

# Newron Pharmaceuticals

Clinical update

## Phase III ENIGMA-TRS 2 trial underway

Healthcare

Newron Pharmaceuticals has announced the launch of its Phase III ENIGMA-TRS 2 trial in the US, marking an important step for the registrational programme for lead candidate evenamide in treatment-resistant schizophrenia (TRS). ENIGMA-TRS 2 is a global, randomised, double-blind, placebo-controlled, 12-week pivotal study designed to enrol c 400 TRS patients. Topline results are anticipated by Q426, at a similar time to the ENIGMA-TRS 1 trial, representing a highly important inflection point for Newron. Additional US sites for ENIGMA-TRS 2 are due to initiate shortly and regulatory submissions are being made to other countries expected to participate in this trial.

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	22.5	N/A
12/25e	15.2	(20.6)	(1.03)	0.00	N/A	N/A
12/26e	7.8	(44.7)	(2.24)	0.00	N/A	N/A

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

As per the [announcement](#), Newron's ENIGMA-TRS 2 trial has commenced in the US. The objective of the ENIGMA-TRS programme is to establish evenamide as an add-on therapy for patients with TRS, a patient population with limited treatment options at present, associated with high morbidity and mortality. Following the launch of the ENIGMA-TRS 1 (expected n=600) trial in [August 2025](#), ENIGMA-TRS 2 has been designed as a Phase III, global, 12-week, randomised, double-blind, placebo-controlled study. It is assessing the efficacy, safety and tolerability of evenamide at a twice-daily dose of 15mg as an add-on medication to current antipsychotics (including clozapine, the only approved drug for TRS) compared to placebo in TRS patients.

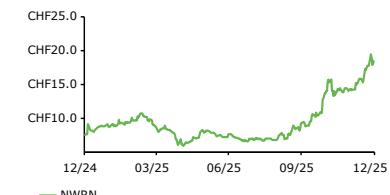
The trial design was cleared by the US FDA, and will aim to enrol c 400 patients across sites in the US, Europe, Asia and Latin America. Before patients are randomised, they undergo a 42-day screening period and review by the Independent Eligibility Committee (consisting of leaders in the field of schizophrenia). The primary efficacy (Positive and Negative Syndrome Scale, the gold standard for assessing the efficacy of antipsychotic treatments and the endpoint measure used in prior clinical studies) and safety outcomes will be assessed 12 weeks after randomisation to treatment. Topline results for both ENIGMA-TRS 1 and ENIGMA-TRS 2 are anticipated in Q426, potentially representing significant catalysts for investor attention.

Evenamide, with its novel dual mechanism of action as a voltage-gated sodium channel blocker and modulator of post-synaptic glutamate release, has already shown [promise](#) in TRS in the previous Phase II trial (study 014/015). The data showed that over 70% of patients achieved a clinically meaningful reduction in condition severity, c 50% of patients no longer met the protocol severity criteria for a diagnosis of TRS, and 25% of patients were described as achieving clinical remission (a phenomenon that, to our knowledge, has not yet been reported in the TRS patient population). In our view, these outcomes laid a robust foundation for evenamide as it enters the Phase III ENIGMA-TRS programme and, should the encouraging results translate, we believe there could be a sizeable commercial opportunity for Newron.

8 December 2025

Price	<b>CHF18.28</b>
Market cap	<b>CHF325m</b>
	€1.07/CHF
Net cash/(debt) at 30 June 2025	€(8.6)m
Shares in issue	17.8m
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.

### Analysts

Jyoti Prakash, CFA	+44 (0)20 3077 5700
Arron Aatkar, PhD	+44 (0)20 3077 5700

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

[Edison profile page](#)

---

### General disclaimer and copyright

This report has been commissioned by Newron Pharmaceuticals and prepared and issued by Edison, in consideration of a fee payable by Newron Pharmaceuticals. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

**Exclusion of Liability:** To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

**No personalised advice:** The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

**Investment in securities mentioned:** Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright 2025 Edison Investment Research Limited (Edison).

---

### Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

---

### New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

---

### United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

---

### United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

---