two separate Phase III trials (instead of a widely anticipated single study) was slightly surprising, although we believe this may be strategic with a view to maximise success potential and gain regulatory approval, particularly in the key US market. The 12-week results from the ENIGMA-TRS 1 study, for which we believe the company is well capitalised, are anticipated in Q426, a major upcoming inflection point for Newron. We will present updated estimates in due course based on this latest news.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/23	9.1	(16.0)	(0.90)	0.00	N/A	N/A
12/24	51.4	21.7	0.87	0.00	10.1	N/A
12/25e	7.4	(32.1)	(1.61)	0.00	N/A	N/A
12/26e	7.9	(19.0)	(0.95)	0.00	N/A	N/A

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

The **ENIGMA-TRS** programme will assess evenamide as an adjuvant to current antipsychotics, including clozapine (the only FDA-approved drug for treatment-resistant schizophrenia, TRS) in at least 1,000 patients with TRS. ENIGMA-TRS 1 will be a 52-week, randomised, double-blinded, placebo-controlled Phase III trial investigating the efficacy, tolerability and safety of evenamide at 15mg and 30mg BID doses, compared to placebo. It will include c 600 patients at study centres in Europe, Asia, Latin America and Canada, with enrolment expected to commence imminently. We estimate total trial costs of c €45m and believe the company is well capitalised to undertake this study, with additional support coming from partners EA Pharma (Japan) and Myung In Pharm (South Korea). The 12-week results are expected in Q426, although patients would stay on treatment for a full 52 weeks.

The second study, ENIGMA-TRS 2, will be a US-focused, 12-week, randomised, double-blinded, placebo-controlled study testing evenamide at a 15mg BID dose in c 400 patients. US investigational centres will launch in the next three months. The need for a second study was slightly surprising (given our understanding that a single pivotal study would suffice given the niche TR targeting), although we understand the decision may have been driven by an effort to derisk the programme with combined data from the two studies. Given the shorter study duration and lower number of participants, we estimate trial costs to be c €25m and funded using proceeds from other regional licensing deals for evenamide (either Latin America, China or India), in line with Newron's commercial strategy for the drug.

Evenamide has a differentiated mechanism of action, which targets glutamatergic dysfunction (rather than dopamine, the target of existing treatments) and has shown favourable results in prior clinical trials. Notably, in the Phase II study 015, >70% of patients achieved a clinically meaningful reduction in condition severity, and c 50% of patients no longer met the protocol severity criteria for a diagnosis of TRS at the 12-month follow-up. Further, 25% of patients achieved clinical remission, not previously seen in TRS, to our knowledge. For a more detailed discussion of Newron's clinical highlights and current activity, see our [January update note](#).

Price

CHF8.24

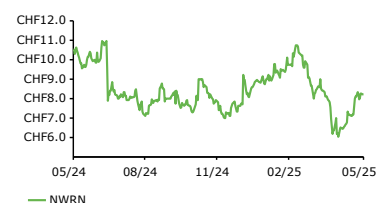
Market cap

CHF164m

€1.07/CHF

Pro forma net cash at 31	€4.6m
December (including €44.4m	
upfront proceeds from EA Pharma)	
Shares in issue	20.0m
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 preparing for a Phase III trial programme targeting treatment-resistant and poorly responding schizophrenia.

Analysts

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