

Newron Pharmaceuticals

Pivotal enrolment complete; FDA review continues

Newron Pharmaceuticals has completed **ENIGMA-TRS 1 enrolment** in treatment-resistant schizophrenia (TRS), with 618 patients randomised and pivotal 12-week data expected in Q127. This removes recruitment uncertainty, although the FDA's US clinical hold on ENIGMA-TRS 2 remains unresolved. The hold concerns potential arrhythmic risk linked to evenamide's sodium channel blockade, following four deaths among treated patients across ENIGMA-TRS 1 and Phase II 014/015, versus one on placebo. However, only one was considered possibly treatment-related, and Newron reports lower exposure-adjusted mortality than placebo, alongside no consistent cardiac safety signal. Management has now proposed enhanced cardiac screening and monitoring, including genetic testing for Brugada syndrome. We view these measures as constructive, although regulatory acceptance remains critical. With Newron targeting an end-October response to the FDA and ENIGMA-TRS 2 continuing ex-US, we retain our 2029 US launch assumption and CHF20.9/share valuation.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/24	51.4	21.7	0.87	0.00	9.9	N/A
12/25	19.1	(12.1)	(0.65)	0.00	N/A	N/A
12/26e	12.6	(30.0)	(1.44)	0.00	N/A	N/A
12/27e	46.7	(3.2)	(0.15)	0.00	N/A	N/A

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

Addressing the regulatory overhang

The latest FDA feedback provides greater clarity on the continued hold, although the absence of a consistent cardiac safety signal offers some reassurance. Importantly, the agency's concerns appear to relate more to a potential mechanism-associated risk rather than a demonstrated pattern of cardiac abnormalities or arrhythmias. This suggests that the proposed enhanced patient screening and monitoring could provide a viable path towards resolving the hold, although FDA acceptance remains key. This would remove a significant regulatory overhang and dictate ENIGMA-TRS 2's ability to meet the target Q327 readout timeline.

ENIGMA TRS-1 enrolment complete; focus on data

Completing enrolment removes execution uncertainty ahead of ENIGMA-TRS 1's Q127 readout. Positive results could validate evenamide's efficacy proposition and potentially strengthen its risk-benefit profile in subsequent FDA discussions. Meanwhile, ENIGMA-TRS 2 is recruiting in Asia and Latin America, with European sites planned, providing operational flexibility against US disruption. Having said that, we acknowledge the risk related to the FDA's acceptance of a predominantly ex-US pivotal dataset and therefore view the lifting of the US clinical hold as a key de-risking milestone for evenamide.

Valuation: Maintained at CHF20.9 per share

Our previous [update](#) already factored in a conservative one-year delay to evenamide's assumed US launch, to 2029, following an NDA filing in 2028. Given these existing allowances for regulatory uncertainty, we retain our valuation of CHF444.2m or CHF20.9 per share and 70% probability of success for evenamide.

Clinical and regulatory update

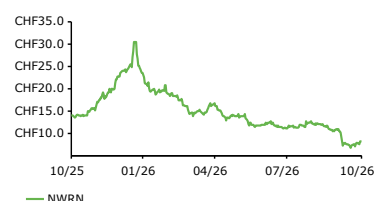
Healthcare

22 October 2026

Price CHF7.96
Market cap CHF169m

Pro forma net cash at 30 June 2026 €5.6m
Shares in issue 21.2m
Free float 95.0%
Code NWRN
Primary exchange SWX
Secondary exchange N/A

Share price performance



% 1m 3m 12m
Abs (28.0) (31.3) (43.4)
52-week high/low CHF31.9 CHF5.7

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.

Next events

FDA response October 2026
submission for
ENIGMA-TRS 2 US
hold
ENIGMA-TRS 1 12-week results Q127

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The FDA's take

Cardiac arrhythmia concerns under scrutiny

Newron's [8 October](#) announcement and subsequent investor call provided greater clarity on the FDA's concerns underpinning the continued US clinical hold on ENIGMA-TRS 2. The hold was initially imposed in April 2026 following a patient death at a non-US site. Despite a constructive Type A meeting in July and subsequent response from Newron, the FDA has decided to leave the hold in place and has requested additional risk-mitigation measures before US recruitment can resume. Importantly, management clarified that this did not reflect any newly identified cardiac abnormalities, but rather the agency's assessment that further safeguards are required.

The FDA's concerns appear to centre on a potential mechanism-associated cardiac risk associated with sodium channel blockade rather than established arrhythmogenic toxicity with evenamide. Evenamide is a first-in-class glutamate modulator acting through selective voltage-gated sodium channel blockade, differentiating it from conventional dopamine-based antipsychotics. While certain sodium channel blockers can interfere with cardiac electrical conduction and potentially trigger arrhythmias in susceptible individuals, this risk has not been demonstrated specifically for evenamide.

The agency highlighted four deaths among evenamide-treated patients across the clinical programme, versus one on placebo. Notably, none occurred in ENIGMA-TRS 2 and three were considered unrelated to treatment by investigators. The remaining death was classified as possibly related because a definitive cause could not be established. Management has highlighted the absence of common cardiac abnormalities or a consistent arrhythmic pattern across the reported cases. While crude mortality incidence was numerically higher among evenamide-treated patients (0.56% versus 0.27% for placebo), exposure-adjusted mortality favoured evenamide, at 1.31 versus 1.81 deaths per 100 patient-years, respectively. This distinction is relevant given the differences in treatment duration across the clinical programme, including long-term extension studies without an ongoing placebo comparator.

We view these exposure-adjusted data as providing useful reassurance, particularly alongside the absence of a consistent cardiac safety signal. Moreover, the available evidence does not conclusively establish a causal association between evenamide and the reported deaths. We believe that this supports Newron's rationale for pursuing targeted risk-mitigation measures rather than reassessing the broader development programme.

QTc shortening: An important mechanistic distinction

The FDA also highlighted the modest QTc shortening observed with evenamide treatment. QTc measures ventricular electrical activation and recovery, adjusted for heart rate. While marked shortening can be associated with arrhythmias in certain conditions, small drug-induced changes are not necessarily clinically significant. Management indicated that evenamide's QTc shortening was limited to a few milliseconds, with no consistent arrhythmic pattern identified across more than 10,000 ECGs from c 700 treated patients.

Importantly, QTc shortening should be distinguished from the broader risks of sodium channel blockade. Inherited cardiac conditions such as Brugada syndrome (estimated global prevalence of c 0.05%) can predispose patients to serious arrhythmias and may be exacerbated by sodium channel-blocking drugs, even when routine ECG findings appear normal. The FDA's concerns therefore extend beyond the magnitude of QTc shortening to the possibility of an underlying susceptibility in a small subset of patients. Unlike QTc prolongation, there is no universally accepted threshold below which QTc shortening can be considered free of arrhythmic risk. This creates regulatory uncertainty despite the modest ECG changes observed with evenamide.

Nevertheless, we believe the absence of a consistent cardiac safety signal, alongside the limited QTc effect, supports Newron's proposal of enhanced screening and monitoring, including genetic testing for Brugada syndrome (discussed in more detail below). Given the condition's low prevalence, we would expect limited direct implications for patient eligibility, although additional screening could increase operational complexity. While FDA acceptance remains critical, we believe these targeted measures offer a plausible route towards resolving the hold without materially disrupting the broader Phase III programme.

Proposed safeguards offer a potential way forward

During the investor call, Newron outlined additional risk-mitigation measures being developed in consultation with independent cardiac electrophysiologists. These include genetic screening for inherited sodium channel disorders (particularly Brugada syndrome), exclusion of patients with relevant personal or family cardiac histories, stricter QT interval eligibility criteria (including a proposed exclusion threshold below 360 milliseconds) and potentially more intensive ECG monitoring. The company is also considering closer monitoring of symptoms such as dizziness, fainting and palpitations in trial participants.

While genetic testing results could take four to six weeks, Newron believes this can be accommodated within ENIGMA-TRS 2's existing 42-day screening period, provided testing is initiated early. We believe this provides some operational flexibility, although these additional requirements are expected to increase costs and screening complexity (a higher number of patients required to be screened given the potentially higher patient exclusions prior to randomisation).

Newron is targeting submission of its revised response to the FDA by end-October, subject to receiving third-party specialist input (including cardiologists). A subsequent FDA response could follow within c 30 days of a complete submission, suggesting that greater regulatory clarity may emerge before year-end, including the likelihood of the hold lifting. Nevertheless, we caution that, pending the FDA decision, the timing of US recruitment resumption remains uncertain.

In parallel, Newron intends to accelerate site activation outside the US to mitigate recruitment delays. The original plan envisaged c 100 US patients, representing approximately 25% of the targeted 400-patient ENIGMA-TRS 2 population. Depending on the timing of FDA clearance, the company now considers a smaller US cohort of c 60–80 patients potentially sufficient, supported by expanded international recruitment. In the meantime, management has confirmed that ENIGMA-TRS 2 continues to recruit in Asia and Latin America

We believe that shifting part of the intended US enrolment to international centres could help offset some incremental expenditure related to the US centres, while supporting the company in meeting its Q327 working expectation for the ENIGMA-TRS 2 top-line readout. Nevertheless, it remains unclear whether the enhanced cardiac screening requirements will extend to non-US sites. If implemented more broadly, these could introduce additional recruitment complexity and potentially affect the study timeline.

Regulatory precedent offers some reassurance

Newron's previous regulatory experience, alongside recent precedents in central nervous system drug development, provides useful context for assessing the potential resolution of the current hold. Notably, safinamide (Xadago), developed by Newron for Parkinson's disease, was placed on FDA clinical hold in December 2008 following retinal safety concerns in non-human primate studies. The hold was subsequently lifted following an independent review, with safinamide ultimately receiving US approval in March 2017.

More recently, the FDA lifted clinical holds on Inhibikase Therapeutics' risvodetinib programme for Parkinson's disease in [January 2023](#), following additional safety assessments and enhanced ophthalmic monitoring, and GH Research's GH001 programme for treatment-resistant depression in [January 2026](#). These examples demonstrate that regulatory concerns can be addressed through additional evidence and targeted risk-mitigation measures, allowing clinical development to resume.

Although not subject to a clinical hold, another relevant comparator is UCB's lacosamide (Vimpat), an approved anti-seizure medication that modulates voltage-gated sodium channels. Despite recognised cardiac electrophysiological effects, including conduction abnormalities and arrhythmia risks, the FDA has considered these manageable through appropriate prescribing precautions and monitoring. Vimpat's approval provides a useful precedent for managing cardiac risks associated with sodium channel modulation should the benefit-risk profile be compelling.

Taken together, we believe these precedents offer some reassurance that Newron's proposed safeguards could provide a viable route towards resolving the hold without fundamentally altering the development programme. Nevertheless, the underlying safety concerns differ across these examples, and FDA acceptance of evenamide's proposed risk-mitigation measures remains the key variable.

Broader ENIGMA-TRS programme progressing

ENIGMA-TRS 1 approaching pivotal readout

Newron's latest update confirmed that ENIGMA-TRS 1 has completed patient enrolment, randomising 618 patients at more than 80 centres in 19 countries across Europe, Asia, Latin America and Canada. Management has reaffirmed its Q127 timeline for the pivotal 12-week readout. We view this as an important execution milestone, removing recruitment uncertainty around the study.

A total of 996 patients were screened, of which 618 (c 62%) were deemed eligible following independent assessment (including five contract research organisation psychiatrists), supporting evaluation in a rigorously defined TRS population. The randomised, double-blind, placebo-controlled Phase III study compares evenamide 15mg and 30mg twice daily with placebo as add-on therapy to second-generation antipsychotics, including clozapine. The primary efficacy endpoint was changed from baseline in Positive and Negative Syndrome Scale (PANSS) total score at 12 weeks, with further assessments at 26 and 52 weeks, to inform durability and longer-term safety.

ENIGMA-TRS 1 represents the most rigorous assessment to date of evenamide's efficacy in TRS, and we therefore view the upcoming top-line data as crucially important. A compelling efficacy result could also strengthen the overall risk-benefit proposition in discussions with regulators, particularly if supported by sustained benefits at 26 and 52 weeks.

Could international data support US approval?

An important question raised during the investor call was whether a predominantly or entirely ex-US ENIGMA-TRS dataset could support an FDA filing should the clinical hold persist. Newron highlighted regulatory precedents for US approvals based on international clinical data, suggesting that positive results from two adequately controlled Phase III studies could provide a basis for future FDA discussions. Management cited safinamide, whose larger pivotal study (Study 016) enrolled no US patients. However, we note that the second pivotal study, SETTLE, included US participants, limiting its direct comparability with an entirely ex-US development programme.

Importantly, while the FDA can accept foreign clinical data, the findings should be applicable to US patients and clinical practice. Although ENIGMA-TRS was designed with US regulatory requirements in mind, we believe the unresolved cardiac safety concerns introduce additional uncertainty around the acceptability of a predominantly or entirely ex-US registrational package. We therefore view explicit FDA agreement on this approach as important to mitigating potential regulatory risks. Although international recruitment provides Newron with an alternative pathway for completing the pivotal programme, it does not eliminate the possibility of additional evidence requirements for the US approval.

Valuation

Our valuation in our previous update note already incorporated a conservative approach to the potential implications of the FDA clinical hold, pushing our assumed US commercial launch back by one year to 2029. This reflects additional time for ENIGMA-TRS 2 recruitment, regulatory submission and review, with our model assuming a New Drug Application (NDA) filing in early 2028. We therefore maintain our valuation of CHF444.2m or CHF20.9 per share.

We believe Newron continues to have funding visibility through its key upcoming pivotal catalysts, supported by the pro forma cash position of c €43.9m at end-June 2026. We estimate that this should support operations through Q327, potentially encompassing both pivotal readouts. Management expects a further €5.5m equity tranche by 30 November 2026, which we reflect in our model as illustrative debt pending issuance. The remaining €12m (part of the €38m equity financing agreement secured in February 2026) could extend the runway towards end-2027, although it remains contingent on positive ENIGMA-TRS readouts. While additional cardiac screening costs and prolonged US recruitment delays could increase funding requirements, we believe the existing liquidity provides operational flexibility, reducing immediate financing pressure ahead of the Q127 ENIGMA-TRS 1 readout.

Exhibit 1: Newron risk-adjusted net present valuation

Product	Indication	Launch	Probability	rNPV (CHFm)	rNPV/share (CHF)
Xadago	Parkinson's disease	2015	100%	16.6	0.8
Evenamide	TRS/Schizophrenia non-responders	2029	70%	475.8	22.4
Total direct product value				492.5	23.2
Direct costs to 2035 less tax				(53.3)	(2.5)
Pro forma gross cash at end-June 2026				39.9	1.9
Loans (fair value June 2026)				(34.9)	(1.6)
Valuation				444.2	20.9

Source: Edison Investment Research. Note: Figures converted to CHF from EUR using 0.91CHF/EUR.

With ENIGMA-TRS 1 enrolment complete, we view the Q127 ENIGMA-TRS 1 readout as the most significant near-term value inflection point for Newron. Positive efficacy data would validate evenamide's differentiated mechanism and could strengthen its position in regulatory and partnering discussions.

However, FDA acceptance of the proposed cardiac risk-mitigation measures is now an equally important determinant of development visibility. A resolution of the hold would facilitate US recruitment and provide greater confidence in the regulatory pathway supporting our 2029 launch assumption.

Conversely, continued regulatory uncertainty could affect ENIGMA-TRS 2 execution, cash requirements and the timing of prospective partnering transactions. While management has indicated that current resources are expected to support operations through most of 2027, any material extension to development timelines could increase funding requirements.

For now, we believe our existing conservative assumptions provide an appropriate basis for retaining estimates and valuation, although we will reassess these as greater clarity emerges on the FDA's decision and subsequent clinical progress.

Exhibit 2: Financial summary

Accounts: IFRS; year end 31 December; €000s	2023	2024	2025	2026e	2027e
PROFIT & LOSS					
Total revenues	9,057	51,390	19,126	12,587	46,733
Cost of sales	0	0	0	0	0
Gross profit	9,057	51,390	19,126	12,587	46,733
Total operating expenses	(20,686)	(25,217)	(23,823)	(41,377)	(45,576)
Research and development expenses	(13,152)	(13,642)	(15,119)	(31,259)	(35,482)
G&A	(7,534)	(11,575)	(8,704)	(10,118)	(10,094)
EBITDA (normalised)	(11,231)	26,621	(4,313)	(28,628)	1,315
Operating income (reported)	(11,629)	26,173	(4,697)	(28,790)	1,156
Finance income/(expense)	(4,571)	(4,779)	(7,657)	(1,204)	(4,342)
Profit before tax (reported)	(16,200)	21,394	(12,354)	(29,994)	(3,186)
Profit before tax (normalised)	(16,003)	21,650	(12,142)	(29,994)	(3,186)
Income tax expense (includes exceptionals)	(24)	(5,551)	(885)	0	0
Net income (reported)	(16,224)	15,843	(13,239)	(29,994)	(3,186)
Net income (normalised)	(16,027)	16,099	(13,027)	(29,994)	(3,186)
Basic average number of shares, m	17,845	18,563	19,960	20,883	21,239
Basic EPS (€)	(0.91)	0.85	(0.66)	(1.44)	(0.15)
Adjusted EPS (€)	(0.90)	0.87	(0.65)	(1.44)	(0.15)
BALANCE SHEET					
Property, Plant and Equipment	53	43	68	108	170
Right of use assets (leases)	352	791	668	540	437
Non-current receivables (Tax credits)	5,809	1,970	1,239	1,239	1,239
Total non-current assets	6,214	2,804	1,975	1,887	1,846
Cash and equivalents	6,338	6,933	12,187	28,753	36,831
Current financial assets	6,261	2,893	16,689	0	0
Trade Accounts Receivable	7,053	51,278	9,203	6,594	6,594
Total current assets	19,652	61,104	38,079	35,347	43,425
Trade Accounts Payable	6,106	9,430	6,691	8,061	7,376
Other Current Liabilities	543	662	5,977	5,977	5,977
Short-term Debt	22,277	13,414	37,463	0	42,963
Total current liabilities	28,926	23,506	50,131	14,038	56,316
Long-term Debt	25,753	36,243	0	42,963	12,000
Leasing Obligations	210	673	583	477	386
Share based liabilities	473	1,568	0	0	0
Long-term Provisions	412	460	476	476	476
Total non-current liabilities	26,848	38,944	1,059	43,916	12,862
Equity attributable to company	(29,908)	1,458	(11,135)	(20,719)	(23,905)
CASH FLOW STATEMENT					
Pre-tax profit	(16,200)	21,394	(12,354)	(29,994)	(3,186)
Net Financial Income	(1,162)	(1,847)	(2,754)	64	53
Tax	0	0	0	0	0
Depreciation and amortisation	201	192	172	162	158
Share-based payments	197	256	212	0	0
Other adjustments	5,311	144	7,449	0	0
Movements in working capital	1,513	(37,753)	39,624	3,979	(685)
Cash from operations (CFO)	(10,140)	(17,614)	32,349	(25,789)	(3,660)
Capex	(11)	(13)	(47)	(74)	(118)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	3,257	3,171	(13,617)	16,689	0
Cash used in investing activities (CFIA)	3,246	3,158	(13,664)	16,615	(118)
Loans received	0	0	0	5,500	12,000
Loan repayments	0	0	(13,584)	0	0
Equity issued	0	15,244	350	20,410	0
Other Financing Cash Flows (leases)	(192)	(193)	(197)	(170)	(144)
Cash from financing activities (CFF)	(192)	15,051	(13,431)	25,740	11,856
Cash and equivalents at beginning of period	13,424	6,338	6,933	12,187	28,753
Increase/(decrease) in cash and equivalents	(7,086)	595	5,254	16,566	8,079
Effect of FX on cash and equivalents	0	0	0	0	0
Cash and equivalents at end of period	6,338	6,933	12,187	28,753	36,831
Net (debt)/cash (including liquid resources)	(35,431)	(39,831)	(8,587)	(14,210)	(18,132)

Source: Company documents, Edison Investment Research

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