

Newron Pharmaceuticals

H125 results

H125 results reflect evenamide progress

H125 saw Newron Pharmaceuticals make significant clinical headway with lead asset evenamide, culminating in the initiation of the first Phase III study, ENIGMA-TRS 1 (international study excluding the US; n=600), by period end. As of August, the first patients have been enroled (following a 42-day screening period) and the 12-week results are expected in Q426. The second study, ENIGMA-TRS 2 (international study including the US; n=400), is set to begin in October, the outcome of which will be key for US regulatory registration. Partner progress in Japan (with EA Pharma) triggered a milestone payment, which, together with the upfront consideration from Myung In Pharm (South Korea), lifted H125 licensing revenue to €7.8m (nil in H124). We expect period-end cash and equivalents of €43.2m to provide a runway into Q226 (accounting for debt repayments). Our valuation upgrades modestly to CHF407.8m or CHF20.4 per share (from CHF392.4m or CHF19.7 per share previously).

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	11.8	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.

Registrational trial underway, backed by partners

With ENIGMA-TRS 1 advancing as planned and ENIGMA-TRS 2 expected to initiate in the near term, we anticipate that Newron's operational priorities through H225 and CY26 will centre on sustaining patient recruitment and ensuring smooth trial execution. Given the randomised study design, we do not anticipate interim efficacy disclosures and expect the next key clinical inflection point will be the 12-week data readout in Q426. We believe that the positive data from the previous studies (014/015 and 008A) and regional licensing deals with EA Pharma (a subsidiary of Eisai) in Japan and Myung In Pharm in South Korea lend external validation and partially de-risk the registrational pathway. We also see scope for further regional licensing partnerships, although the US commercial rights will likely be retained, given the sizeable market opportunity.

Cash runway into Q226

Supported by partner funding (including €42m from EA Pharma in January 2025), Newron closed H125 with gross cash and equivalents of €43.2m. Based on our projections for R&D and other costs, we estimate these funds will provide a cash runway into Q226 after accounting for scheduled debt repayments to the European Investment Bank (EIB). A renegotiation of repayment terms (which we believe is likely) could extend the runway into Q426.

Valuation: CHF407.8m or CHF20.4 per share

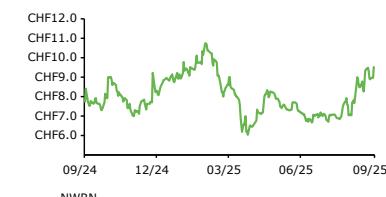
We make only minor adjustments to our estimates following the [H125 results](#). Incorporating the latest net debt position and benefits from a model roll-forward, our valuation upgrades slightly to CHF407.8m or CHF20.4 per share (from CHF392.4m or CHF19.7 per share previously).

Healthcare

18 September 2025

Price	CHF9.51
Market cap	CHF190m
	€1.07/CHF
Net cash/(debt) at 30 June 2025	€(8.6)m
Shares in issue	20.0m
Free float	95.0%
Code	NWRN
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	27.7	24.3	8.2
52-week high/low	CHF11.0	CHF5.2	

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

ENIGMA-TRS 2 launch	October 2025
ENIGMA-TRS 1 12-week results	Q426

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CNS pipeline led by evenamide programme in TRS

Newron Pharmaceuticals, based in Bresso (Italy) and listed on the SIX Swiss Exchange, has a clinical focus on conditions of the central nervous system (CNS) (Exhibit 1). The company's top strategic priority is evenamide, its proprietary small molecule drug candidate with a dual mechanism of action as a voltage-gated sodium channel inhibitor and modulator of post-synaptic glutamate release. [Research](#) has demonstrated that this mechanism has the potential to ameliorate schizophrenia-related dysfunction (addressing positive, cognitive and negative symptoms), showcasing its promise. It is primarily being developed for treatment-resistant schizophrenia (TRS), a sub-population of schizophrenia (c 30% prevalence) characterised as schizophrenia that does not respond to two or more medications, each with at least six weeks of treatment duration. We discuss this lead programme in further detail below.

Beyond evenamide, Newron has demonstrated its ability to bring a CNS drug to the market with its product for Parkinson's disease, Xadago (generic name: safinamide). Xadago has been approved in over 20 countries (including the US, the UK, the EU, Switzerland and Japan), with commercial support from partners Zambon Pharma, Supernus Pharmaceuticals and Meiji Seika Pharma, generating a steady revenue stream for Newron. For example, Xadago royalties from Zambon amounted to €3.8m in H125, representing an 11% increase from the prior period. We note that Xadago is approaching the end of its market exclusivity period (in place until at least 1 December 2027). Hence, the strategic focus for Newron lies firmly with evenamide, a candidate with blockbuster potential, should the data from the ENIGMA-TRS programme further strengthen the already robust data package from prior clinical studies.

Exhibit 1: Newron's product pipeline

Product		Phase I	Phase II	Phase III	Market	Commercial Rights
Xadago® (safinamide)	Adjunctive therapy in Parkinson's disease (PD)				Zambon	
					Zambon/Supernus (USA)	
					Meiji Seika/Eisai (Asia)	
Evenamide (NW-3509)	Adjunctive therapy in Schizophrenia				Newron	
	Adjunctive therapy in TRS*				EAP (a subsidiary of Eisai) (Japan/Asia)	
Raloxifene	Orphan indication in neuropathic pain				Newron	

*Treatment-Resistant Schizophrenia

Source: Newron Pharmaceuticals H125 report

Full speed ahead with the ENIGMA-TRS programme

Plans for Newron's registrational Phase III ENIGMA-TRS programme were [unveiled](#) in May 2025. As part of this update, it was announced that the programme will comprise two studies that will run in parallel. Together, ENIGMA-TRS 1 and ENIGMA-TRS 2 will investigate evenamide as an add-on therapy to current antipsychotics (including clozapine, the only FDA-approved drug for TRS) and, should the data be supportive, form the basis of the submission for regulatory approval in major geographies such as the US, Europe and key countries in Asia. It was determined that the primary endpoint measure will be the Positive and Negative Syndrome Scale (PANSS) total change from baseline, and we highlight that this is considered the gold standard for assessing the efficacy of antipsychotic treatments. This efficacy measure was utilised in the preceding Phase II trial (study 014/015) and, encouragingly, statistically significant benefits were observed following evenamide treatment. For a more detailed overview of the positive clinical data that make up the current data package for evenamide, as well as additional discussion around the current unmet needs in the schizophrenia space that Newron is looking to address with evenamide, we direct readers to our July 2025 [outlook note](#).

ENIGMA-TRS 1 (Exhibit 2) is a 52-week, randomised, double-blinded, placebo-controlled Phase III trial. It is assessing the efficacy, safety and tolerability of evenamide at 15mg and 30mg twice-daily doses (both of which were tested in study 014/015) compared to placebo. It will involve c 600 patients across study centres in Europe, Asia, Latin America and Canada, and, as of August 2025, it was [confirmed](#) that enrolment was underway. The results at 12 weeks post-randomisation are expected to be announced in Q426, representing a major upcoming potential catalyst for Newron. The trial will then continue in a double-blinded and placebo-controlled setting up to the one-year point, providing additional data on the durability of the treatment. We estimate total trial costs of c €45m, with funding support from EA Pharma in Japan and Myung In Pharm in South Korea. We note that under the terms of its agreement, Myung In Pharm will contribute 10% of the total patient population (c 60 patients) to be enroled in ENIGMA-TRS 1, and it will cover the costs related to this population. For this trial, patients will undergo a 42-day screening period, during which their TRS diagnosis, antipsychotic plasma levels and conformance to protocol selection criteria will be assessed by an independent eligibility assessment committee (IEAC) of three leading international schizophrenia experts.

ENIGMA-TRS 2 (Exhibit 3) has been designed as a 12-week, randomised, double-blinded, placebo-controlled Phase III trial, evaluating evenamide at a 15mg dose in c 400 patients, compared to placebo. This will be an international study, undertaken at centres in the US, and selected additional countries. Enrolment is on track to start in October 2025, and endpoint analysis will be conducted at 12 weeks. Given the shorter duration and lower number of participants, we estimate trial costs of c €25m. In ENIGMA-TRS 2, patients will also be evaluated by the IEAC. We expect Newron to seek additional regional licensing deals for evenamide, in line with its commercial strategy (likely either in Europe, Latin America, China and/or India), with the related inflows, if realised, providing further capital to support the two trials.

Exhibit 2: ENIGMA-TRS 1 study design

ICF	Baseline Day 0 Eligibility Randomization	12-week	26-week	52-week
<p>Screening – 42 days</p> <p>Confirmation of treatment resistance TRRIP criteria*</p> <p>Eligibility (IEAC#) AP plasma levels x 3</p> <p>≥ 900 patients</p>	<p>PIVOTAL STUDY ENDPOINT</p> <p>Primary Efficacy Endpoint</p> <p>PANSS Total change from baseline</p> <p>Key secondary Endpoint</p> <p>CGI-S: Change from Baseline</p>	<p>MAINTENANCE ENDPOINT</p> <p>Second (long-term) Efficacy Endpoint</p> <p>PANSS total change from baseline (Maintenance of efficacy)</p> <p>No re-randomization</p>	<p>LONG-TERM EFFICACY</p> <p>Third (1-year) Efficacy Endpoint</p> <p>PANSS total change from baseline (Long-Term efficacy)</p> <p>No re-randomization</p>	<p>Double-blind treatment of 52 weeks</p> <p>≥ 600 patients randomized to: Evenamide OR Placebo 200 (15 mg bid) : 200 (30 mg bid) : 200 (placebo)</p>

Source: Company resources

Exhibit 3: ENIGMA-TRS 2 study design

ICF	Baseline Day 0 Eligibility Randomization	12-week
<p>Screening – 42 days</p> <p>Confirmation of treatment resistance TRRIP criteria*</p> <p>Eligibility (IEAC#) AP plasma levels x 3</p> <p>≥ 400 patients</p>	<p>PIVOTAL STUDY ENDPOINT</p> <p>Primary Efficacy Endpoint</p> <p>PANSS Total change from baseline</p> <p>Key secondary Endpoint</p> <p>CGI-S: Change from Baseline</p>	<p>Treatment of 12 weeks</p> <p>≥ 400 patients randomized 1:1 to: 200 (15 mg bid) : 200 (placebo)</p>

Source: Company resources

Financials

Licensing income from partners supports top-line growth

H125 was an active period for Newron. The company reported total revenues of €11.9m, up c 250% from €3.4m in H124. This difference was primarily driven by €7.8m in licensing income recognised in H125 in the form of the first development milestone payment from EA Pharma and upfront payment from Myung In Pharm (related to the licensing deal signed in January 2025 for South Korea). In addition, the company reported royalty income of €3.8m (+10.9% y-o-y) from its marketed product, Xadago (targeting Parkinson's disease), and another €0.3m in other contractual income (nil in H124). Total operating expenses stayed broadly flat at €10.6m (€11.1m in H124), with R&D expenses contributing c 58%. R&D expenses in H125 were €6.1m, down 5.8% y-o-y from €6.5m in H124. This was attributed to lower clinical-related activities for the majority of H125 relative to H124 (which included the Phase II/III study 008A). With the initiation of ENIGMA-TRS 1 towards the end of the period, and with ENIGMA-TRS 2 set to initiate in October, we expect a material rise in R&D expenses in H225 and FY26. SG&A expenses in H125 were €4.4m, compared to €4.6m in H124, with the decline primarily attributed to lower expenses related to intellectual properties, offsetting the slight increase in staff costs. Overall, the company reported an operating profit of €1.3m in H125 versus an operating loss of €7.7m in H124. Net loss for the period was materially lower at €0.07m, from a loss of €9.6m in H124. This included €2.2m in interest expenses related to the €40m EIB loan (current outstanding loan of €51.8m, including accrued interest payable at expiry). Reflecting the operating performance and the €42m in upfront payment from EA Pharma received in January 2025, Newron reported operating cash inflows of €33.4m in H125 versus an outflow of €8.8m in H124. We note that the contractual milestone invoiced to EA Pharma in Q225 has been cash in Q325, which should reflect in lower receivables in H225.

Estimates revision

Based on the H125 results and trends, we make certain adjustments to our FY25 and FY26 forecasts. We raise our FY25 revenue estimate to €15.2m from €7.3m previously, reflecting the €7.8m licensing income recognised in H125. We also pare our R&D estimates for FY25 to €21.3m from €27.7m, shifting some of our R&D expectations to FY26 (€36.3m versus €29.9m previously). This is based on the increased clarity of the timelines for the second Phase III trial, ENIGMA-TRS 2. We also modestly trim our G&A estimates to reflect the H125 trend (FY25: €10.9m versus €11.6m previously; FY26: €11.0m versus €11.7m previously). Overall, we now project operating losses of €17.1m in FY25 (€32.1m previously) and €39.7m in FY26 (€34.0m previously).

Funded into Q226

Newron closed H125 with a gross cash position of €26.6m and another €16.6m in other current financial and liquid assets (including bonds and investment funds), supported by the upfront payment from EA Pharma received in early 2025. The company also has €51.8m of debt on its books, consisting of the €40m loan from the EIB as well as accrued interest. The first €10m tranche is due in November 2025, with the other four tranches (€7.5m each) maturing in 2026 (tranche 2 – April 2026, tranche 3 – June 2026 and tranches 3 & 4 – September 2026). Based on cash at the end of the period, the debt repayment schedule and our burn projections, we estimate the company to be funded into Q226. Should Newron be successful in restructuring the debt repayment terms with the EIB (we see this as highly likely), the cash runway would extend through 2026. In the absence of a debt renegotiation, we estimate the company needs to raise €55m in 2026 to service the EIB loan and to fund the Phase III studies. We reflect this additional capital as illustrative debt in our model. We note that these estimates do not reflect any additional non-dilutive funding from other potential regional licensing deals for evenamide, which would impact our runway projections.

Valuation

We recently presented our revised estimates for evenamide and our refreshed valuation for Newron in an [outlook](#) note. Following the H125 results, our long-term underlying assumptions are unchanged. Incorporating the latest net debt (€8.6m/ CHF8.2m) and model roll-forward, our valuation adjusts slightly to CHF407.8m or CHF20.4 per share (from CHF392.4m or CHF19.7 per share previously). A breakdown of our risk-adjusted net present value (rNPV) valuation for Newron is presented in Exhibit 4.

Exhibit 4: Newron rNPV valuation

Product	Indication	Launch	Probability	rNPV (CHFm)	rNPV/share (CHF)
Xadago	Parkinson's disease	2015	100%	22.8	1.1
Evenamide	TRS/Schizophrenia non-responders	2028	70%	451.4	22.6
Total direct product value				474.2	23.8
Direct costs to 2034 less tax				(58.2)	(2.9)
Gross cash at end-June 2025				41.0	2.1
Loans (fair value June 2025)				(49.2)	(2.5)
Valuation				407.8	20.4

Source: Edison Investment Research. Note: Per-share value is based on 19.96m shares outstanding.

As noted above, we estimate Newron will need to raise €55m in 2026 with non-dilutive inflows from a European licensing deal in FY27. If we were to assume no further licensing deals and self-commercialisation in Europe and the US, we estimate the company would need to raise an additional €25m in 2027 before achieving profitability in 2028. Should this requirement (€80m across FY26 and FY27) be fulfilled by issuing equity, we calculate the company would need to issue 8.0m shares (at the current trading price of CHF9.51), resulting in the per-share valuation diluting to CHF17.3, from CHF20.4 currently (shares outstanding would increase to 28.0m from 20.0 currently).

Exhibit 5: Financial summary

Accounts: IFRS; year end 31 December; €000s	2022	2023	2024	2025e	2026e
PROFIT & LOSS					
Total revenues	6,094	9,057	51,390	15,202	7,778
Cost of sales	0	0	0	0	0
Gross profit	6,094	9,057	51,390	15,202	7,778
Total operating expenses	(19,396)	(20,686)	(25,217)	(32,337)	(47,469)
Research and development expenses	(12,005)	(13,152)	(13,642)	(21,323)	(36,340)
G&A	(7,391)	(7,534)	(11,575)	(11,014)	(11,129)
EBITDA (normalised)	(12,620)	(11,231)	26,621	(16,740)	(39,469)
Operating income (reported)	(13,302)	(11,629)	26,173	(17,136)	(39,690)
Finance income/(expense)	(4,170)	(4,571)	(4,779)	(3,467)	(4,960)
Profit before tax (reported)	(17,472)	(16,200)	21,394	(20,603)	(44,650)
Profit before tax (normalised)	(16,992)	(16,003)	21,650	(20,603)	(44,650)
Income tax expense (includes exceptional)	(21)	(24)	(5,551)	0	0
Net income (reported)	(17,493)	(16,224)	15,843	(20,603)	(44,650)
Net income (normalised)	(17,013)	(16,027)	16,099	(20,603)	(44,650)
Basic average number of shares, m	17,845	17,845	18,563	19,960	19,960
Basic EPS (€)	(0.98)	(0.91)	0.85	(1.03)	(2.24)
Adjusted EPS (€)	(0.95)	(0.90)	0.87	(1.03)	(2.24)
BALANCE SHEET					
Property, Plant and Equipment	72	53	43	54	69
Right of use assets (leases)	455	352	791	413	216
Non-current receivables (Tax credits)	8,175	5,809	1,970	96	96
Total non-current assets	8,702	6,214	2,804	564	381
Cash and equivalents	13,424	6,338	6,933	6,425	3,358
Current financial assets	9,350	6,261	2,893	16,556	0
Trade Accounts Receivable	5,719	7,053	51,278	9,278	9,278
Total current assets	28,493	19,652	61,104	32,259	12,636
Trade Accounts Payable	4,869	6,106	9,430	9,322	9,376
Other Current Liabilities	172	543	662	662	662
Short-term Debt	0	22,277	13,414	33,414	3,414
Total current liabilities	5,041	28,926	23,506	43,398	13,452
Long-term Debt	45,165	25,753	36,243	6,243	61,243
Leasing Obligations	325	210	673	300	89
Share based liabilities	220	473	1,568	1,568	1,568
Long-term Provisions	474	412	460	460	460
Total non-current liabilities	46,184	26,848	38,944	8,571	63,360
Equity attributable to company	(14,030)	(29,908)	1,458	(19,145)	(63,795)
CASH FLOW STATEMENT					
Pre-tax profit	(17,472)	(16,200)	21,394	(20,603)	(44,650)
Net Financial Income	(1,183)	(1,162)	(1,847)	34	10
Tax	0	0	0	0	0
Depreciation and amortisation	202	201	192	396	221
Share-based payments	480	197	256	0	0
Other adjustments	4,996	5,311	144	1,874	0
Movements in working capital	1,885	1,513	(37,753)	41,892	54
Cash from operations (CFO)	(11,092)	(10,140)	(17,614)	23,592	(44,366)
Capex	(18)	(11)	(13)	(30)	(38)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	(299)	3,257	3,171	(13,663)	16,556
Cash used in investing activities (CFIA)	(317)	3,246	3,158	(13,693)	16,518
Loans received	0	0	0	0	55,000
Loan repayments	0	0	0	(10,000)	(30,000)
Equity issued	0	0	15,244	0	0
Other Financing Cash Flows (leases)	(186)	(192)	(193)	(407)	(220)
Cash from financing activities (CFF)	(186)	(192)	15,051	(10,407)	24,780
Cash and equivalents at beginning of period	25,019	13,424	6,338	6,933	6,425
Increase/(decrease) in cash and equivalents	(11,595)	(7,086)	595	(508)	(3,067)
Effect of FX on cash and equivalents	0	0	0	0	0
Cash and equivalents at end of period	13,424	6,338	6,933	6,425	3,358
Net (debt)/cash (including liquid resources)	(22,391)	(35,431)	(39,831)	(16,676)	(61,299)

Source: Company documents, Edison Investment Research

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