EDISON

Newron Pharmaceuticals

Evenamide enters ENIGMA-TRS programme

Company outlook

Healthcare

2 July 2025

Newron Pharmaceuticals is making significant headway in progressing its drug candidate, evenamide, to become an effective treatment option for patients suffering with treatment-resistant schizophrenia (TRS). The latest update from the company confirmed that the registrational ENIGMA-TRS Phase III programme (expected n=1,000) will consist of two separate studies (versus a single trial as originally planned). The first of these commenced within H125 (according to management), and it is anticipated to report top-line results from Q426. We update our estimates to reflect the second international Phase III study and adjust our model to factor in self-commercialisation in the US. Our valuation adjusts to CHF392.4m or CHF19.7/share, from CHF385.6m or CHF19.3/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	8.3	N/A
12/25e	7.3	(37.2)	(1.86)	0.00	N/A	N/A
12/26e	7.8	(40.2)	(2.01)	0.00	N/A	N/A

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

Path laid out for evenamide in Phase III

In May 2025, Newron received regulatory clearance for its registrational Phase III programme, which will include two separate trials. ENIGMA-TRS 1 is a 600-patient international study; screening started in H125 and top-line results are expected from Q426. ENIGMA-TRS 2 will be a 400-patient international study (including the US) with enrolment expected to commence by Q425. We believe the decision to conduct two studies was made with the aim of de-risking the programme, by maximising the data package and potential for regulatory approval. If successful, this programme should support commercialisation in all major geographies.

Targeting an untapped space in schizophrenia

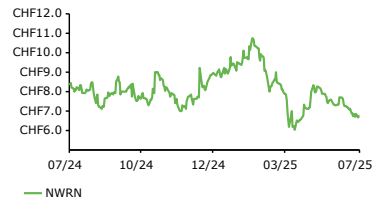
Schizophrenia has been a relatively stagnant field since the 1950s despite it afflicting c 1% of the global population. The approval of Cobenfy in 2024 marked a resurgence in the area, amid a wider growth of interest in the CNS space. Newron's evenamide should not be considered a direct competitor because it is specifically targeting the TRS sub-population (30% of all schizophrenia patients). In our view, the licensing deals Newron has secured to date (EA Pharma in Japan; Myung In Pharm in South Korea) reflect the industry's positive opinion of evenamide's potential.

Valuation: CHF392.4m or CHF19.7 per share

We update our estimates to reflect the second Phase III trial (ENIGMA-TRS 2), assuming clinical trial costs of €25m, which we assume may be partially funded from proceeds from other regional licensing deals (likely Latin America, China and India). Given the updated trial plans, we have also adjusted our model and licensing deal assumptions to reflect self-commercialisation in the US and post Phase-III partnering in Europe. Our valuation of Newron adjusts to CHF392.4m or CHF19.7/share, from CHF385.6m or CHF19.3/share previously. Reflecting the additional R&D, we estimate the company is funded into early 2026 (H126 previously).

Price	**CHF6.74**
Market cap	**CHF135m**
	€1.06/CHF
Pro forma net cash at 31 December 2024 (including €44.4m upfront proceeds from EA Pharma)	€4.6m
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	2.2	(26.1)	(24.6)
52-week high/low		CHF11.2	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 preparing for a Phase III trial programme targeting treatment-resistant and poorly responding schizophrenia.

Next events

ENIGMA-TRS 1 launch	Mid-25
ENIGMA-TRS 2 launch	Q425
ENIGMA-TRS 1 results	Q426

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Investment summary

Company description: CNS specialist with a schizophrenia focus

Newron Pharmaceuticals is a biopharmaceutical company focused on developing new therapies for the treatment of central nervous system (CNS) conditions. Its strategic priority is the registrational ENIGMA-TRS Phase III programme for evenamide, which has a novel mechanism of action, to address the unmet need in TRS. The drug candidate has shown encouraging results in the clinic, including a prior Phase II trial (study 014/015) where, notably, 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 the patients were described as achieving clinical remission. Further, evenamide has shown notable benefits in poorly responding schizophrenia patients (study 008A), broadening its potential use. Evenamide has been found to be safe and well tolerated across clinical trials, laying a robust foundation for these late stages of development. ENIGMA-TRS aims to replicate the positive results of study 014/015, but in a larger, randomised, placebo-controlled setting. It will involve two studies that will run in parallel. ENIGMA-TRS 1 (expected n=600) will be based in Europe, Asia, Latin America and Canada, and, according to management, screening commenced within H125. ENIGMA-TRS 2 (expected n=400) will be an international study (including the US); enrolment is due to start by early Q425. Together, these studies should meet the requirements for regulatory submission, covering major geographies such as Europe and the US. Beyond evenamide, Newron has demonstrated its ability to bring CNS drugs to market, as its first marketed product (Xadago, for Parkinson's disease) generates a steady revenue stream.

Valuation: CHF392.4m or CHF19.7 per share

We value Newron at CHF392.4m or CHF19.7 per share, based on a risk-adjusted net present value (rNPV) calculation for its two in-house programmes, Xadago and evenamide. Given that Xadago is a mature asset (patent expiry in 2027), the bulk of our valuation for Newron is derived from evenamide (95% of our implied enterprise value). Our updated valuation reflects the company's recent decision to conduct two separate Phase III trials instead of the previously planned single study. We now incorporate a second, international clinical trial in our model, assuming total clinical trial costs of €25m. We also adjust our estimates to build in a self-commercialisation model in the US (vs out-licensing as previously assumed) in line with our understanding that the company is more inclined to retain the US rights given the revised clinical plans. We continue to assume a 2028 launch with a 70% probability of success and peak sales of €1.7bn. Note that the peak sales estimate includes the potential upside opportunity from label expansion into treating poorly responding patients (c 40% of the schizophrenia population), which includes the sub-set of schizophrenia patients with inadequate response to traditional antipsychotics, although not termed treatment resistant.

Financials: Cash runway into 2026

While Newron generates royalty income from Xadago, its investment case rests on its lead asset evenamide, which has demonstrated compelling clinical data to date in TRS. FY24 was a particularly strong year for the company, with a €44.4m upfront payment from EA Pharma (for licensing rights in Japan) supporting recognition of €26.2m in operating profit for the year as well as a healthy pro-forma gross cash balance of €51.5m. Based on our revised cash burn estimates (reflecting additional R&D related to the second Phase III study), we estimate the company to be funded into early 2026 (H126 previously), factoring in a €10m debt repayment due in Q425.

Sensitivities: Value appreciation tied to Phase III programme outcome

Newron is subject to typical biotech risks: clinical development delays or failures; regulatory outcomes; competitor successes; partnering setbacks; and financing and commercial risks. However, some of these are somewhat offset by Newron's track record, having successfully marketed Xadago. More specific sensitivities lie around ENIGMA-TRS, as its only active clinical-stage programme. While the results of prior study 014/015 in TRS were promising, this was an open-label trial. As such, ENIGMA-TRS includes double-blinded trials, to mitigate potential biases in patient assessments. In terms of financing, Newron is supported by regional licensing deals in place for Japan and South Korea, which should help offset some of the financing requirements of the planned clinical trials. Further, management is actively seeking additional partnerships, and if these come into fruition, the company could receive additional non-dilutive funding to take the programme through to completion. The main sensitivity faced by Newron will be the ENIGMA-TRS results (12-week results for ENIGMA-TRS 1 are anticipated from Q426), and whether the data will be sufficient for regulatory approval.

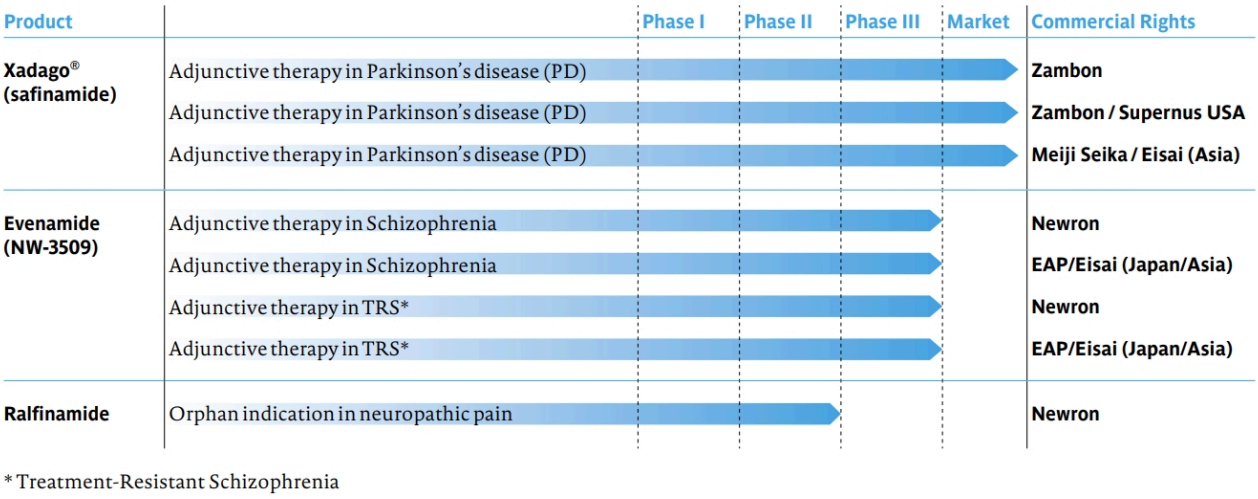
CNS clinical pipeline focused on schizophrenia

Newron is focused on the field of drug development for CNS conditions, as reflected by its pipeline (Exhibit 1). The company's top strategic priority is evenamide, which has a dual mechanism of action as a voltage-gated sodium channel blocker and modulator of post-synaptic glutamate release. It is being evaluated in the pivotal ENIGMA-TRS programme, which we discuss in further detail below.

Newron's first marketed drug was Xadago (generic name: safinamide), which serves as an adjunctive treatment for Parkinson's disease patients. Xadago has received regulatory approval in over 20 markets (including the US, the UK, the EU, Switzerland and Japan), and is supported commercially by partners Zambon, Supernus and Meiji Seika. According to Newron's latest financial update (FY24 results), Xadago continues to be a steady revenue stream, and we note that over €85m has been booked by Newron to date through a combination of milestone payments and royalties. However, the drug is approaching the end of its market exclusivity period, which is in place until at least 1 December 2027. Nevertheless, it showcases Newron's capabilities in bringing drugs for CNS conditions to the market, providing a solid foundation as evenamide enters the pivotal ENIGMA-TRS programme.

The third candidate in Newron's clinical pipeline is ralfinamide, which has been designed as a potential therapy for the orphan indication of neuropathic pain. However, we understand that this programme has been de-prioritised over the past few years, while management focuses on the lead schizophrenia programme. As such, ralfinamide is not included in our valuation for Newron.

Exhibit 1: Newron's clinical development pipeline



Source: Newron's 2024 annual report

ENIGMA pivotal Phase III programme

In May 2025, Newron introduced ENIGMA-TRS, following regulatory clearance for this registrational Phase III programme. It will comprise two concurrent studies, ENIGMA-TRS 1 and ENIGMA-TRS 2, which together will evaluate evenamide as an add-on therapy to current antipsychotic medications, including clozapine (the only FDA-approved drug for TRS). Collectively, these studies should meet the regulatory requirements to submit registration applications in major geographies, including Europe and the US. The primary efficacy measure will be the Positive and Negative Syndrome Scale (PANSS) total change from baseline, which is widely considered the gold standard for evaluating antipsychotic treatment efficacy.

ENIGMA-TRS 1 will be a 52-week, randomised, double-blinded, placebo-controlled Phase III trial. It will assess the efficacy, safety and tolerability of evenamide at 15mg and 30mg twice-daily doses (both of which were tested in the prior TRS trial, study 014/015), compared to placebo. It will involve c 600 patients across study centres in Europe, Asia, Latin America and Canada, and management has communicated that the first patients entered the 42-day screening protocol in H125. The results at 12 weeks post-randomisation are anticipated to be reported in Q426, likely representing a major inflection point for the programme and the company. The trial will continue in a double-blind and placebo-controlled

setting up to the one-year time point. We estimate total trial costs of c €45m, with funding support coming from its partners: EA Pharma (Japan) and Myung In Pharm (South Korea). 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 will be a 12-week, randomised, double-blinded, placebo-controlled Phase III trial, assessing evenamide at a 15mg dose in c 400 patients. This will be an international study, undertaken at centres in the US, alongside selected additional countries. Enrolment is expected to commence by Q425 and endpoint analysis will be conducted at 12 weeks. Given the shorter duration and lower expected number of participants, we estimate trial costs of c €25m. In this trial, patients will also be evaluated by the above-mentioned IEAC. We expect Newron to seek other regional licensing deals for evenamide, in line with its commercial strategy (either Latin America, China or India), with the related inflows providing further funding support to the two studies.

Programme de-risked by licensing deals

Newron secured a licensing agreement with EA Pharma (a subsidiary of Eisai) in December 2024, to develop, manufacture and commercialise evenamide in Japan and other Asian territories (including Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam). This €117m deal includes an upfront payment of €44m, plus financial contributions to the Phase III programme, as well as regulatory and commercialisation milestones, and tiered royalties up to a double-digit percentage of evenamide net sales. We view the terms as highly attractive for Newron given the front-end-loaded nature of the deal, indicative of EA Pharma's opinion of the drug's potential. Japan is a key market for Newron and, according to a report by Delve Insight, it accounted for c 18% of all schizophrenia cases and c 8.5% of the market value among the top seven major markets (in 2022). We note that regulatory approval in Japan requires a separate and independent Phase III trial, but we understand that EA Pharma will initiate and sponsor this study in full in 2026, utilising insights from Newron's planned international ex-Japan Phase III programme, ENIGMA-TRS. In addition to the upfront payment, we estimate EA Pharma's contribution to the costs of the ENIGMA-TRS programme to be c €10m.

In January 2025, Newron announced a further licensing deal, in South Korea, with Myung In Pharm. While specific terms were not disclosed for, we understand that further to the typical upfront, milestone and royalty payments, Myung In Pharm will also contribute 10% of the total patient population (c 60 patients) to Newron's landmark international Phase III study, ENIGMA-TRS 1, and will cover the expenses associated with the trial in South Korea, in addition to the regulatory, registration, marketing and commercialisation costs in the country.

Collectively, we believe that these licensing deals will support Newron in maximising the commercial potential of evenamide. We also understand that although the ENIGMA-TRS programme commenced in H125, management is, in parallel, exploring additional regional partnerships for the development and commercialisation of evenamide in TRS. We believe that given the market opportunity in the US (which is the largest pharma market globally), Newron intends to retain commercial rights in the US (at least until end of the Phase III programme but potentially also through commercialisation), while out-licensing distribution in other regions, likely including Europe.

Evenamide: A strong track record in the clinic

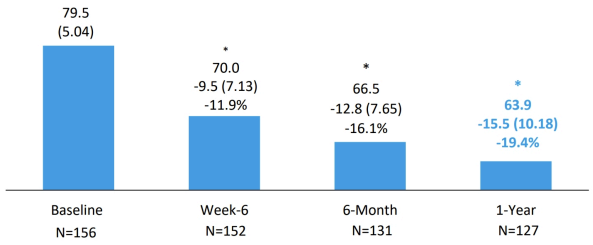
Study 014/015 paved the way for a new treatment paradigm in TRS

The results from study 015 (the extension of study 014) were first reported in January 2024. Study 014/015 was an open-label, rater-blinded, multi-centre (India, Italy and Sri Lanka) Phase II clinical trial, designed to assess evenamide at either 7.5mg, 15mg, or 30mg BID, in patients with TRS as an add-on treatment to any single antipsychotic (excluding clozapine). Study 014 refers to the initial six-week treatment period, while study 015 included the 12-month extension. 161 patients were initially randomised, 153 completed the initial six-week treatment period and 144 went on to enter the extension study. 132 of these patients completed the treatment protocol up to the six-month follow-up, and 121 completed treatment up to the 12-month follow-up. The overall attrition observed (c 25% in total) was attributed to withdrawal of consent (14.3%), not rolling over into the extension study (5.6%), lost to follow-up (3.1%) and adverse dropouts (1.9%).

The results after the 12-month follow-up showed a statistically significant improvement in PANSS mean percentage change from baseline (p-value <0.001: paired t-test, OC/LOCF). The data reflect a sustained and durable benefit from longer-term treatment with evenamide, with improvements observed from the six-week, through the six-month and up

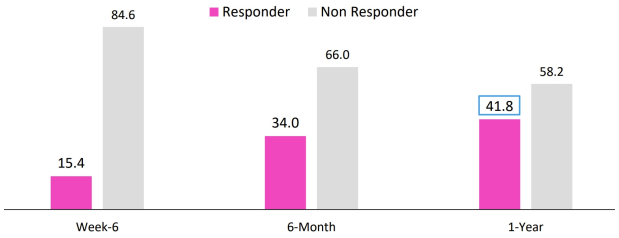
to the 12-month follow-up (Exhibit 2). Furthermore, 40% of patients showed clinically meaningful responses based on PANSS measures (defined as showing an improvement from baseline of ≥20%) at the 12-month follow-up (Exhibit 3). In our view, this is particularly significant, since all patients were already on therapeutic doses of antipsychotics before commencing the study, and therefore the improvements are purely reflective of evenamide's benefit. Additionally, the data showed that 90% of patients who initially responded to the treatment at the six-week follow-up (ie, considered PANSS responders, c 45% of patients) maintained their favourable responses after being treated with evenamide for 12 months.

Exhibit 2: PANSS mean percentage change from baseline (standard deviation in brackets)



Source: Newron's FY24 results presentation. Note: *p-value vs baseline <0.001, paired t-test, Observed Case (OC).

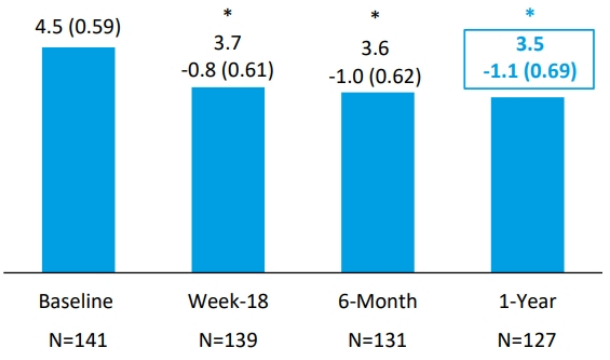
Exhibit 3: PANSS responder analysis (PANSS responder defined as showing a total improvement from baseline of ≥20%)



Source: Newron's FY24 results presentation

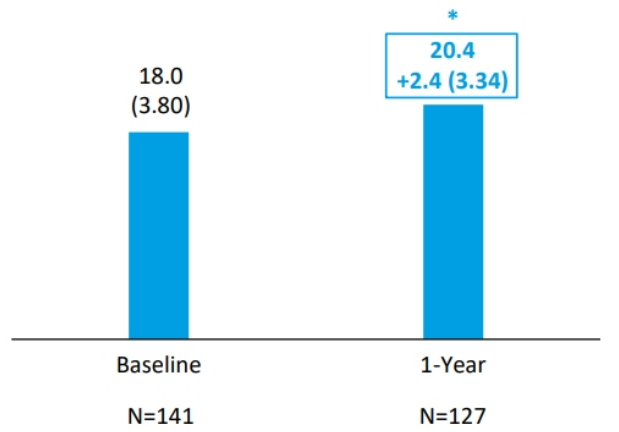
In addition to the primary outcome measures above, condition severity was also assessed by Clinical Global Impressions (CGI) measures, and these also showed statistically significant improvements compared to baseline (Exhibit 4). Further, level of functioning (LOF) was evaluated, and also showed statistically significant benefits, with over 60% of patients showing an improvement at the 12-month follow-up (Exhibit 5).

Exhibit 4: CGI-S mean percentage change from baseline (standard deviation in brackets)



Source: Company resources. Note: *p-value vs baseline <0.001, paired t-test, Observed Case (OC).

Exhibit 5: Level of functioning mean percentage change from baseline (standard deviation in brackets)



Source: Company resources. Note: *p-value vs baseline <0.001, paired t-test, Observed Case (OC).

Overall, these results were highly positive, in our view. For the full population, over 70% of TRS patients experienced clinically meaningful reductions in condition severity, and interestingly, c 50% of the patients did not meet the protocol severity criteria for a diagnosis of treatment-resistance after 12 months of treatment with evenamide. Collectively, the data demonstrate the effectiveness of evenamide to overcome a treatment-resistance diagnosis, offering a durable benefit over the treatment duration. We also highlight that 25% of patients were described as achieving 'remission', a phenomenon that has not yet been reported in the TRS patient population, to our knowledge. In terms of safety, the use of evenamide in combination with antipsychotics was well-tolerated, with a low incidence of treatment-emergent adverse dropouts. Furthermore, there were no instances of patient relapses throughout the 12-month treatment period. We therefore view the results as promising, suggesting that evenamide may be used as an add-on therapy without risk of drug-drug interaction or additional toxicity, making it a potentially effective treatment option to address TRS.

Remission in TRS

Remission in schizophrenia has been researched by Lieberman et al. in 1993 and by Andreasen et al. in 2005; they sought definitions based on precise measures of what would consist remission of the condition (including PANSS and CGI). For the purposes of its clinical research, Newron describes remission as a level of symptoms that does not interfere with an individual's behaviour, and is also below that required for a diagnosis of schizophrenia. Such symptom improvements should persist for a significant time period in order for remission to be considered achieved. Remission would represent the highest level of improvements that can be obtained in a schizophrenia patient.

Newron believes that remission in TRS patients has not yet been achieved with existing (approved) therapies. However, its analysis of the data from study 014/015 suggested that a notable portion of patients treated with evenamide did meet the criteria for remission, with 27.6% of patients meeting the definition of Lieberman et al. (a maintenance requirement of eight weeks) and 25% meeting the definition of Andreasen et al. (a maintenance requirement of 24 weeks).

Study 008A data supportive, from a randomised, placebo-controlled setting

The positive sentiment continued beyond the conclusion of study 014/015, when in April/May 2024, Newron announced positive results from the Phase II/III trial, study 008A, which focused on patients with poorly managed schizophrenia who were already taking antipsychotics, but not defined as having TRS. This was a four-week, international, double-blinded, randomised, placebo-controlled trial (n=291), evaluating evenamide at 30mg BID. The study met both its primary and secondary endpoints with statistical significance. For the primary efficacy measure, improvement on the PANSS score from baseline, evenamide treatment was associated with a reduction in PANSS total score of 10.2 points, compared to 7.6 points with placebo at day 29 (p-value 0.006). The key secondary endpoint measure was improvement on the CGI-S scale, and the results showed a least square mean difference of 0.16 between treatment with evenamide and placebo (p-value 0.037). Furthermore, 31.3% of the 132 patients treated with evenamide were rated as 'much improved', compared to 17.3% of the 159 patients who received placebo. Overall, the results of study 008A consolidated the already robust data from study 014/015, and also showed that the benefit according to all the major efficacy measures increased over the four-week period, but in a larger, randomised, placebo-controlled setting. The trial also confirmed the safety of evenamide, showing a similar tolerability profile to placebo (there was a 25.0% rate of adverse events with evenamide, compared to 25.8% with placebo).

Understanding the trial assessment parameters

For Newron's clinical trials assessing the effectiveness of evenamide, the efficacy scales used include:

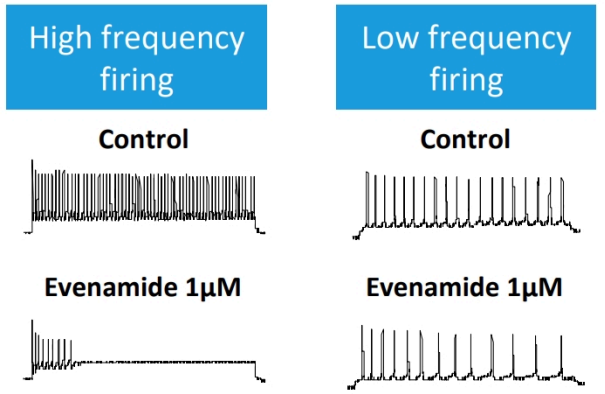
- Positive and Negative Syndrome Scale (PANSS)
  The PANSS is a 30-item scale developed to provide a balanced representation of symptoms, both positive (seven items) and negative (seven items), associated with schizophrenia, and understand their relationship to one another, as well as to general symptoms of psychopathology (16 items). The PANSS is intended to be a brief interview (c one hour), and to ensure standardisation, interviewers must be trained to a sufficient level of reliability.
- Clinical Global Impressions (CGI)
  The CGI scales are established rating tools used for all psychiatric disorders, not just limited to schizophrenia. The CGI are intended to provide an overall clinician-determined summary assessment (c 10 minutes) based on an overall view (observations and reported symptoms) of the global functioning of a patient population across a treatment period.
- Strauss-Carpenter Level of Functioning (LOF)
  The LOF scale uses a semi-structured interview (c 20 minutes) focused on quality of life across four domains: social contacts; work; symptomatology; and function.

Efficacy attributable to evenamide's novel mechanism of action

The majority of antipsychotic drugs were designed based on the dopamine hypothesis of schizophrenia pathophysiology (discussed in further detail below). However, evenamide has a unique two-pronged mechanism of action, designed for voltage-gated sodium channel (VGSC) inhibition, and the modulation of post-synaptic glutamate release (primarily in the hippocampus of the brain). VGSCs play a crucial role in the CNS, mediating neuronal signal transduction by cycling through three states: closed (resting but capable of being activated or opened by depolarization), open and inactive (temporarily non-functional and cannot be activated until it returns to a closed state). Conformational

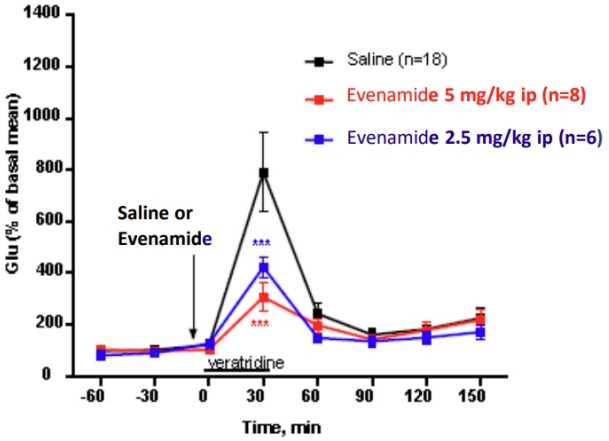
adjustments (changes in shape) offer the opportunity to design small molecule inhibitors targeting one of these three states specifically. Rapidly firing channels exist for longer in an inactive state than a closed (resting) state, and therefore, inhibitors can preferentially modulate a channel based on its firing frequency. Evenamide has been designed to exploit these features of VGSCs to attenuate excessive signalling in glutamatergic systems, and this formed the basis of Newron's preclinical research into the candidate as a potential treatment for schizophrenia. Evenamide has been shown to selectively stop high-frequency firing neurons over low frequency neurons (Exhibit 6). This was found to translate to an in vivo reduction in excessive glutamate release caused by high-frequency firing (induced by veratridine in pre-clinical studies), without causing a reduction of normal levels of glutamate release (Exhibit 7). To our knowledge, there are no other drug candidates in clinical development for schizophrenia that operate by this mechanism of action.

Exhibit 6: Evenamide modulates sustained repetitive firing without inducing impairment of normal neuronal excitability



Source: Company resources

Exhibit 7: Dose-dependent demonstration of evenamide's mechanism of action as a glutamate modulator



Source: Company resources

Schizophrenia: A field at the start of a resurgence

Schizophrenia is a chronic and severe neurological condition characterised by disruptions in thought processes, reality perception, emotions and social functioning. Symptoms of the disorder can be placed into three categories:

1. **Positive symptoms**: hallucinations (such as hearing voices), delusions (fixed, false beliefs), disorganised speech or behaviour.
2. **Negative symptoms**: affective flattering (reduced emotional expression), alogia (reduced speech), anhedonia (lack of interest, enjoyment, or pleasure from life experiences), social withdrawal.
3. **Cognitive symptoms**: impaired memory and attention, reduced executive function (such as planning and decision-making).

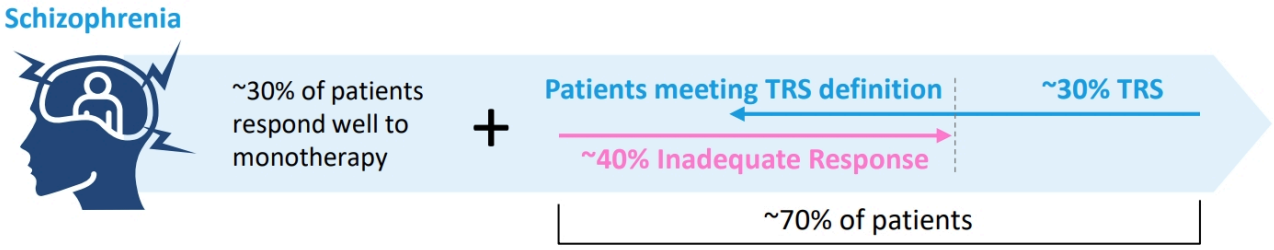
Historically, the standard of care for schizophrenia has been based on the hypothesis that schizophrenia is caused by dopamine hyperactivity (dopaminergic dysregulation). As such, 'typical' antipsychotics (for example: chlorpromazine, haloperidol, pimozide, loxapine) that inhibit the dopamine D2 receptor were developed in the 1950s. The 1970s saw the development of 'atypical' antipsychotic drugs (for example: clozapine, olanzapine, risperidone, quetiapine), which target serotoninergic receptor 5-HT2A, in addition to blocking the dopamine D2 receptor, and are associated with fewer side effects. In more recent years, a third generation of antipsychotics emerged, which are only partial agonists at the dopamine D2 receptor, designed to modulate, rather than block, dopamine activity in the brain (examples include: cariprazine, brexpiprazole, aripiprazole). These third-generation anti-psychotics are associated with a more favourable side effect profile compared to typical and atypical antipsychotics, in particular related to motor-related symptoms. However, overall, while the three aforementioned types of drugs can be effective in managing the positive symptoms of schizophrenia, many patients find that they have limited efficacy against the negative and cognitive symptoms of the condition.

Targeting the unmet need in the space

Schizophrenia afflicts c 1% of the global population. However, despite over 30 available treatment options, at least

30% of this population remains treatment-resistant (defined as schizophrenia that does not respond to two or more medications, each with at least six weeks of treatment duration), and a further c 40% are considered poor responders to treatment (patients who respond initially to first-line antipsychotic treatment but subsequently develop some resistance) , meaning only c 30% respond adequately to standard-of-care antipsychotic treatment (Exhibit 8). It is possible that TRS as a sub-population may not stem from dysregulated levels of dopamine, but rather, may be caused by other abnormalities, such as in the glutamatergic system, and this may be why current standard-of-care antipsychotics can be ineffective in managing TRS. Clozapine is the only drug that approved specifically for TRS (first approved in 1989), but usage remains limited, estimated at c 5% of the overall schizophrenia patients, most likely due to its side effect profile. We therefore believe that TRS and poorly responding patients remain areas with significant unmet need, requiring new treatment modalities with a differentiated mechanism of action.

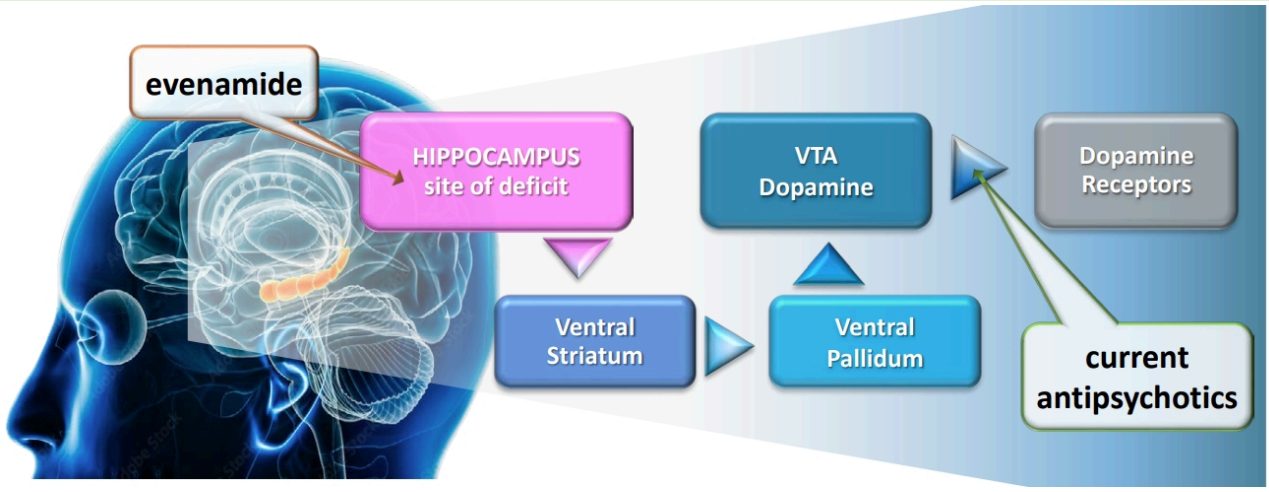
Exhibit 8: Newron is targeting the unmet need schizophrenia



Source: Company resources

While schizophrenia has been a relatively stagnant disease area in terms of the number of new approved drugs (until recently), understanding of schizophrenia pathophysiology has progressed, and in our view, the field is now at a precipice of a new era of treatments. This has been exemplified by the recent FDA approval of Bristol Myers Squibb's Cobenfy (generic name: xanomeline/trospium, also known as KarXT). Cobenfy works by a novel mechanism of action, selectively targeting the muscarinic receptors M1 and M4 (primarily in the cerebral cortex, hippocampus and striatum of the brain), which are associated with cognition, learning and memory. The approval of Cobenfy marked a major milestone for the field, however, we highlight that TRS is not included in its label. As such, Cobenfy should not be considered as a direct competitor to evenamide at the current stage, as evenamide aims to deliver durable responses for the TRS patient population. We also note that Newron's management is confident that evenamide may further differentiate itself from available treatment options with a more favourable side effect profile. In our view, there is a sizeable opportunity for Newron to address the unmet need that remains in the space, specifically targeting the TRS sub-population, backed by its novel mechanism of action targeting the root cause of schizophrenia pathophysiology. In April 2025, it was announced that Cobenfy was not found to be more beneficial than placebo in a trial assessing its potential as an add-on therapy to atypical antipsychotics, raising some questions around its commercial potential. As such, evenamide remains the only drug candidate, to our knowledge, as an add-on treatment to all currently approved antipsychotics, potentially bolstering the market opportunity.

Exhibit 9: Evenamide targets the root cause of schizophrenia pathophysiology



Source: Company resources

Resurgence of interest in CNS

Generally, we are seeing a resurgence of interest in the field of CNS therapeutics within the healthcare sector. In the past 20 months, there have been four multi-billion-dollar acquisitions of biotech players, including Bristol Myers Squibb's acquisition of Karuna Therapeutics, with KarXT as the main focus of the deal, at a 53% premium in December 2023. Other key deals include: Cerevel Therapeutics (acquired by AbbVie at a 22% premium), Longboard Pharmaceuticals (by Lundbeck at a 54% premium) and, most recently in January 2025, Intra-Cellular Therapies (by Johnson & Johnson at a 39% premium). In our view, this trend is a signal of investor confidence within the field of CNS therapeutics, despite broader market volatility, which may be considered favourable for Newron, as it takes its schizophrenia candidate through the late stages of clinical development, through to potential commercialisation.

Management team

CEO: Stefan Weber. Stefan Weber was appointed chief executive officer and executive director of Newron in 2012. He had been chief financial officer of the company since April 2005. Stefan holds a master's degree in business management from FernUniversität Hagen (Diplom-Kaufmann). He has more than 30 years of industry experience in finance and general management. From 2001 to 2005, he was the chief financial officer of Biofrontera, a company active in drug discovery and development. He joined Girindus, a fine chemistry process development and scale-up provider, in 1999, and was appointed chief financial officer in 2000. From 1987 to 1999, he was with Lohmann Group, a worldwide producer of pharmaceutical, medical, technical and consumer products. His final position was head of finance of the group. Stefan has executed numerous major financing transactions, debt, equity and mezzanine, as well as national and European grants. He has also executed successful IPOs on the Frankfurt and Zurich stock exchanges and has been involved in a number of M&A transactions, divestments and strategic restructurings.

See below for an Edison TV executive interview we recently conducted with Stefan Weber.

CMO: Ravi Anand. Ravi Anand, a Swiss resident, has been the company's chief medical officer since 2005. He received his university education in New Delhi, India, and his medical training, specialising in psychiatry and neurology, in the US. For over 20 years, Ravi has worked in international drug development and regulatory affairs at major pharmaceutical companies, including F. Hoffmann-La Roche (Switzerland), Sandoz/Novartis (US) and Organon (Netherlands). From 1993 to 1997, Ravi was the medical director of CNS, clinical research at Sandoz Research Institute. From 1997 to 2001, he served as the international Head of CNS Medical Affairs at Novartis and, from 2001 to 2003, as the global Head of CNS Clinical Research at Organon. Since 2003, Ravi has been acting as a consultant for Newron and other clients. During his tenure in the pharmaceutical industry, he worked in all phases (I through III) of drug development as well as in post-marketing studies (Phase IV). In total, he has been responsible for conducting clinical trials in over 30 countries, and has been involved in over 30 investigational new drug applications and over seven international new drug applications. He has published over 50 papers and 200 abstracts, posters and presentations. He is both a US and a Swiss citizen.

CFO: Roberto Galli. Roberto Galli was appointed chief financial officer of Newron effective 1 July 2023. He has been vice president finance of the company since 2012. He has more than 20 years of experience in industry finance and auditing. He joined Newron in 2002. He has held several management positions within the Finance Department and has been involved in the company's IPO, as well as M&A and other strategic corporate transactions: he was instrumental in finalising the European Investment Bank (EIB) funding facility. Before joining Newron, he was senior auditor & business advisor at PricewaterhouseCoopers (PwC), leading auditing projects in companies from the pharmaceutical, fashion, energy and automotive industries. He started his career as an auditor at Coopers&Lybrand. He holds a master's degree in business economics from the University Luigi Bocconi in Milan and is registered with the national register of auditors. He is also a member of the Italian Angels for Biotech association.

Newron Pharmaceuticals – Edison TV executive interview

Source: Edison Investment Research

Sensitivities

Newron is subject to the usual risks associated with drug development. It is sensitive to clinical development delays or failures, regulatory outcomes, competitor successes, partnering setbacks, as well as typical financing and commercial risks. However, we believe that some of these risks are somewhat offset by Newron's track record, as it has successfully brought Xadago to the market.

More specific sensitivities for Newron lie around ENIGMA-TRS, as its only active clinical-stage programme. This accentuates Newron's exposure to binary risk events, notably the success or failure of the Phase III programme. While the prior study 014/015 results in TRS were promising, this was an open-label trial. ENIGMA-TRS will include double-blinded trials, designed to mitigate any potential biases in the assessment of patients. The main sensitivity faced by Newron will be the ENIGMA-TRS results (12-week results for ENIGMA-TRS 1 are anticipated from Q426), and whether the data will be sufficient for regulatory approval. We note however that the decision to conduct two separate studies (one specifically focused on the US) aims to mitigate this possibility. Running two parallel studies also alleviates the chance of timeline slippages, should regulators seek a second confirmatory study.

In terms of financing the Phase III programme, Newron is currently supported by regional licensing deals in place for Japan and South Korea, somewhat mitigating the financing risk related to its clinical development plans. However, as highlighted previously, with the decision to undertake another Phase III trial, we estimate the company will need to raise fresh funds by early 2026. Note that management is actively seeking additional partnerships, and if these come into fruition, the company could have access to additional non-dilutive funding. However, forecasting the precise timing of such deals and actual deal terms is a common challenge in this sector.

The need for further funding will also be contingent on the company's ambitions to broaden its clinical pipeline, though we do not believe that it has any immediate plans to do so, as management has communicated that the evenamide programme is the current strategic priority.

Financials

Newron recently reported its FY24 results; the key highlight was the front-end loaded licensing deal with EA Pharma

(for evenamide's licensing rights in Japan), inflows from which supported the company in reporting a strong operating performance in FY24. We analysed the FY24 results in our last update note and briefly present the central points below.

FY24 revenue grew over 5.6x year-on-year to €51.4m (FY23: €9.1m), supported by the €44.4m upfront payment from EA Pharma and €6.9m in royalty inflows from its on-market drug Xadago. In the absence of further licensing deals, we expect the topline to normalise in FY25 and FY26. Total operating expenses for the year were up 21.9% y-o-y to €25.2m, driven primarily by a 53.7% y-o-y jump in G&A expenses to €11.6m. R&D expenses stayed broadly flat at €13.6m (€13.2m in FY23). Overall, benefiting from the upfront payment, Newron reported operating income of €26.2m in FY24, versus an operating loss of €11.6m in the previous year. The company recorded a profit before tax of €21.4m in FY24, compared to a loss of €16.2m in FY23, which incorporated €4.3m in interest expenses related to accrual of the outstanding €40m loan from the EIB, secured in October 2018.

Latest revisions to estimates

Following management's recent decision to conduct two Phase III trials (instead of the previously assumed single study), we have updated our forecasts to incorporate the additional R&D spending related to the second trial. We assume ENIGMA-TRS 2 will commence in Q425 and cost the company another c €25m across FY25 and FY26. We split this as €5m in FY25 and €20m in FY26. Note that while these costs are lower than the €45m estimate for ENIGMA-TRS 1, we believe this to be a reasonable assumption given the shorter study duration (12 weeks, vs 52 weeks for ENIGMA-TRS 1) and lower number of participants (400, vs 600 for ENIGMA-TRS 1). We also believe that the decision to conduct two separate Phase III trials was strategic in nature, with a view to derisking the programme (with the combined data from the two studies) and maximising the potential for success in gaining regulatory approval, particularly in the key US market (with a separate dedicated study). Adjusting for the increased R&D spending, we now forecast operating losses of €32.1m in FY25 (compared to a loss of €27.0m previously) and €34.0.0m in FY26 (loss of €13.9m previously). For details on our estimates for the other line items, we direct readers to our previous update note.

Increased funding requirements with ENIGMA-TRS 2

Newron exited FY24 with cash and cash equivalents of €9.8m and subsequently (in January 2025) realised the €44.4m upfront payment from EA Pharma, which results in a pro forma gross cash balance of €54.2m. The company also has €49.7m of debt on its books, comprising the €40m loan from the EIB and accrued interest. The first €10m tranche is due in November 2025, with the other four tranches maturing in 2026.

Reflecting the R&D expenses associated with the second Phase III study (ENIGMA-TRS 2), we raise our cash burn projections for FY25 and FY26: we now expect an operating cash inflow of €3.5m FY25 (vs an inflow of €8.6m previously) and an outflow of €39.1m in FY26 (vs €17.9m previously). Based on the increased outflows and incorporating the €10m debt repayment in November 2025, we now estimate the funds at hand provide the company with an operating runway into early FY26 (vs H126 previously). We calculate Newron needs to raise €70m in early 2026 (€50m previously) to service the remaining €30m EIB debt and continue to fund the Phase III studies. These funding requirements will change if the EIB debt repayment is renegotiated and/or rescheduled. We note that Newron has successfully renegotiated EIB repayments in the past, and we understand that management is now in discussions again with EIB to refinance the loan.

Valuation

We have revised our forecasts and valuation for Newron to reflect the company's latest announcement; we now include an additional international Phase III trial for evenamide (ENIGMA-TRS 2), with the corresponding increase in R&D expenses. We also expect the company to support the second trial (which we estimate will commence in Q425) with non-dilutive funding from other regional licensing deals for evenamide (similar to the ones in Japan and South Korea) as part of its commercial strategy. We see the largest probability of this from Latin America, China and India, with an outside opportunity from licensing the European rights ahead of Phase III completion (as our base case assumes a European licensing deal after the completion of the Phase III trials).

Another key change to our long-term estimates comes from the US opportunity. While we previously assumed that Newron would outlicense evenamide in both the US and Europe following completion of the Phase III programme, we now believe that the company may be inclined to retain commercial sales and marketing rights in the US (which is the biggest pharma market globally and has the largest commercial potential) for evenamide, while outlicensing the European sales and distribution. Based on this assumption, we have updated our model to reflect self-commercialisation in the US and outlicensing in Europe following the Phase III trial results. We have adjusted our expected licensing deal

terms, now estimating a total deal value of €250m for the European rights (vs €1bn previously, which included the US commercial rights as well), including an upfront payment of €50m to be received in FY27. For the US operations, we assume COGS and S&M expenses to be 20% and 30% of sales, respectively.

We continue to expect a market launch in 2028, assigning a 70% probability of success, with peak sales of c €1.7bn (including the US, Europe and Japan), to be achieved in 2034. Reflecting the aforementioned changes and latest forex adjustments, our valuation for Newron is now CHF392.4 or CHF19.7 per share, from CHF385.6m or CHF19.3 per share previously. A breakdown of our risk-adjusted valuation for Newron is presented in Exhibit 10.

Exhibit 10: Newron rNPV valuation

Product	Indication	Launch	Probability	rNPV (CHFm)	rNPV/share (CHF)
Xadago	Parkinson's Disease	2015	100%	22.2	1.1
Evenamide	TRS/Schizophrenia non-responders	2028	70%	427.7	21.4
Total direct product value				**449.9**	**22.5**
Direct costs to 2034 less tax				(61.8)	(3.1)
Pro-forma gross cash at end-December 2024				51.5	2.6
Loans (fair value December 2024)				(47.2)	(2.4)
Valuation				**392.4**	**19.7**

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

Note that our model currently does not include any other regional licensing deals in FY25 or FY26, with the required funding needs in FY26 presented as illustrative debt. We also remind readers that Newron has been contemplating a US equity market uplisting in 2026, which may also bring in additional liquidity. Given that the exact timing for a secondary listing would depend on the market appetite and other external factors, we do not currently factor it into our estimates.

As noted above, we estimate Newron will need €70m in funds in early 2026 (which we reflect as illustrative debt in our model) with inflows from a European licensing deal in FY27. As an added sensitivity, if we were to assume no further licensing deals and self-commercialisation by Newron in Europe, we estimate the company would need to raise an additional €30m in 2027 before achieving profitability in 2028. Should this requirement (€100m across FY26 and FY27) be fulfilled by issuing equity, we calculate the company would need to issue an additional 14.8m shares (at the current trading price of CHF6.74), resulting in the per share valuation diluting to CHF14.1, from CHF19.7 currently (shares outstanding would increase to 34.8m from 20.0 currently). We note that this would still be a material upside to the current trading price.

Exhibit 11: Financial summary

Accounts: IFRS; year end 31 December; €000s	2022	2023	2024	2025e	2026e
PROFIT & LOSS					
Total revenues	6,094	9,057	51,390	7,284	7,778
Cost of sales	0	0	0	0	0
Gross profit	6,094	9,057	51,390	7,284	7,778
Total operating expenses	(19,396)	(20,686)	(25,217)	(39,422)	(41,763)
Research and development expenses	(12,005)	(13,152)	(13,642)	(27,723)	(29,940)
G&A	(7,391)	(7,534)	(11,575)	(11,699)	(11,823)
EBITDA (normalised)	(12,620)	(11,231)	26,621	(31,742)	(33,724)
Operating income (reported)	(13,302)	(11,629)	26,173	(32,139)	(33,985)
Finance income/(expense)	(4,170)	(4,571)	(4,779)	(5,031)	(6,168)
Profit before tax (reported)	(17,472)	(16,200)	21,394	(37,170)	(40,153)
Profit before tax (normalised)	(16,992)	(16,003)	21,650	(37,170)	(40,153)
Income tax expense (includes exceptionals)	(21)	(24)	(5,551)	0	0
Net income (reported)	(17,493)	(16,224)	15,843	(37,170)	(40,153)
Net income (normalised)	(17,013)	(16,027)	16,099	(37,170)	(40,153)
Basic average number of shares, m	17,845	17,845	18,563	19,959	19,959
Basic EPS (€)	(0.98)	(0.91)	0.85	(1.86)	(2.01)
Adjusted EPS (€)	(0.95)	(0.90)	0.87	(1.86)	(2.01)
BALANCE SHEET					
Property, Plant and Equipment	72	53	43	35	28
Right of use assets (leases)	455	352	791	513	333
Non-current receivables (Tax credits)	8,175	5,809	1,970	2,057	2,152
Total non-current assets	8,702	6,214	2,804	2,606	2,513
Cash and equivalents	13,424	6,338	6,933	2,907	3,490
Current financial assets	9,350	6,261	2,893	0	0
Trade Accounts Receivable	5,719	7,053	51,278	9,278	9,278
Total current assets	28,493	19,652	61,104	12,185	12,768
Trade Accounts Payable	4,869	6,106	9,430	7,768	8,599
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	41,844	12,675
Long-term Debt	45,165	25,753	36,243	6,243	76,243
Leasing Obligations	325	210	673	387	201
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	8,658	78,472
Equity attributable to company	(14,030)	(29,908)	1,458	(35,712)	(75,865)
CASH FLOW STATEMENT					
Pre-tax profit	(17,472)	(16,200)	21,394	(37,170)	(40,153)
Net Financial Income	(1,183)	(1,162)	(1,847)	21	12
Tax	0	0	0	0	0
Depreciation and amortisation	202	201	192	396	260
Share-based payments	480	197	256	0	0
Other adjustments	4,996	5,311	144	(87)	(94)
Movements in working capital	1,885	1,513	(37,753)	40,338	831
Cash from operations (CFO)	(11,092)	(10,140)	(17,614)	3,498	(39,144)
Capex	(18)	(11)	(13)	(111)	(73)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	(299)	3,257	3,171	2,893	0
Cash used in investing activities (CFIA)	(317)	3,246	3,158	2,782	(73)
Loans received	0	0	0	0	70,000
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)	(307)	(199)
Cash from financing activities (CFF)	(186)	(192)	15,051	(10,307)	39,801
Cash and equivalents at beginning of period	25,019	13,424	6,338	6,933	2,907
Increase/(decrease) in cash and equivalents	(11,595)	(7,086)	595	(4,026)	584
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	2,907	3,490
Net (debt)/cash (including liquid resources)	(22,391)	(35,431)	(39,831)	(36,750)	(76,167)

Source: Company documents, Edison Investment Research

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Revenue by geography

N/A

Management team

CEO: Stefan Weber

Stefan Weber was appointed CEO and executive director of Newron in 2012. He had been CFO of the company since April 2005. Stefan holds a master's degree in business management from FernUniversität Hagen (Diplom-Kaufmann). He has more than 30 years of industry experience in finance and general management. From 2001 to 2005, he was the CFO of Biofrontera, a company active in drug discovery and development. He joined Girindus, a fine chemistry process development and scale-up provider, in 1999, and was appointed CFO in 2000. From 1987 to 1999, he was with Lohmann Group, a worldwide producer of pharmaceutical, medical, technical and consumer products. His final position was head of finance. Stefan has executed numerous major financing transactions, debt, equity and mezzanine as well as national and European grants. He has also executed successful IPOs to the Frankfurt and Zurich stock exchanges and has been involved in a number of M&A transactions, divestments and strategic restructurings. He is German.

CMO: Ravi Anand

Ravi Anand, a Swiss resident, has been the company's chief medical officer since 2005. He received his university education in New Delhi, India, and his medical training, specialising in psychiatry and neurology, in the US. For over 20 years, Ravi has worked in international drug development and regulatory affairs at major pharmaceutical companies, including F. Hoffmann-La Roche (Switzerland), Sandoz/Novartis (US) and Organon (Netherlands). From 1993 to 1997, Ravi was the medical director of CNS, Clinical Research at Sandoz Research Institute. From 1997 to 2001, he served as the international head of CNS medical affairs at Novartis and, from 2001 to 2003, as the global head of CNS clinical research at Organon. Since 2003, Ravi has been acting as a consultant for Newron and other clients. During his tenure in the pharmaceutical industry, he worked in all phases (I through III) of drug development as well as in post-marketing studies (Phase IV). In total, he has been responsible for the conduct of clinical trials in over 30 countries and been involved in over 30 investigational new drug applications and over seven international new drug applications. He has published over 50 papers and 200 abstracts, posters and presentations. He is both a US and a Swiss citizen.

CFO: Roberto Galli

Roberto Galli was appointed CFO of Newron effective 1 July 2023. He has been vice president finance of the company since 2012. He has more than 20 years of experience in industry finance and auditing. He joined Newron in 2002. He has held several management positions within the Finance Department and was involved in the company's IPO, as well as M&A and other strategic corporate transactions: he was instrumental in finalising the EIB funding facility. Before joining Newron, he was senior auditor & business advisor at PwC, leading auditing projects in companies from the pharmaceutical, fashion, energy and automotive industries. He started his career as an auditor at Coopers&Lybrand. He holds a master's degree in business economics from the University Luigi Bocconi in Milan and is registered with the national register of auditors. He is also a member of the Italian Angels for Biotech association. Roberto Galli is Italian.

VP Commercial Affairs: Dennis Dionne

Dennis Dionne has been vice president of commercial affairs since January 2017. He joined Newron as executive director of commercial operations in 2015. Dennis has tremendous experience in the CNS arena and served in a variety of commercial leadership roles at Johnson & Johnson (21 years) and Novartis (six years) and has pioneered a number of small venture start-ups. He has proven abilities in planning and management at both strategic and operational levels, including building full life-cycle commercial strategies at the pre-launch stage and managing the business through various stages of growth. Dennis holds a BA in biology and chemistry from Roger Williams University, Bristol, Rhode Island, and has successfully completed executive leadership programs in general management and operational leadership, commercial policies and practices, marketing and project management and global cross-functional team leadership. Dennis Dionne is a US citizen.

VP Operations: Filippo Moriggia

Filippo Moriggia was appointed vice president of operations effective 1 July 2022. He has held several management positions, including in IT, HR and compliance responsibilities, since he joined Newron in 2016. He has more than 15 years of experience as an IT professional advisor. He started his career as a technical editor for different national magazines of the Mondadori Group. He holds a master's degree in engineering from the Politecnico di Milano and has been a licensed professional engineer since 2005. Filippo Moriggia is Italian.

VP Business Development: Laura Faravelli

Laura Faravelli was appointed vice president of business development on 1 July 2023. Since 2015, Laura has held various management roles in Newron's business development function. She has over 20 years of experience in international research, development and regulatory approval of new products for CNS indications and in drug repositioning. Laura holds a PhD in neurobiology and a master's degree in regulatory affairs and market access. Before transitioning to business development, she held management positions in Newron's R&D unit, including in discovery, pharmacology research and non-clinical development, contributing to successful European Medicines Agency marketing authorisation application (MAA) and US Food and Drug Administration new drug application (NDA) processes. She started her post-academic career at Pharmacia & Upjohn. Laura Faravelli is Italian.

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	%
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Heights Capital Management	2.8%
Zürcher Kantonalbank	1.8%
UBS Fund Management	1.3%
UBS Asset Management	1.0%
Baader Bank	0.8%
Aramea Asset Management	0.4%
DJE Kapital	0.3%

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