Newron Pharmaceuticals

H126 results

H126 results: Evenamide pivotal readout nears

Healthcare

23 September 2026

Newron Pharmaceuticals has reported its H126 results as lead asset evenamide approaches its first pivotal Phase III readout in treatment-resistant schizophrenia (TRS). The ENIGMA-TRS programme continues to make progress, with screening intake for ENIGMA-TRS 1 now closed after 996 patients entered the process, and target enrolment of at least 600 patients is expected around mid-October. Newron continues to guide to Q127 for the primary 12-week ENIGMA-TRS 1 efficacy readout, and expects topline results from both studies during 2027. For ENIGMA-TRS 2, recruitment remains ongoing outside the US and, following its constructive Type A meeting with the FDA in July, Newron expects US enrolment to resume in the near term, subject to FDA clearance. Following the H126 results, our valuation updates to CHF444.2m or CHF20.9 per share (from CHF431.6m or CHF20.8 per share previously).

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/24	51.4	21.7	0.87	0.00	13.7	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.

All eyes on the first pivotal readout in Q127

Evenamide is Newron's principal value driver, being developed as an add-on to existing antipsychotics. Its glutamatergic mechanism is differentiated from conventional dopamine-based approaches, while prior studies provide a robust foundation across both TRS and poorly responding schizophrenia. Regional partnerships provide further external validation, with Newron recently receiving a €5.5m milestone from EA Pharma. Importantly, ENIGMA-TRS 1 represents the first large placebo-controlled test of evenamide in the intended TRS population.

Current funding may cover both pivotal readouts

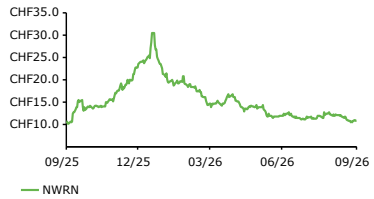
Newron reported H126 revenues of €3.2m, versus €11.9m in H125, with the prior period benefiting from licensing income, while R&D expenses increased to €14.6m from €6.1m as the ENIGMA-TRS programme advanced. The company ended June with €32.9m in cash and other current financial assets, subsequently strengthened by c €11m from the second equity financing tranche and a further EA Pharma milestone. Another €5.5m financing tranche is expected by end-November. Management expects available resources to fund operations through most of 2027, potentially beyond the 12-week readouts from both pivotal studies.

Valuation: CHF444.2m or CHF20.9 per share

With the revised timeline for ENIGMA-TRS 1 and our assumptions on the resolution of the ENIGMA-TRS 2 US hold, we conservatively push out evenamide's launch by one year to 2029, though acknowledge that 2028 is still feasible and would represent upside to our current case. We retain a 70% probability of success and extend patent protection to 2044 in line with recent developments. With this and the updated pro forma net cash position, our valuation moves to CHF444.2m or CHF20.9/share, from CHF431.6m or CHF20.8/share.

Price	**CHF11.14**
Market cap	**CHF237m**
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	(9.3)	(9.3)	6.3
52-week high/low		CHF31.9	CHF9.8

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 1 target enrolment completion	October 2026
ENIGMA-TRS 1 12-week results	Q127

Analysts

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

healthcare@edisongroup.com
Edison profile page

Newron Pharmaceuticals is a research client of Edison Investment Research Limited

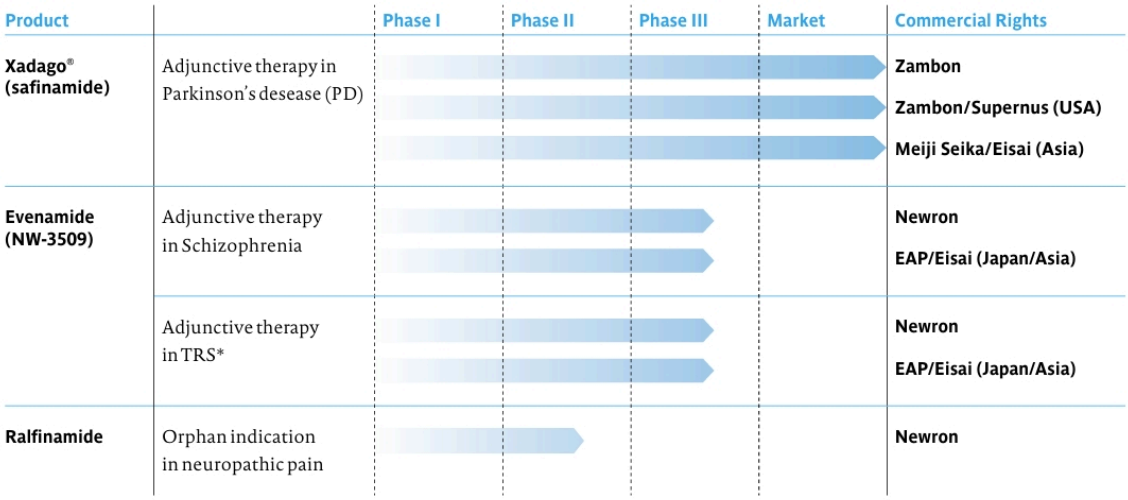
CNS pipeline led by evenamide in schizophrenia

Proven CNS development capabilities

Newron Pharmaceuticals is a biopharmaceutical company headquartered in Bresso, near Milan, listed on the SIX Swiss Exchange, focused on conditions of the central nervous system (CNS) (Exhibit 1). While the company's current strategic focus is firmly on evenamide, its operating track record is supported by Xadago (safinamide), a treatment for Parkinson's disease that Newron progressed from development, through regulatory approval, and into commercialisation across multiple major markets. Xadago is approved in more than 20 regions, including the US, the UK, the EU, Switzerland and Japan, and is commercialised through regional partners including Zambon, Supernus Pharmaceuticals and Meiji Seika Pharma. This commercial experience provides useful evidence of Newron's ability to advance a CNS asset through late-stage development and regulatory review, while also establishing partnerships capable of supporting international commercialisation. Xadago continues to provide a recurring source of royalty income, with royalties of €3.1m recognised in H126, compared with €3.8m in H125. The product is currently protected from generic competition in the US until at least December 2027, supporting a continued revenue contribution in the near term.

However, the strategic priority for Newron is evenamide in TRS, which represents the principal clinical and valuation driver.

Exhibit 1: Newron's product pipeline



Source: Newron Pharmaceuticals H126 report

We note that the third candidate in Newron's clinical pipeline, ralfinamide, has been de-prioritised over the past few years while management focuses on the lead schizophrenia programme.

A differentiated approach to schizophrenia

Evenamide is a first-in-class glutamate modulator being developed as an add-on therapy for schizophrenia patients. Its mechanism is differentiated from conventional schizophrenia treatments, which predominantly act through dopamine signalling. Evenamide selectively modulates voltage-gated sodium channels and excessive glutamate release, with the aim of normalising abnormal neuronal activity while preserving normal neuronal function. The mechanistic rationale centres on the hippocampus, a key region of the brain implicated in schizophrenia pathology. Newron's preclinical work suggests that excessive hippocampal activity may contribute to downstream disruption of dopamine signalling, which in turn is associated with the positive, negative and cognitive symptoms of the condition. By acting further upstream on glutamatergic signalling, evenamide is designed to address this abnormal neuronal activity through a pathway distinct from currently available dopamine-based antipsychotics.

Importantly, evenamide is being developed as an adjunct to existing antipsychotic regimens, rather than as a replacement therapy. This approach could support broad applicability across commonly used treatments and reduce

the disruption associated with switching therapies. Prior clinical work has included patients receiving several standard antipsychotics, including clozapine (the only therapy specifically approved for TRS, though its use has safety and monitoring limitations), supporting the rationale for use alongside established treatment options.

Partnerships provide external validation

Newron has secured regional partnerships for evenamide that provide both commercial validation and financial support for evenamide's global development programme. In December 2024, the company entered into a licensing agreement with EA Pharma, a subsidiary of Eisai, covering the development, manufacture and commercialisation of evenamide in Japan and selected Asian territories. The agreement is worth up to €117m in upfront and milestone payments, alongside tiered royalties of up to a double-digit percentage of net sales. EA Pharma is also responsible for the separate Japanese Phase III programme, which commenced in January 2026, supporting the regulatory pathway in an important schizophrenia market. Newron received a further €5.5m milestone payment from EA Pharma in September 2026, reflecting continued progress with the evenamide development programme in this region, under the existing agreement.

Newron added a second regional partner in January 2025 through its agreement with Myung In Pharm for South Korea. Under the terms of the deal, Myung In Pharm is contributing around 10% of the total ENIGMA-TRS 1 patient population and covering the associated study costs in South Korea, reducing Newron's direct funding burden for the pivotal programme.

We view these agreements as a useful external validation of evenamide's clinical and commercial potential, while broadening the programme's geographic reach and supporting Phase III execution. Newron continues to explore additional development and commercial opportunities for evenamide. Management has indicated that several expressions of interest have been received, with potential transactions being assessed according to their ability to maximise shareholder value.

Intellectual property

Evenamide is supported by an expanding intellectual property portfolio, with existing US composition-of-matter protection to 2035 and process patent protection extending to 2042. Newron was granted a patent providing composition-of-matter protection with exclusivity to 2044 by the European Patent Office in January 2026, and has indicated that equivalent claims have been filed across major markets and remain under review. If maintained through commercialisation, this should provide a lengthy exclusivity runway relative to the anticipated development and launch timeline.

ENIGMA-TRS programme approaches its first pivotal readout

ENIGMA-TRS 1: Screening complete, randomisation nearing completion

ENIGMA-TRS 1 is the lead study in Newron's global registrational programme for evenamide and is designed as a 52-week, prospective, randomised, double-blind, placebo-controlled Phase III trial in at least 600 patients with documented TRS (Exhibit 2). Participants are randomised across three arms, with approximately 200 patients receiving evenamide 15mg twice daily, 200 receiving 30mg twice daily and 200 receiving placebo, in all cases as an add-on to existing antipsychotic therapy. Background treatment may include clozapine, supporting evaluation of evenamide across a broad range of current standard-of-care regimens.

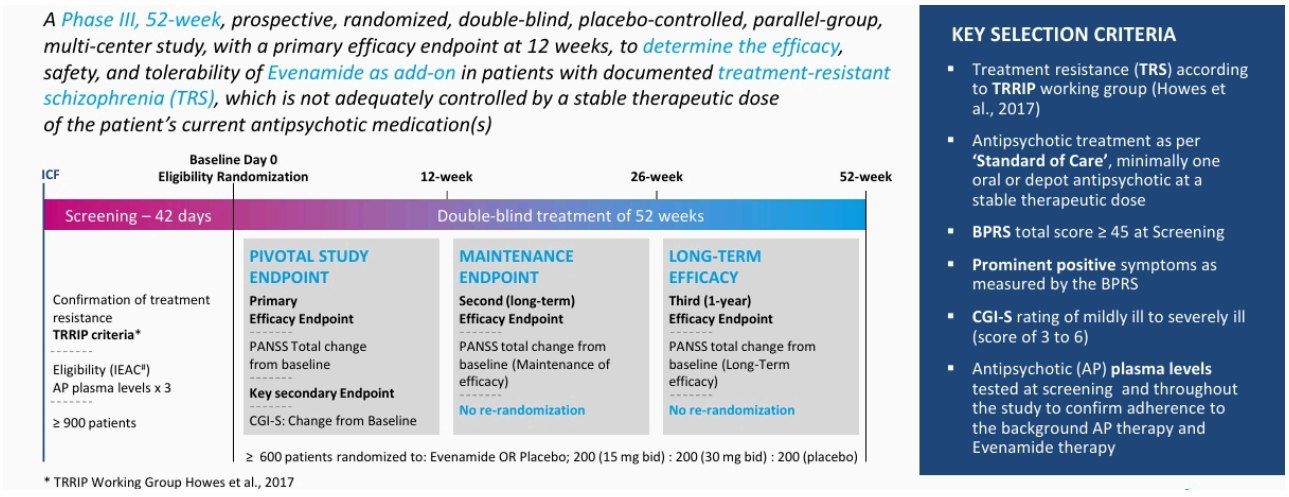
A notable feature of the study is its rigorous 42-day screening process, which is intended to confirm that patients meet accepted criteria for treatment-resistant schizophrenia and are adherent to their existing antipsychotic treatment. This includes independent eligibility assessment and repeated plasma-level testing of background antipsychotics. In our view, this should strengthen the interpretability of the eventual efficacy dataset by reducing the risk that apparent treatment resistance reflects misclassification or poor adherence rather than underlying disease. It also helps explain why the number of patients screened is materially higher than the final randomised population.

The primary efficacy assessment takes place at week 12 and measures change from baseline in Positive and Negative Syndrome Scale (PANSS) total score, with change in Clinical Global Impression – Severity (CGI-S) as the key secondary endpoint. Patients then continue on their originally assigned treatment without re-randomisation, allowing maintenance and longer-term efficacy to be assessed at weeks 26 and 52, respectively.

Operationally, screening intake for ENIGMA-TRS 1 has now closed. Newron reported in early September 2026 that 996

patients had entered the process, with 411 already randomised and 352 still progressing through screening at that time. Based on observed eligibility rates, management has reiterated that it expects the study to exceed its 600-patient target, with the final patient currently anticipated to be randomised by mid-October 2026. The primary 12-week readout remains guided for Q127 and, in our view, represents the most important near-term clinical inflection point for the evenamide programme.

Exhibit 2: Design of the ENIGMA-TRS 1 study and key efficacy assessments

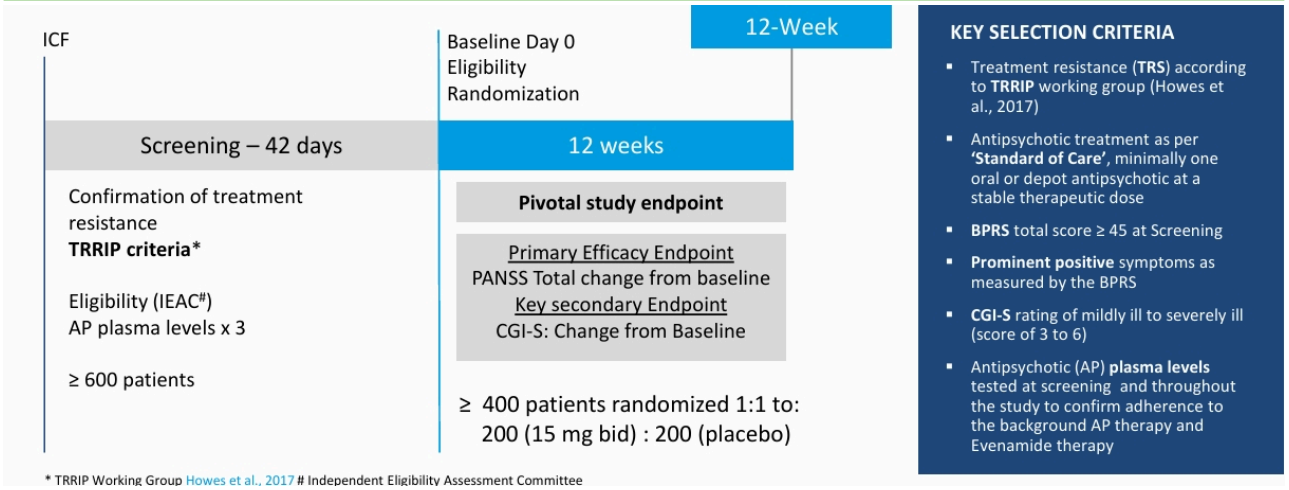


Source: Newron Pharmaceuticals corporate presentation (September 2026)

ENIGMA-TRS 2: US enrolment expected to resume in the near term

ENIGMA-TRS 2 is the second pivotal study in Newron's registrational programme and is designed to complement the longer ENIGMA-TRS 1 trial with a separate 12-week efficacy dataset. The study is expected to randomise at least 400 patients with TRS on a 1:1 basis to receive either evenamide 15mg twice daily or placebo, in addition to their existing antipsychotic treatment (Exhibit 3). As with ENIGMA-TRS 1, the trial incorporates a 42-day screening period to confirm treatment resistance, eligibility and adherence to background therapy before randomisation.

Exhibit 3: ENIGMA-TRS 2 design



Source: Newron Pharmaceuticals corporate presentation (September 2026)

The FDA had previously authorised the study, which was initiated in the US in December 2025. However, enrolment at five US centres was paused in April 2026 following the sudden death of a participant at a non-US site. Importantly, the investigator assessed the event as unrelated to evenamide, while the independent safety monitoring board reviewed the case and recommended that the broader ENIGMA-TRS programme continue as designed. Recruitment continued at sites outside the US, including in Asia and Latin America.

Newron held a Type A meeting with the FDA in July, with discussions focused on the information already submitted and the changes required before US recruitment could resume. The company is now implementing the proposed changes discussed with the agency and expects enrolment at US sites to restart following FDA clearance. Management

has communicated that it expects this to occur in the near future, while recruitment at sites outside the US remains unaffected. Newron now expects topline results from both ENIGMA-TRS studies during 2027, although it has not provided more precise timing for the ENIGMA-TRS 2 readout.

Dual pivotal studies designed to support major-market filings

ENIGMA-TRS 1 and ENIGMA-TRS 2 have been designed to provide complementary datasets for the evenamide registrational package. ENIGMA-TRS 1 is the larger and longer study, evaluating both the 15mg and 30mg twice-daily doses and providing efficacy, durability and safety data through 52 weeks. ENIGMA-TRS 2 provides a separate 12-week placebo-controlled assessment of the 15mg dose in at least 400 patients, including US sites. Both studies use PANSS total change from baseline as the primary efficacy endpoint and employ closely aligned screening criteria. Together, the two trials are intended to support regulatory submissions in major markets, while providing independent evidence of efficacy in a well-defined TRS population.

Clinical evidence supports the Phase III rationale

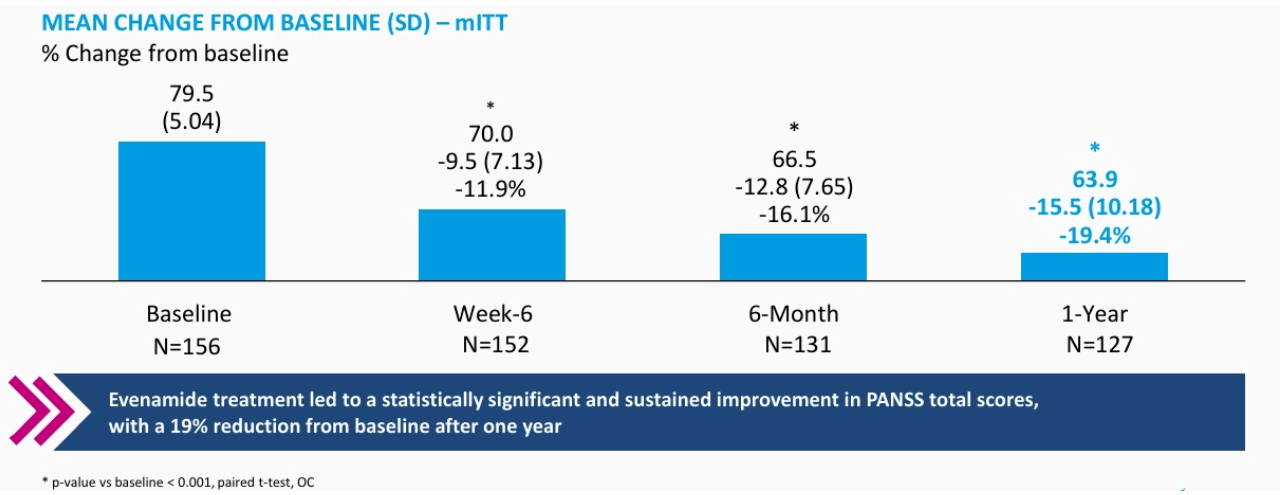
Recap: Sustained benefit observed in TRS

Study 014/015 provides the most relevant longer-term clinical evidence for evenamide in TRS. Study 014 was a pilot, randomised, open-label, rater-blinded trial in TRS patients, with participants able to continue into the extension study (015), for treatment of up to one year.

The results showed that efficacy improved progressively over time. Mean PANSS total score declined from 79.5 at baseline to 63.9 at one year, corresponding to a 15.5 point, or 19.4%, reduction (Exhibit 4). Furthermore, the proportion of patients achieving at least a 20% improvement in PANSS increased from 15.4% at week six to 41.8% at one year (Exhibit 5). Encouragingly, approximately half of patients no longer met the protocol severity criteria for a diagnosis of treatment-resistance after 12 months of treatment with evenamide by the end of the study. In addition, approximately a quarter of the participants were described as achieving remission, which we highlight is a phenomenon that has not yet been reported in TRS, to our knowledge, serving as a promising indication of evenamide's effectiveness in this setting.

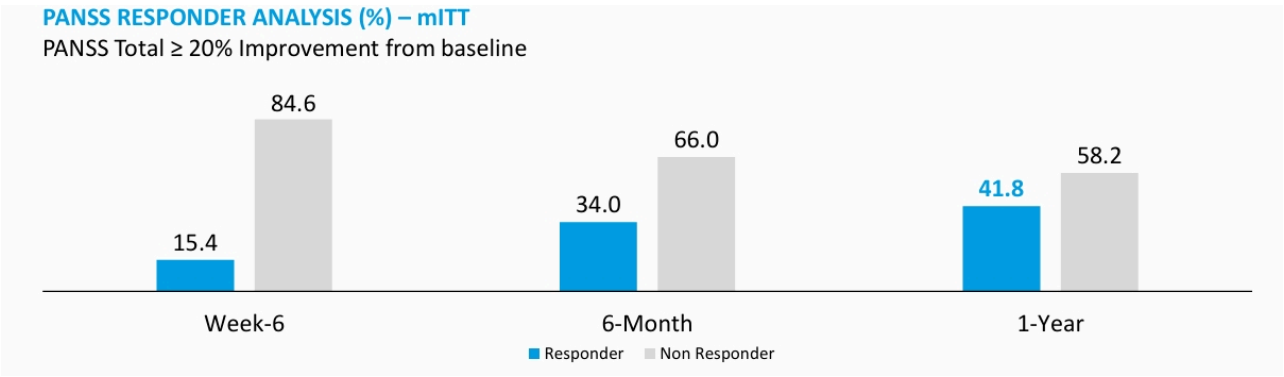
These findings are encouraging, in our view, particularly given the progressive improvement with treatment duration; however, we note that they should be interpreted in the context of the open-label design and absence of a long-term placebo control.

Exhibit 4: Study 015 results – PANSS mean change from baseline



Source: Newron Pharmaceuticals corporate presentation (September 2026)

Exhibit 5: Study 015: PANSS responder analysis



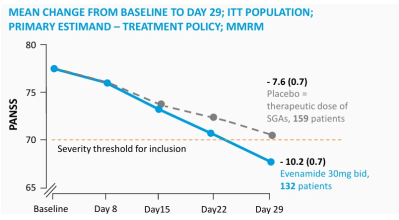
Source: Newron Pharmaceuticals corporate presentation (September 2026)

Recap: Randomised data provide more rigorous validation

Study 008A provides more rigorous placebo-controlled evidence supporting evenamide's activity in schizophrenia. The randomised, double-blind study enrolled 291 poorly responding patients (albeit, not classified as specifically having TRS) who remained symptomatic despite treatment with stable doses of second-generation antipsychotics, with participants receiving either evenamide 30mg twice daily or placebo over four weeks. At day 29, PANSS total score declined by 10.2 points in the evenamide arm versus 7.6 points with placebo, giving a placebo-adjusted difference of 2.5 points in favour of evenamide (p=0.006) (Exhibit 6). A statistically significant benefit was observed on CGI-S, with a placebo-adjusted difference of 0.16 points (p=0.037).

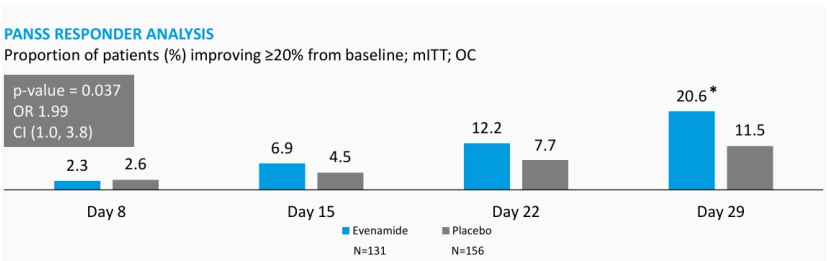
Responder analyses were directionally consistent with the primary results. At day 29, 20.6% of evenamide-treated patients achieved at least a 20% improvement in PANSS versus 11.5% on placebo (Exhibit 7), while 31.3% were rated as at least 'much improved' on CGI-C compared with 17.3% of placebo recipients. Importantly, treatment-emergent adverse events were broadly comparable between groups, with no new safety signals identified. Improvements were also observed across multiple background antipsychotics, including clozapine, supporting the rationale for evenamide as an adjunctive therapy.

Exhibit 6: Study 008A – PANSS improvement vs placebo



Source: Newron Pharmaceuticals corporate presentation (September 2026)

Exhibit 7: Study 008A – responder rate vs placebo



Source: Newron Pharmaceuticals corporate presentation (September 2026)

Phase III remains the key test...

Taken together, studies 014/015 and 008A provide an encouraging, but still incomplete, clinical foundation for evenamide. The broader evidence package was also recognised in early 2026 with findings from the evenamide programme published in peer-reviewed journal *Therapeutic Advances in Psychopharmacology*. Study 014/015 demonstrated a sustained benefit in the target TRS population, but without a long-term placebo comparator, while study 008A provided randomised, placebo-controlled evidence in patients with an inadequate response to antipsychotics rather than the intended registrational TRS population. The ENIGMA-TRS programme brings these two elements together, combining a rigorous placebo-controlled design with a well-defined TRS population. As such, the Q127 12-week readout should provide the clearest test to date of whether evenamide's earlier efficacy signals translate into the pivotal setting.

… with potential to highlight the continued benefit over time

One key take-away we highlight from the results of study 015 was that efficacy appeared to strengthen with treatment duration. Mean PANSS improvement increased over time, while the proportion of patients achieving at least a 20% reduction in PANSS similarly rose through to one year. Again, while these findings should be interpreted cautiously given the absence of a long-term placebo comparator, we believe they do provide a rationale for looking beyond the primary 12-week ENIGMA-TRS 1 readout. The subsequent 26- and 52-week assessments should therefore offer useful insight into the durability of response, and whether the progressive pattern observed previously can be reproduced in a controlled Phase III setting.

Schizophrenia innovation and CNS strategic activity

Schizophrenia has historically seen relatively limited therapeutic innovation, with most available antipsychotics centred on dopamine signalling. This began to change with the US approval of Cobenfy in September 2024, which targets muscarinic receptors and represented an important validation of differentiated, non-dopamine approaches to the condition. More broadly, this supported renewed interest in schizophrenia as a drug development area and supports the rationale for exploring mechanisms such as glutamatergic modulation.

However, demonstrating incremental benefit on top of established antipsychotics remains challenging. In April 2025, Bristol Myers Squibb reported that the Phase III ARISE study of Cobenfy as an adjunct to atypical antipsychotics did not achieve statistical significance on its primary PANSS endpoint, despite numerical improvement. While the populations and mechanisms differ materially from evenamide, the result highlights the challenges faced by the industry and reinforces the importance of the ENIGMA-TRS programme, should it deliver positive results.

There is a clear unmet need in TRS, where clozapine is an important treatment option but carries recognised safety and monitoring requirements. While the FDA has removed the formal clozapine 'risk evaluation and mitigation strategy' programme, monitoring for severe neutropenia remains recommended. As such, an efficacious and well tolerated add-on therapy that can be used alongside existing antipsychotics could provide a potentially sizeable commercial opportunity, in our view.

Financials

Phase III execution drives H126 R&D

Newron's H126 financial performance reflects the transition of evenamide into full Phase III execution following the initiation of both pivotal studies in H225. Revenue declined 73.2% y-o-y to €3.2m from €11.9m in H125, with the comparable period benefiting from €7.8m of licence income related to the first milestone under the EA Pharma agreement in Japan and the upfront payment from South Korean partner Myung In Pharm. In H126, revenue was predominantly derived from Xadago royalties, which declined 18.9% y-o-y to €3.1m from €3.8m, while licence income fell to just €0.1m from €7.8m. We expect Xadago's contribution to moderate over time as the franchise matures, particularly following the earliest permitted entry of generic safinamide in the US from December 2027.

The more important development, in our view, was the expected ramp-up in clinical investment. R&D expenditure increased 139% y-o-y to €14.6m from €6.1m, driven primarily by the ongoing ENIGMA-TRS Phase III programme. Outsourced clinical services were the main contributor, rising to €10.4m from €3.4m as both pivotal trials moved into active execution. Nevertheless, spending was somewhat below the run-rate implied by our previous FY26 R&D estimate of €41.3m. We believe this likely reflects, at least in part, the temporary pause in new US enrolment for ENIGMA-TRS 2 from April, which would have deferred certain site- and patient-related costs. We therefore expect the R&D run-rate to increase again as US recruitment resumes. G&A expenses rose 15.3% y-o-y to €5.1m from €4.4m, partly reflecting higher staff costs associated with the issuance of stock appreciation rights. Taken together, this resulted in an operating loss of €16.6m, versus a €1.3m operating profit in H125.

The net loss widened to €16.4m in H126 from a €0.1m loss in H125, although the net financial result was more favourable year-on-year. Interest expense declined 27.6% to €1.6m from €2.2m, primarily reflecting the repayment of the first tranche of the European Investment Bank (EIB) facility in November 2025 (€38.3m outstanding at end-H126), while financial income increased to €2.0m from €0.9m, largely due to a €1.6m fair-value gain on the EIB warrants. Operating cash flow, however, swung to an outflow of €10.8m from an inflow of €33.4m in H125, reflecting the higher Phase III

investment and the absence of the sizeable partnering-related cash inflows that benefited the prior-year period. We note that H125 cash generation was supported by the €43.3m upfront payment from EA Pharma received in January 2025.

Estimates revision

We make modest adjustments to our FY26 and FY27 estimates, based on the H126 performance. For FY26, we raise our revenue estimate to €12.6m from €7.8m, principally to incorporate the €5.5m milestone payment from EA Pharma received in September 2026. This is partly offset by a more conservative assumption for Xadago royalties, which we reduce to €7.0m from €7.8m, reflecting the softer H126 contribution and the product's maturing commercial profile.

The more material change relates to our R&D assumptions, which we have trimmed to €31.3m for FY26 from €41.3m, accounting for the temporary pause on new US patient enrolment for ENIGMA-TRS 2 from April 2026. However, we view this more as a rephasing of expenses and model these costs shifting to FY27m under the assumption that US recruitment resumes in Q426. We modestly raise our G&A estimate to €10.1m from €8.9m, reflecting the H126 run-rate. Taken together, these revisions reduce our FY26 operating loss estimate materially to €28.8m from €42.3m previously.

For FY27, we now forecast revenue of €46.7m versus €66.6m previously, comprising c €7.1m of Xadago royalties and risk-adjusted income from our assumed European licensing transaction for evenamide. At the same time, the rephasing of ENIGMA-TRS 2 costs into FY27 results in a higher operating cost base than previously anticipated. We now estimate a more modest operating profit of €1.2m (€37.2m previously), highlighting that the FY27 financial performance remains particularly sensitive to both the timing and economics of any potential European licensing agreement and the pace of ENIGMA-TRS 2 execution.

Balance sheet strengthened ahead of pivotal readouts

Newron ended H126 with €16.1m in cash and €16.8m in other current financial assets, primarily comprising bonds and investment funds, for total liquidity of €32.9m. This position was supported by the initial €15m tranche of the up to €38m equity financing agreed in February 2026, under which c 780k shares were issued at €19.24 per share.

Liquidity was strengthened further post-period. In September, Newron received an additional €5.5m equity investment from the same investor group (against an issue of 433,070 shares at €12.7 per share), alongside a separate €5.5m milestone payment from Japanese partner EA Pharma, taking pro forma liquidity to c €43.9m. A further €5.5m equity tranche is expected by 30 November 2026, which we continue to reflect in our model as illustrative debt pending issuance. The remaining €12m under the financing agreement is contingent on positive ENIGMA-TRS results and is therefore excluded from our base case, although it represents a potentially meaningful source of additional funding in 2027.

Together with the extension of the outstanding EIB facilities to June 2028, these measures have materially improved Newron's funding visibility. Based on our revised cash burn assumptions, we estimate that the c €43.9m pro forma liquidity position should support operations through Q327, versus our previous expectation of H127. This takes Newron beyond the ENIGMA-TRS 1 12-week readout expected in Q127 and potentially through the ENIGMA-TRS 2 top-line readout, assuming the FDA hold is lifted and US sites resume enrolment in Q426. If the additional €12m contingent equity tranche becomes available following positive pivotal data, we estimate the runway could extend to around end-FY27.

Importantly, these estimates assume no additional non-dilutive proceeds from regional partnering, an avenue management continues to actively pursue. As noted above, our model builds in Newron licensing the European rights to evenamide following supportive pivotal data in Q127, incorporating a risk-adjusted upfront payment of c €35m in FY27 revenues.

Valuation

We update our evenamide assumptions to reflect the revised Phase III timeline. Following the constructive Type A meeting with the FDA in July, Newron is implementing the proposed changes discussed with the agency and expects US enrolment in ENIGMA-TRS 2 to resume once these are completed. Assuming the company is able to submit an acceptable response in the near term, we model the FDA hold being lifted and US sites restarting recruitment during Q426. Allowing for the study's screening and 12-week treatment periods, for the purposes of our model, we now expect ENIGMA-TRS 2 topline data in Q327, though we note that management has not provided formal guidance on this, and it will be contingent on US sites commencing enrolment again.

On this basis, we push our assumed NDA filing to early 2028 and US launch to 2029, from 2028 previously. While ENIGMA-TRS 1 is expected to report its primary 12-week endpoint in Q127, we do not assume these data alone would support a US filing, given that Newron's registrational programme comprises two pivotal Phase III studies. Our early-2028 filing assumption also allows time for the more mature 52-week ENIGMA-TRS 1 data to become available. Given target enrolment is expected to complete around mid-October 2026, the final patients should reach the 52-week time point around Q427. We view this as a conservative, albeit prudent regulatory assumption, with potential timing upside if ENIGMA-TRS 2 recruitment recovers more quickly following US site reactivation.

However, the impact on the risk-adjusted valuation from pushing back commercial cash flows by a year has been largely offset by the materially longer patent runway to 2044. Newron received a decision to grant European patent in January 2026, covering the crystalline forms of evenamide, their preparation and uses, with protection scheduled to October 2044. Equivalent claims have been filed in other major markets. We now incorporate this extended exclusivity into our model, adding several years of protected, mature-market revenues and materially mitigating the effect of the later launch.

We also retain our 70% probability of success for the evenamide programme. The FDA action relates to a pause in new enrolment at US ENIGMA-TRS 2 sites rather than a halt to the broader programme. ENIGMA-TRS 1 has completed patient screening and recruitment outside the US remains unaffected by the hold. Given the constructive Type A meeting and management's expectation that US recruitment will resume following implementation of the proposed changes, we currently view the development primarily as a timing issue rather than a fundamental change in the programme's risk profile. Resolution of the hold nevertheless remains an important near-term milestone.

Incorporating the revised 2029 launch, extended 2044 commercial runway, updated pro forma cash position and model roll-forward, our valuation increases modestly to CHF444.2m or CHF20.9 per share, from CHF431.6m or CHF20.8 per share previously. A breakdown of our risk-adjusted net present value model for Newron is presented in Exhibit 8.

Exhibit 8: 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.

US hold remains the key sensitivity

We note that the FDA hold on US enrolment in ENIGMA-TRS 2 remains the principal near-term sensitivity to our forecasts, given the strategic importance of the US to evenamide. ENIGMA-TRS 2 was specifically designed to provide a substantial US patient exposure given it is also the single most important commercial market for schizophrenia therapies. This is particularly relevant for Newron, which has previously contemplated retaining US commercial economics, including potential self-commercialisation in the geography. A prolonged hold could therefore have implications beyond trial timing, potentially delaying US regulatory submission, commercialisation and strategic financing or partnering activity. Conversely, FDA clearance and the resumption of US recruitment would remove a meaningful overhang and provide greater visibility on the path to our assumed 2029 launch.

Exhibit 9: 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

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.

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 sol icitation 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.

London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom