

**FOCUS AREA: DISEASES OF THE CENTRAL NERVOUS SYSTEM (CNS) AND ORPHAN DISEASES**

KEY DATA		SIX: NWRN	
MARKET CAPITALIZATION (CHF MN)	147	PRICE ON 30 APRIL 2024	8.2
ENTERPRISE VALUE (CHF MN)	134	RISK-ADJUSTED NPV PER SHARE (CHF)	17.3
CASH (31 DECEMBER 2023) (CHF MN)	12	UPSIDE/DOWNSIDE (%)	110%
MONTHLY OPERATING EXPENSE (CHF MN)	1.4	RISK PROFILE	HIGH RISK
CASH RUNWAY (YEAR)	WELL INTO 2025	SUCCESS PROBABILITY LEAD PIPELINE DRUG	65%
BREAK-EVEN (YEAR)	2024*	EMPLOYEES (GROUP)	22
FOUNDED (YEAR)	1998	LISTED (YEAR)	2006
KEY PRODUCTS:	STATUS	MAJOR SHAREHOLDERS:	(%)
- XADAGO (PARKINSON'S DISEASE)	MARKETED	- ZAMBON GROUP	4.4
- EVENAMIDE (NON-TREATMENT-RESISTANT SCHIZOPHRENIA - NON-TRS)	POSITIVE PHASE II/III	- EUROPEAN INVESTMENT BANK	3.7
- EVENAMIDE (TREATMENT-RESISTANT SCHIZOPHRENIA (TRS) INCL. CTRS**)	POC ESTABLISHED	- EXECUTIVE MANAGEMENT	0.6
		- FREE FLOAT	99.4
		- AVERAGE TRADING VOLUME (30-DAYS)	66'804
UPCOMING CATALYSTS:	DATE	ANALYST(S):	BOB POOLER
- EVENAMIDE - RELEASE MORE DETAILED "STUDY 008A" DATA	COMING WEEKS		BP@VALUATIONLAB.COM
- EVENAMIDE - PARTNERING AGREEMENT	BEFORE START "STUDY 017"		+41 79 652 67 68
- EVENAMIDE - START PIVOTAL "STUDY 017" IN TRS* PATIENTS	Q4 2024		

\* ASSUMES PARTNERING EVENAMIDE IN 2024; \*\*CTRS = CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA; \* TRS = TREATMENT-RESISTANT SCHIZOPHRENIA  
 ESTIMATES AS OF 1 MAY 2024

SOURCE: VALUATIONLAB ESTIMATES, NEWRON PHARMACEUTICALS

# A pivotal year

## Positive "Study 008A" results to trigger a partnering deal

Newron Pharmaceuticals has a product pipeline that targets diseases of the peripheral & central nervous system (CNS) and rare diseases. Key value drivers include 1) Xadago, a once-daily oral add-on therapy for Parkinson's disease with a unique dual mechanism of action, launched in the EU (2015), US (2017), and Japan (2019), and 2) evenamide, an add-on therapy for schizophrenia and treatment-resistant schizophrenia (TRS), including CTRS (clozapine treatment-resistant schizophrenia, an orphan-like indication). With cash and current financial assets of EUR 12.6 mn (31 December 2023), increasing Xadago revenues, Italian R&D tax credits, and a recent share subscription by an institutional healthcare investor, Newron sees a cash runway well into 2025. The company is adequately funded beyond its key value inflection points, including the first of two potentially pivotal phase II/III trials with evenamide in schizophrenia and TRS. We derive a sum-of-parts risk-adjusted (r)NPV value of CHF 17.3 per share, with 8% of the value related to Xadago, 89% to evenamide, and 3% to cash. Newron's risk profile is High Risk as the company is loss-making with revenues only from Xadago royalties in Parkinson's disease.

### Key catalysts:

- **Release of more detailed data of "Study 008A" (coming weeks):** This is helpful to better understand the impact evenamide may have in schizophrenia patients who are inadequate responders to second-generation antipsychotics with implications for market penetration and potential pricing.
- **Partnering evenamide with a major CNS player (before starting "Study 017"):** Out-licensing evenamide to a major CNS player in return for substantial upfront, regulatory, and sales milestones and royalties on sales extends the cash runway substantially and can be used to in-license new CNS compounds and sell evenamide in CTRS through a small in-house commercial team of key account managers in the US.
- **Start pivotal "Study 017" trial of evenamide in TRS (Q4 2024):** this marks the second potentially pivotal phase III trial needed for approval of evenamide in schizophrenia, including (clozapine) treatment-resistant schizophrenia; our success rate increases to 50% (phase II/III trial) from 35% (POC established) resulting in an increase of our rNPV by CHF 1.0 per share.

# Flash Update

## **Evenamide meets primary and key secondary endpoint in pivotal “Study 008A” in schizophrenia inadequate responders – first-ever add-on treatment to show a benefit on top of current treatment – lucrative partnering deal for evenamide expected shortly**

On 30 April 2024, positive top-line results were reported from evenamide’s potentially pivotal phase II/III trial, “Study 008A, evaluating the safety, tolerability, and efficacy of evenamide 30 mg twice-daily (BID) in patients with chronic schizophrenia treated with a second-generation antipsychotic including clozapine, but with an inadequate response to current treatment. The trial met its primary endpoint of improvement on the Positive and Negative Syndrome Scale (PANSS) Total Score and the key secondary endpoint of improvement of the Clinical Global Impression of Severity (CGI-S) after only 4 weeks of treatment. The favorable safety profile was confirmed, with 96% of patients completing the trial. These results, together with the recently reported one-year efficacy results of the POC trial “Study 014/015” in treatment-resistant schizophrenia (TRS) patients, confirm the central role of glutamate in finding new treatments for schizophrenia patients. Following these positive pivotal results and the exciting results in TRS, we expect Newron to sign a lucrative partnering agreement with a major CNS player, replenishing its cash position and funding the start of the second pivotal phase III trial, “Study 017” of evenamide in TRS planned to start in Q4 2024.

“**Study 008A**” was an international, four-week, randomized, double-blind, and placebo-controlled, potentially pivotal phase IIb/III trial performed in 45 trial centers in 11 countries in Europe, Asia, and Latin America. The trial was designed to evaluate the efficacy, tolerability, and safety (including effects on electroencephalogram (EEG) of the 30 mg twice-daily (BID) dose of evenamide in chronic moderate to severe schizophrenia patients on second-generation antipsychotics, including clozapine. 291 patients were enrolled and randomized equally in two treatment arms:

**Arm 1)** Evenamide 30 mg BID as an add-on to their current second-generation antipsychotic

**Arm 2)** Placebo as an add-on to their current second-generation antipsychotic

The primary endpoint was the improvement in the Positive and Negative Symptom Scale (PANSS) Total Score from baseline. The PANSS is a frequently used scale to rate the symptoms of schizophrenia. Secondary endpoints include additional efficacy scores and safety and tolerability measures, including the Clinical Global Impression of Severity (CGI-S) scale, which is used to establish how mentally ill a patient is.

**Primary endpoint met:** In “Study 008A”, the addition of 30 mg (BID) of evenamide to the patients’ current antipsychotic medication was associated with a highly statistically significant ( $p$ -value = 0.006) reduction (= improvement) in the PANSS Total Score of 10.2 points, compared to 7.6 points in patients treated with placebo at day 29; the least square mean difference (LS mean difference) was 2.5.

**Key secondary endpoint met:** For the key secondary measure, the Clinical Global Impression of Severity (CGI-S), the LS mean difference between patients treated with evenamide and placebo was 0.16 with a statistically significant  $p$ -value of 0.037.

**Safety profile confirmed:** The favorable safety and tolerability profile of evenamide was confirmed with a high completion rate. Of the 291 patients, 280 (96%) completed the trial, with only three (1%) patients discontinuing due to adverse events; two of them on evenamide and one patient on placebo who died during the trial. No new or specific adverse events were seen in the trial; only 25% of the patients in the trial experienced at least one adverse event (evenamide 25% versus placebo 25.8%). There was no difference in the incidence of CNS (central nervous system), psychiatric, gastrointestinal, or other side effects between evenamide and placebo. The most common side effects reported in the evenamide group were headache, nasopharyngitis (common cold), and vomiting (three patients each). Similar numbers of patients on placebo experienced these adverse events.

**Additional details from “Study 008A”** will be disclosed in the coming weeks.

**Impact on pivotal trial “Study 017” in TRS:** Based on the positive findings in the pivotal “Study 008A” of evenamide in chronic schizophrenia, Newron plans minor tweaks to the second pivotal trial “Study 017” in TRS, including a potential extra efficacy measure, monitoring criteria, training of investigators, statistical plan, and using the intent-to-treat (ITT) population now required by the regulators instead of the modified intent-to-treat (mITT) population. This could lead to a small delay of 1-2 months on the start of “Study 017”, which was originally planned for Q3 2024.

**Lucrative partnering deal with a major CNS player before starting “Study 017” in Q4**  
Based on the positive topline results of the first potentially pivotal trial, “Study 008A” of evenamide in chronic schizophrenia patients who inadequately respond to current antipsychotic therapy and the unprecedented findings of the “Study 014/015” trial in TRS, we expect Newron to sign a global (co)development and commercialization agreement with a major CNS player shortly, in return for substantial upfront, regulatory and sales milestones and royalties on sales before the starting the second pivotal “Study 017” of evenamide in TRS now planned for Q4 2024. This should strengthen the company’s cash position substantially with the potential to in-license external CNS and rare disease clinical compounds. We assume Newron will sell evenamide in the CTRS orphan indication in the lucrative US market through a small in-house commercialization team of key account managers to optimize its long-term value.



### **Italian biopharmaceutical company specializing in CNS and rare diseases**

Newron Pharmaceuticals S.p.A. is an Italian biopharmaceutical company specializing in prescription drugs to treat peripheral & central nervous system (CNS) disorders and rare, so-called orphan diseases, with expertise in ion channel blockers, an important class of CNS drugs. Newron is based in Bresso, near Milan, Italy, and was established in December 1998 as a spin-off from Pharmacia & Upjohn (now part of Pfizer). In 2014, the company opened a US office in Morristown, New Jersey, USA. Currently, the group has 23 employees. Newron was listed on the SIX Swiss Stock Exchange in 2006 with the ticker code “NWRN”. In addition to the primary listing in Switzerland, Newron began trading in Germany on the Düsseldorf Stock Exchange and XETRA (ticker code “NP5”) to facilitate access for investors based in the EU via EU brokers in 2019.

### **Strategy to develop CNS drug to an optimal value, then out-license major indications and preferably market orphan indications by an own small specialist salesforce**

Newron's strategy is to develop drugs originated from earlier discovery capabilities, acquire or in-license CNS disease drugs and develop them to their optimal value, and in case of rare diseases like evenamide in clozapine treatment-resistant schizophrenia (CTRS), whenever possible, commercialize them to optimize long-term value. Where necessary or advantageous, the company seeks co-development and commercialization agreements to reduce research and development costs and generate revenue through R&D funding, milestone payments, and royalties on future sales.

### **Newron's pipeline consists of a nice mix of major and rare disease indications**

Newron's pipeline consists of a nice mix of major indications, such as Xadago, which already generates revenues through its partners in Parkinson's disease, and evenamide as an add-on to antipsychotics in schizophrenia, and an orphan-like indication, such as evenamide in CTRS (clozapine treatment-resistant schizophrenia) with a high unmet medical need. Substantial value will be unlocked with the approval and launch of evenamide in schizophrenia with blockbuster sales potential. Newron's individual products include:

- **Evenamide – A new paradigm in schizophrenia, transformational potential**

Evenamide is Newron's pipeline project with the highest peak sales potential, targeting a USD 12 bn schizophrenia market, and will be transformational for Newron upon approval. In 2017, evenamide established proof-of-concept (POC) as an add-on to current antipsychotics in patients with schizophrenia. The compound is being developed as an add-on treatment for 1) non-treatment-resistant schizophrenia (non-TRS) patients experiencing inadequate response to current atypical antipsychotic monotherapy and 2) treatment-resistant schizophrenia (TRS) patients who are not responding adequately to any second-generation antipsychotics, including the orphan-like indication clozapine treatment-resistant schizophrenia (CTRS), covering roughly 70% of schizophrenia patients. Approximately 30% of schizophrenia patients respond well to monotherapy.

Health authorities (Spain, Denmark, Sweden, Germany, UK, CHMP, US, Canada) have agreed with the current phase III development program for evenamide in schizophrenia. In 2021, Newron provided additional informative trials requested by the FDA before starting phase III development. The preclinical part of the safety work was completed and submitted to the FDA with no toxicity issues reported. The first 4-week clinical safety (EEG – electroencephalogram) trial dubbed “Study 008” in 138 patients was completed in March 2021, with no safety issues.

**“Study 014/015”:** In January 2024, unprecedented topline results were presented of the open-label (unblinded) phase II “Study 014/015” safety and dose-ranging trial of evenamide (twice daily 7.5 mg, 15 mg, or 30 mg evenamide, no placebo) as an add-on to current antipsychotics (excluding clozapine) in 161 patients suffering from TRS. This was the final safety requirement by the FDA before starting phase III development in schizophrenia.

**“Study 008A”:** On 30 April 2024, positive topline results were reported of the first potentially pivotal phase II/III “Study 008A” trial of evenamide in 291 non-TRS patients in Europe, Asia, and Latin America. Evenamide met its primary endpoint, a statistically significant reduction in the PANSS Total Score, and its key secondary endpoint, the CGI-S scale, after only 4 weeks of evenamide treatment on top of current antipsychotic therapy, including clozapine. Its favorable safety and tolerability profile was confirmed.

**“Study 017”:** Newron plans to start the potentially pivotal phase III “Study 017” trial of evenamide in TRS patients in Q4 2024. Newron plans to recruit roughly 15-20% of clozapine treatment-resistant schizophrenia (CTRS) patients to address this orphan-like population. If the exceptional results seen in “Study 014/015” are replicated, approval of evenamide in TRS could follow swiftly based on this single pivotal trial alone. Evenamide could become the first drug for TRS since clozapine in 1989.

**Co-development and commercialization partner:** The company plans to out-license evenamide to global and/or local CNS players for substantial upfront, regulatory, and sales milestones and royalties on sales. This is expected to occur before the start of the pivotal “Study 017” in Q4 2024. Newron would like to commercialize evenamide in CTRS in the lucrative US market to optimize the long-term value, as limited marketing resources are required for this niche indication.

- **Xadago – First product to reach market – sales uptake hampered by generics**  
Xadago (safinamide) is Newron’s first-ever approved drug for treating patients with mid-to-late-stage Parkinson’s disease and was launched by its partners in the EU in 2015 and in the US in 2017 and in Canada (branded Onstryv) and Japan (branded Equfina) in 2019. Xadago stems from Newron’s earlier ion channel discovery capabilities and is the first New Chemical Entity (NCE) approved and launched for treating Parkinson’s disease in over a decade. The company receives sales royalties and milestone payments from its development and commercialization partners Zambon (worldwide rights excluding Meiji Seika territories) and Meiji Seika (Japan and Asia). Uptake in the lucrative US market (marketed by Supernus Pharma) is hampered by widespread cheap generic versions of Teva’s Azilect (rasagiline), which belongs to the same drug class as Xadago. In 2021, several generic manufacturers filed Paragraph IV ANDA’s for Xadago in the US. Newron and its partners Zambon and Supernus have reached a settlement agreement with the generic manufacturers, allowing them to enter the US market no earlier than 1 December 2027. Supplementary Protection Certificates (SPCs) have been approved in most major markets, and Newron is confident these will be granted in all key territories, providing protection until 2029.

### **Newron sufficiently funded into 2025 beyond key value inflection points**

With EUR 12.6 mn in cash and short-term investments (31 December 2023), increasing royalty payments on Xadago sales, Italian R&D tax credits (approximately EUR 16 mn in the next 2 years), the recent share subscription agreement with an institutional healthcare

investor with up to EUR 15 mn in funding, and the deferral of the repayment of the first three tranches of the EUR 40 mn EIB loan by roughly 1 ½ years now starting in November 2025, Newron expects to be sufficiently funded well into 2025 beyond key value inflection points.

Following the positive topline results of the pivotal trial “Study 008A” and unprecedented “Study 014/015” topline results, Newron is evaluating potential options for partnering or co-developing evenamide in schizophrenia to share the development risk, reduce the cash burn, and replenish its cash position. This will increase financial flexibility, which can be used to broaden the pipeline with promising external CNS compounds.

**Newron’s key priorities in the next 12-18 months include:**

- The continued rollout of Xadago in Parkinson’s disease by its partners in new countries/areas and contracting new commercialization/distribution partners for Xadago beyond the EU, US, Japan, and Asia.
- Submit the pivotal phase II/III “Study 008A” trial results of evenamide in schizophrenia to the US and EU regulators.
- Submit the exciting “Study 014/015” trial results to the FDA to address the remaining safety issues and finalize the protocol for the pivotal “Study 017” trial of evenamide in TRS.
- Determine potential options for global or local partnering or co-development and commercialization of evenamide before the start of the pivotal “Study 017”.
- Start the second pivotal “Study 017” trial of evenamide in TRS patients in Q4 2024
- Seek new CNS development projects to replenish the company’s development pipeline.

# Valuation Overview

## Sum-of-parts risk-adjusted (r)NPV points to a fair value of CHF 17.3 per share

We derive a sum-of-parts rNPV of CHF 17.3 per share, with cash of CHF 0.8 per share (31 December 2023), overhead of CHF 6.9 per share (including the repayment of the EUR 40 mn EIB loan starting in November 2025), with a WACC of 10% (consisting of a market risk premium of 6%, a beta of 1.5, and a risk-free rate (10-year Swiss bond yield) of 1%).

SUM OF PARTS							
PRODUCT NAME	INDICATION	PEAK SALES (EUR MN)	LAUNCH YEAR	UNADJUSTED NPV/SHARE	SUCCESS PROBABILITY	RISK-ADJUSTED NPV/SHARE (CHF)	PERCENTAGE OF TOTAL
XADAGO (SAFINAMIDE)	PARKINSON'S DISEASE	91	2015 (EU)   2017 (US)	1.9	100%	1.9	8%
EVENAMIDE	SCHIZOPHRENIA (INADEQUATE RESPONDERS, TRS*)	910	2027	29.4	65%	19.1	79%
EVENAMIDE	CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA (CTRS)	139	2027	7.0	35%	2.4	10%
RALFINAMIDE	NEUROPATHIC PAIN	NON CORE					
CASH & CASH EQUIVALENTS (31 DECEMBER 2023)				0.8		0.8	3%
<b>TOTAL ASSETS</b>				<b>39.0</b>		<b>24.2</b>	<b>100%</b>
OVERHEAD EXPENSES (INCLUDING REPAYMENT OF THE EUR 40 MN EIB LOAN)				-6.9		-6.9	
<b>NPV/SHARE (CHF)</b>				<b>32.1</b>		<b>17.3</b>	
PRICE ON 30 APRIL 2024						8.2	
PERCENTAGE UPSIDE / (DOWNSIDE)						110%	
* TRS - TREATMENT RESISTANT SCHIZOPHRENIA							
ESTIMATES AS OF 1 MAY 2024							

SOURCE: VALUATIONLAB ESTIMATES

## Newron's key value drivers include:

### Xadago (Parkinson's disease) - NPV of CHF 1.9 per share

Xadago is Newron's first-ever drug to be approved and launched and marks the first new chemical entity (NCE) for Parkinson's disease in over a decade. The drug was launched in the EU (2015), in the US (2017), and in Japan (2019) to treat mid-to-late-stage Parkinson's disease. In the lucrative US market, sales uptake continues to be hampered by cheap generic versions of Teva's Azilect (rasagiline), which belongs to the same drug class as Xadago. Following the agreement with generic manufacturers we now assume generic versions of Xadago to enter the US market as early as December 2027 (previously 2031). We assume Newron will receive from its partners Zambon (and sub-licensors) and Meiji Seika (and partner Eisai) royalties on sales ranging between 10-12% in EU/ROW, 7% in the US, and 2.5% in Japan. We calculate an NPV of CHF 1.9 per share with peak sales of around EUR 90 mn for Xadago in Parkinson's disease.

### Evenamide (schizophrenia) – risk-adjusted NPV of CHF 19.1 per share

Evenamide targets a global USD 17 bn antipsychotics market. Evenamide could become the first add-on antipsychotic to be approved for inadequately responding and treatment-resistant schizophrenia (TRS) patients and the first drug for TRS since the approval of clozapine in 1989. In April 2024, Newron reported positive topline results of the first potentially pivotal phase II/III "Study 008A" trial of evenamide in non-TRS patients who inadequately respond to current antipsychotic monotherapy, including clozapine. The second pivotal "Study 017" phase III trial of evenamide in TRS is expected to start in Q4 2024, with topline results expected approximately 18 months later. Based on the positive "Study 008A" trial results and the exciting one-year efficacy data seen in "Study 014/015" in TRS, we assume Newron to out-license evenamide to a major CNS player for substantial upfront, regulatory, and sales milestone payments and royalties on sales. We forecast peak sales for evenamide to amount to around EUR 900+ mn in schizophrenia and TRS (excluding CTRS), with the first launches in H1 2027. We calculate an rNPV of CHF 19.1 per share with a conservative 65% (positive single pivotal phase II/III) success rate, with Newron receiving up to EUR 387 mn in global upfront, development, regulatory, and sales



milestones and 15% royalties on net sales.

### **Evenamide (CTRS) – risk-adjusted NPV of CHF 2.4 per share**

Newron's development plans for evenamide to include clozapine treatment-resistant schizophrenia (CTRS) next to schizophrenia were triggered by the high unmet medical need for new treatments, with studies suggesting the involvement of the glutamate system in CTRS and US orphan disease designation. CTRS provides a fast-to-market indication (we expect the US launch in H1 2027 based on accelerated approval) with 7-year orphan disease market exclusivity upon US approval. We assume Newron to commercialize evenamide in CTRS in the US through a small in-house commercial team of key account managers and seek partners outside the US in return for EUR 15 mn upfront, development, regulatory, and sales milestones, and 15% royalties on net sales. We forecast peak sales to amount to EUR 139 mn. Our rNPV is CHF 2.4 per share with a conservative 35% (proof-of-concept established) success rate.

**NOTE:** Our success rate for evenamide in CTRS will increase to 50% (single potentially pivotal trial) when the second pivotal "Study 017" phase III trial of evenamide in TRS, including CTRS, starts in Q4 2024. Consequently, our rNPV for evenamide in CTRS will increase by CHF 1.0 per share to CHF 3.4 per share.

An additional upside to our forecasts could come from higher pricing if the results of the phase III program point to a new treatment paradigm with evenamide increasing quality of life and significantly reducing the social burden. CTRS patients consume the most resources of all schizophrenia patients and would justify higher pricing if evenamide is effective.

## Sensitivities that can influence our valuation

**Development risk:** With Xadago approved in the major markets, Newron's major risk is the development risk of evenamide as an add-on therapy for treating schizophrenia and CTRS. We have a conservative 65% (positive potentially pivotal phase II/III) success rate for evenamide in schizophrenia. Our 35% (POC established) success rate for CTRS will also increase to 50% once the phase III "Study 017" trial in TRS starts in Q4 2024. Successful development and approval of evenamide in schizophrenia will be transformational for Newron. The company has secured the necessary funds to develop evenamide in schizophrenia and CTRS. Additional funding is expected from the (global) partnering of evenamide.

**Pricing and reimbursement:** Following EMA and FDA approval, Xadago and evenamide must be priced and reimbursed by local healthcare providers. In the EU, pricing and reimbursement occur on a country-by-country base, leading to different pricing and reimbursement and potential market launch delays. Pricing and reimbursement have been established in the US.

**Partnering:** In 2012, Newron out-licensed Xadago to Zambon, which gained worldwide rights, excluding Japan and Asia, which Meiji Seika acquired. Zambon lacks a strong CNS presence in all markets and needs to secure strong commercialization partners in some regions. In June 2020, Supernus Pharmaceuticals acquired the commercial rights of Xadago from US WorldMeds for the critical US market. We assume Newron to seek a global (co)development and commercialization partner for evenamide in schizophrenia in return for substantial upfront, development, regulatory and sales milestones, and royalties on sales. Partnering will reduce the development risk and cash burn and increase financial flexibility for Newron to acquire external CNS clinical compounds to boost its pipeline. Timing and terms could differ from our forecasts.

**Commercialization:** Newron's revenues and earnings for Xadago are entirely dependent on its commercialization partners to position successfully and market Xadago against existing Parkinson's treatments such as Teva's Azilect (rasagiline) and generic versions of rasagiline. Newron needs a major CNS player to commercialize evenamide in schizophrenia and other antipsychotic indications successfully. Revenues and earnings for evenamide in schizophrenia will depend entirely on its commercialization partner to successfully position and market evenamide against existing and new treatments. Newron plans to sell evenamide in CTRS in the US with a small in-house commercial team of key account managers, which could require additional funding.

**Patent and market exclusivity:** Xadago's composition of matter patent expired in 2010. Patent protection and market exclusivity beyond this period rely heavily on the combination patent with levodopa that runs until 2024 (EU) and 2026 (US) with extensions of up to 5 years. A synthesis patent provides additional protection until 2027. We assume patent protection for Xadago in the EU/ROW until 2029 and following an agreement with several generic manufacturers who filed a Paragraph IV ANDA for Xadago in the US until December 2027. Evenamide's patent protection runs until 2028, with extensions of up to another five years. NCE (new chemical entity) exclusivity amounts to 5 years in the US, orphan disease exclusivity adds 7 years upon US approval, while data protection provides 10-year exclusivity in the EU.

# Catalysts

CATALYST TIMELINES					
TIME LINE	PRODUCT	INDICATION	MILESTONE	COMMENT	IMPACT ON RNPV/SHARE
<b>2024</b>					
4 JAN	EVENAMIDE	TREATMENT-RESISTANT SCHIZOPHRENIA (TRS)	"STUDY 014/15" - FINAL (1-YEAR) RESULTS	FINAL RESULTS OF THE 1-YEAR "STUDY 015" EXTENSION TRIAL OF EVENAMIDE AS ADD-ON TREATMENT TO ANTIPSYCHOTICS IN TRS SHOW UNPRECEDENTED RESULTS WITH >70% PATIENTS HAVING MEANINGFUL REDUCTION IN DISEASE SEVERITY, ~50% OF PATIENTS NO LONGER MEETING TRS PROTOCOL SEVERITY CRITERIA, AND ~25% ACHIEVING REMISSION (NEVER SEEN BEFORE IN A TRS TRIAL)	
14 MAR			SHARE SUBSCRIPTION AGREEMENT WITH INSTITUTIONAL INVESTOR	SHARE SUBSCRIPTION AGREEMENT WITH AND INSTITUTIONAL INVESTOR FOCUSED ON HIGH-GROWTH HEALTHCARE FIRMS; AN INITIAL 750,000 NEWLY ISSUED SHARES AT A SUBSCRIPTION PRICE OF EUR 7.33/SHARE WITH GROSS PROCEEDS OF EUR 5.5 MN; UP TO AN ADDITIONAL 1.3 MN NEWLY ISSUED SHARES UNTIL NO LATER THAN 31 JANUARY 2025 AT A SUBSCRIPTION PRICE ACCORDING TO AN AGREED FORMULA AMOUNTING UP TO EUR 9.5 MN IN ADDITIONAL PROCEEDS	
15 MAR			EIB AGREEMENT TO EXTEND EARLY TRANCHE REPAYMENT DATES	AGREEMENT WITH EIB (EUROPEAN INVESTMENT BANK) ON EUR 40 MN LOAN TO SHIFT REPAYMENT OF TRANCHES 1 (EUR 10 MN), 2 (EUR 7.5 MN) AND 3 (EUR 7.5 MN) FROM JUNE 2024 TO APRIL 2025 FOR NOVEMBER 2025, APRIL 2026 AND JUNE 2026 RESPECTIVELY; DUE DATES FOR TRANCHES 4 (EUR 7.5 MN) SEPTEMBER 2026 AND TRANCHE 5 (EUR 7.5 MN) OCTOBER 2026 REMAIN UNCHANGED; THE EIB WILL QUALIFY FOR CERTAIN PERFORMANCE-BASED RENUMERATION	
19 MAR			FY 2023 RESULTS	CASH: EUR 12.6 MN (31 DECEMBER 2023) WITH CASH RUNWAY WELL INTO 2025 (INCLUDING ROYALTY INCOME & R&D TAX CREDIT, RECENT PROCEEDS RAISED UP TO EUR 15 MN); 2023 TOTAL REVENUES: EUR 9.1 MN (+49%) LARGELY FROM XADAGO ROYALTIES AND OTHER INCOME FROM CONTRACTS WITH CUSTOMERS	
17 APR			AGM	MARGARITA CHAVEZ APPOINTED AS MEMBER OF THE BOARD; ALL MOTIONS FOR THE ORDINARY PART OF AGM APPROVED; MOTIONS ON AGENDA FOR EXTRAORDINARY PART OF MEETING NOT PUT TO VOTE AS REQUIRED QUORUM NOT REACHED	
30 APR	EVENAMIDE	NON-TREATMENT-RESISTANT RESISTANT SCHIZOPHRENIA (NTRS)	"STUDY 008A" - POSITIVE TOPLINE RESULTS (1ST PIVOTAL TRIAL)	<b>POSITIVE TOPLINE RESULTS REPORTED OF THE FIRST POTENTIALLY PIVOTAL PHASE III/III "STUDY 008A" OF EVENAMIDE AS AN ADD-ON THERAPY IN SCHIZOPHRENIA PATIENTS WHO ARE INADEQUATE RESPONDERS TO SECOND-GENERATION ANTIPSYCHOTICS, A DOUBLE-BLINDED TRIAL IN 291 PATIENTS RANDOMIZED TO 30 MG BID EVENAMIDE AND PLACEBO AND TREATED FOR 4 WEEKS</b>  <b>PRIMARY END POINT MET</b> WITH A STATISTICALLY SIGNIFICANT (P-VALUE = 0.006) REDUCTION IN THE PANSS TOTAL SCORE OF 10.2 POINTS VS. 7.6 FOR PLACEBO  <b>KEY SECONDARY END POINT MET</b> WITH THE CGI-S WITH THE LS MEAN DIFFERENCE BETWEEN PATIENTS TREATED WITH EVENAMIDE AND PLACEBO OF 0.16 WITH A P-VALUE OF 0.037	
BEFORE START "STUDY 017"	EVENAMIDE	SCHIZOPHRENIA	POTENTIAL PARTNERING AGREEMENT(S)	NEWRON EXPECTS A POTENTIAL (CO-) DEVELOPMENT AND COMMERCIALIZATION AGREEMENT(S) WITH (A) MAJOR CNS PLAYER(S) FOR EVENAMIDE TO ENHANCE DEVELOPMENT AND COMMERCIALIZATION, REDUCE CASH BURN AND STRENGTHEN ITS CASH POSITION	
19 SEP Q4	EVENAMIDE	TREATMENT-RESISTANT SCHIZOPHRENIA (TRS)	H1 2024 RESULTS START "STUDY 017" (2ND PIVOTAL TRIAL)	H1 2024 RESULTS RELEASE; TYPICALLY NO CONFERENCE CALL START SECOND POTENTIALLY PIVOTAL PHASE III "STUDY 017" OF EVENAMIDE IN TREATMENT-RESISTANT SCHIZOPHRENIA (TRS) INCLUDING CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA (CTRS) IN PATIENTS WITH ONE OF THE LEADING 2ND GENERATION ANTIPSYCHOTICS; 12-WEEK, RANDOMIZED, DOUBLE-BLIND PLACEBO-CONTROLLED GLOBAL TRIAL IN >510 TRS PATIENTS; TOPLINE RESULTS END 2025	+ CHF 1.0
DURING 2024			EXTERNAL CNS PIPELINE PRODUCTS	ONGOING SEARCH FOR STRATEGICALLY RELEVANT ASSETS TO ADD TO NEWRON'S CNS PIPELINE	

ESTIMATES AS OF 1 MAY 2024

SOURCE: VALUATIONLAB ESTIMATES, NEWRON PHARMACEUTICALS

# Forecasts & Sensitivity Analysis

## Schizophrenia - Inadequate responders (non-TRS) and TRS (excl. CTRS)

EVENAMIDE - FINANCIAL FORECASTS FOR SCHIZOPHRENIA												
<b>INDICATION</b>	ADD-ON THERAPY TO ANTIPSYCHOTICS FOR REDUCING POSITIVE SYMPTOMS AND PSYCHOTIC WORSENING IN PATIENTS WITH SCHIZOPHRENIA											
<b>DOSEAGE</b>	30 MG TWICE DAILY (TBD)											
<b>PRICE</b>	USA: USD 15/DAY, EU/ROW: EUR 10/DAY; PRICING MAY PROVE CONSERVATIVE IF EVENAMIDE BECOMES A NEW TREATMENT PARADIGM IN SCHIZOPHRENIA											
<b>STANDARD OF CARE</b>	ATYPICAL (2ND GENERATION) ANTIPSYCHOTICS SUCH AS ZYPREXA, SEROQUEL, RISPERDAL, GEODON, ABILIFY											
<b>UNIQUE SELLING POINT</b>	FIRST ADD-ON TO MAINSTAY ANTIPSYCHOTICS FOR SCHIZOPHRENIA WITH THE POTENTIAL TO PROLONG RESPONSE RATES AND REDUCE FREQUENT SWITCHING											
<b>7Ps ANALYSIS</b>												
<b>PATENT</b>	US: PROTECTION UNTIL 2033 BASED ON COMPOSITION OF MATTER PATENT GRANTED UNTIL 2028 + 5 YEARS EXTENSION; EU: 10-YEARS DATA EXCLUSIVITY											
<b>PHASE</b>	POSITIVE TOPLINE RESULTS PHASE III/III "STUDY 008A" (NON-TRS) IN APRIL 2024; PHASE III "STUDY 017" (TRS) START Q4 2024, RESULTS END 2025, LAUNCH H1 2027											
<b>PATHWAY</b>	1) TWO POSITIVE PHASE III TRIALS (6 MONTHS TREATMENT); 2) AT LEAST 1,500 TREATED (INCL. SEVERAL HUNDRED 6 MONTHS); 3) AT LEAST 100 TREATED FOR 1 YEAR											
<b>PATIENT</b>	POORLY RESPONDING PATIENTS CAN POTENTIALLY REGAIN A NORMAL SOCIAL AND PRODUCTIVE LIFE WITH A HIGHER LIFE EXPECTANCY											
<b>PHYSICIAN</b>	POTENTIAL TO ADDRESS POORLY RESPONDING PATIENTS OR PATIENTS WITH BREAKTHROUGH SYMPTOMS ON CURRENT ANTIPSYCHOTIC TREATMENT											
<b>PAYER</b>	SUBSTANTIAL REDUCTION OF ASSOCIATED COSTS SUCH AS UNEMPLOYMENT, LONG-TERM CARE, HOSPITALIZATION, SUICIDE RISK											
<b>PARTNER</b>	PHASE IIA POC COMPLETED; NEXT STEPS: FUNDS SECURED TO START REGISTRATIONAL TRIALS; GLOBAL PARTNERING LIKELY ON POSITIVE "STUDY 008A" RESULTS											
<b>REVENUE MODEL</b>												
<b>EUROPE / REST OF WORLD (PARTNER TBD)</b>	<b>2023E</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>	<b>2027E</b>	<b>2028E</b>	<b>2029E</b>	<b>2030E</b>	<b>2031E</b>	<b>2032E</b>	<b>2033E</b>	
NUMBER OF PATIENTS (MN)	5.7	5.8	5.9	6.0	6.1	6.2	6.3	6.4	6.5	6.5	6.6	
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	
PERCENTAGE WITH POSITIVE SYMPTOMS (%)	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	
PATIENTS WITH POSITIVE SYMPTOMS (MN)	4.0	4.1	4.1	4.2	4.3	4.3	4.4	4.4	4.5	4.6	4.7	
COMPLIANCE RATE (%)	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	
PATIENTS TREATED	1'002'020	1'017'051	1'032'306	1'047'791	1'063'508	1'079'460	1'095'652	1'112'087	1'128'768	1'145'700	1'162'886	
-/- PATIENTS WITH CTRS (SEE EVANAMIDE CTRS MODEL)	-42'211	-42'844	-43'487	-44'139	-44'801	-45'473	-46'155	-46'848	-47'550	-48'264	-48'988	
INADEQUATE RESPONDERS (~57%)	547'091	555'298	563'627	572'082	580'663	589'373	598'213	607'186	616'294	625'539	634'922	
TREATMENT RESISTANT SCHIZOPHRENIA (TRS) PATIENTS (~43%)	412'718	418'906	425'192	431'570	438'044	444'614	451'284	458'053	464'924	471'898	478'976	
PATIENTS TREATED (EXCLUDING CTRS PATIENTS)	959'809	974'206	988'820	1'003'652	1'018'707	1'033'987	1'049'497	1'065'239	1'081'218	1'097'436	1'113'898	
PENETRATION (%)	0%	0%	0%	0%	5%	8%	10%	11%	12%	13%	13%	
NUMBER OF TREATED PATIENTS	0	0	0	0	50'935	82'719	104'950	117'176	129'746	137'180	144'807	
COST OF THERAPY PER YEAR (EUR)	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650	
<b>SALES (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>186</b>	<b>302</b>	<b>383</b>	<b>428</b>	<b>474</b>	<b>501</b>	<b>529</b>	
CHANGE (%)						62%	27%	12%	11%	6%	6%	
ROYALTY (%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	
ROYALTIES (EUR MN)	0	0	0	0	28	45	57	64	71	75	79	
UPFRONT & MILESTONE PAYMENTS (EUR MN)		20	10	20	15	30		40		50		
R&D COSTS	-12	-2	0	0	0	0	0	0	0	0	0	
<b>PROFIT BEFORE TAX (EUR MN)</b>	<b>-12</b>	<b>18</b>	<b>10</b>	<b>20</b>	<b>43</b>	<b>75</b>	<b>57</b>	<b>104</b>	<b>71</b>	<b>125</b>	<b>79</b>	
TAXES (EUR MN)	0	-1	-2	-3	-13	-24	-18	-33	-22	-39	-25	
<b>PROFIT (EUR MN)</b>	<b>-12</b>	<b>17</b>	<b>8</b>	<b>17</b>	<b>29</b>	<b>52</b>	<b>39</b>	<b>71</b>	<b>49</b>	<b>86</b>	<b>54</b>	
<b>UNITED STATES (PARTNER TBD)</b>	<b>2023E</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>	<b>2027E</b>	<b>2028E</b>	<b>2029E</b>	<b>2030E</b>	<b>2031E</b>	<b>2032E</b>	<b>2033E</b>	
NUMBER OF PATIENTS (MN)	2.7	2.7	2.8	2.8	2.8	2.9	2.9	3.0	3.0	3.1	3.1	
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	
PERCENTAGE WITH POSITIVE SYMPTOMS (%)	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	
PATIENTS WITH POSITIVE SYMPTOMS (MN)	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.2	
COMPLIANCE RATE (%)	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	
PATIENTS TREATED	467'218	474'226	481'339	488'559	495'888	503'326	510'876	518'539	526'317	534'212	542'225	
-/- PATIENTS WITH CTRS (SEE EVANAMIDE CTRS MODEL)	-22'962	-23'307	-23'656	-24'011	-24'371	-24'737	-25'108	-25'485	-25'867	-26'255	-26'649	
INADEQUATE RESPONDERS (~57%)	253'226	257'024	260'879	264'793	268'764	272'796	276'888	281'041	285'257	289'536	293'879	
TREATMENT RESISTANT SCHIZOPHRENIA (TRS) PATIENTS (~43%)	191'030	193'895	196'804	199'756	202'752	205'793	208'880	212'013	215'194	218'422	221'698	
PATIENTS TREATED (EXCLUDING CTRS PATIENTS)	444'255	450'919	457'683	464'548	471'516	478'589	485'768	493'055	500'450	507'957	515'577	
PENETRATION (%)	0%	0%	0%	0%	6%	10%	12%	13%	14%	15%	8%	
NUMBER OF TREATED PATIENTS	0	0	0	0	29'753	50'333	61'305	67'410	73'684	80'132	40'667	
COST OF THERAPY PER YEAR (EUR)	5'113	5'086	5'106	5'106	5'106	5'106	5'106	5'106	5'106	5'106	5'106	
<b>SALES (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>152</b>	<b>257</b>	<b>313</b>	<b>344</b>	<b>376</b>	<b>409</b>	<b>208</b>	
CHANGE (%)						69%	22%	10%	9%	9%	-49%	
ROYALTY (%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	
ROYALTIES (EUR MN)	0	0	0	0	23	39	47	52	56	61	31	
UPFRONT & MILESTONE PAYMENTS (EUR MN)		19	0	19	19	23	28	0	37	0	0	
<b>PROFIT BEFORE TAX (USD MN)</b>	<b>0</b>	<b>20</b>	<b>0</b>	<b>20</b>	<b>44</b>	<b>66</b>	<b>80</b>	<b>55</b>	<b>101</b>	<b>66</b>	<b>33</b>	
TAXES (EUR MN)	0	-1	0	-3	-13	-19	-24	-16	-29	-19	-10	
<b>PROFIT (EUR MN)</b>	<b>0</b>	<b>18</b>	<b>0</b>	<b>16</b>	<b>28</b>	<b>42</b>	<b>51</b>	<b>35</b>	<b>64</b>	<b>42</b>	<b>21</b>	
<b>GLOBAL SALES (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>338</b>	<b>559</b>	<b>696</b>	<b>772</b>	<b>850</b>	<b>910</b>	<b>736</b>	
CHANGE (%)						65%	25%	11%	10%	7%	-19%	
<b>GLOBAL PROFIT (EUR MN)</b>	<b>-12</b>	<b>35</b>	<b>8</b>	<b>33</b>	<b>58</b>	<b>94</b>	<b>91</b>	<b>107</b>	<b>113</b>	<b>128</b>	<b>76</b>	
CHANGE (%)		-390%	-77%	301%	78%	63%	-3%	18%	6%	13%	-41%	
WACC (%)	10%											
<b>NPV TOTAL PROFIT (CHF MN)</b>	<b>524</b>											
NUMBER OF SHARES (MN)	17.8											
NPV PER SHARE (CHF)	29											
SUCCESS PROBABILITY	65% (POSITIVE PIVOTAL PHASE IIB TRIAL)											
<b>RISK ADJUSTED NPV PER SHARE (CHF)</b>	<b>19.1</b>											
<b>SENSITIVITY ANALYSIS</b>												
		<b>WACC (%)</b>										
	CHF/SHARE	8	9	10	11	12						
<b>SUCCESS PROBABILITY</b>	100%	33.2	33.2	29.4	27.7	26.1						
	90%	29.9	29.9	26.4	24.9	23.5						
	80%	26.6	26.6	23.5	22.1	20.9						
	70%	23.3	23.3	20.6	19.4	18.3						
	65%	21.6	21.6	19.1	18.0	17.0						
	50%	16.6	16.6	14.7	13.8	13.1						
	40%	13.3	13.3	11.7	11.1	10.4						

ESTIMATES AS OF 1 MAY 2024

SOURCE: VALUATIONLAB ESTIMATES

# Clozapine treatment-resistant schizophrenia (orphan-like indication)

## EVENAMIDE - FINANCIAL FORECASTS FOR CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA (CTRS)

<b>INDICATION</b>	ADD-ON THERAPY TO ANTIPSYCHOTICS FOR REDUCING POSITIVE SYMPTOMS & PSYCHOTIC WORSENING IN CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA (CTRS)
<b>DOSAGE</b>	15 OR 30 MG TWICE DAILY (TBD)
<b>PRICE</b>	USA: USD 15/DAY, EU/ROW: EUR 10/DAY; PRICING MAY PROVE CONSERVATIVE IF EVENAMIDE BECOMES A NEW TREATMENT PARADIGM IN SCHIZOPHRENIA
<b>STANDARD OF CARE</b>	CLOZAPINE AND OTHER ATYPICAL (2ND GENERATION) ANTIPSYCHOTICS SUCH AS ZYPREXA (OLANZAPINE), SEROQUEL (QUETIAPINE), RISPERDAL (RISPERIDONE)
<b>UNIQUE SELLING POINT</b>	POTENTIALLY FIRST ADD-ON THERAPY TO ANTIPSYCHOTICS IN PATIENTS WITH CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA (ORHPAN INDICATION)
<b>7Ps ANALYSIS</b>	
<b>PATENT</b>	US: PATENT PROTECTION UNTIL 2033 BASED ON COMPOSITION OF MATTER PATENT GRANTED UNTIL 2028 + 5 YEARS EXTENSION; EU: 10-YEAR DATA EXCLUSIVITY
<b>PHASE</b>	FILINGS RELATING TO ORPHAN/PRIME/FAST TRACT DESIGNATION; START PHASE III "STUDY 017" TRS TRIAL Q4 2024, RESULTS END 2025; LAUNCH H1 2027
<b>PATHWAY</b>	PHASE III TRIAL IN INADEQUATE RESPONDERS + PHASE III TRIAL IN TREATMENT-RESISTANT SCHIZOPHRENIA (INCL. CTRS); 18 MONTHS TO COMPLETION FOR EACH TRIAL
<b>PATIENT</b>	CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA PATIENTS CAN POTENTIALLY REGAIN A NORMAL SOCIAL AND PRODUCTIVE LIFE WITH A HIGHER LIFE EXPECTANCY
<b>PHYSICIAN</b>	POTENTIAL TO ADDRESS TREATMENT-RESISTANT PATIENTS WHERE CLOZAPINE NO LONGER WORKS OR OTHER ATYPICAL ANTIPSYCHOTICS
<b>PAYER</b>	TREATMENT-RESISTANT SCHIZOPHRENIA IS ASSOCIATED WITH SOME OF THE HIGHEST HOSPITALIZATION COSTS, COSTS TO SOCIETY AND RISK OF SUICIDE
<b>PARTNER</b>	PHASE IIA POC COMPLETED IN SCHIZOPHRENIA; FUNDS SECURED TO COMPLETE BOTH PHASE III TRIALS; OWN US SALES FORCE, PARTNERING ON PHASE III IN EU/ROW

### REVENUE MODEL

	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
<b>EUROPE / REST OF WORLD (PARTNER TBD)</b>											
NUMBER OF PATIENTS (MN)	5.7	5.8	5.9	6.0	6.1	6.2	6.3	6.4	6.5	6.5	6.6
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PERCENTAGE WITH POSITIVE SYMPTOMS (%)	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
PATIENTS WITH POSITIVE SYMPTOMS (MN)	4.0	4.1	4.1	4.2	4.3	4.3	4.4	4.4	4.5	4.6	4.7
TREATMENT-RESISTANT SCHIZOPHRENIA (%)	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
TREATMENT-RESISTANT SCHIZOPHRENIA PATIENTS	1'202'424	1'220'461	1'238'768	1'257'349	1'276'209	1'295'353	1'314'783	1'334'505	1'354'522	1'374'840	1'395'463
PATIENTS ON CLOZAPINE (%)	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%
PATIENTS ON CLOZAPINE	140'703	142'814	144'956	147'131	149'338	151'578	153'851	156'159	158'501	160'879	163'292
CLOZAPINE-RESISTANT SCHIZOPHRENIA (%)	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
CLOZAPINE-RESISTANT SCHIZOPHRENIA PATIENTS	42'211	42'844	43'487	44'139	44'801	45'473	46'155	46'848	47'550	48'264	48'988
PENETRATION (%)	0%	0%	0%	0%	12%	20%	26%	30%	32%	33%	34%
NUMBER OF TREATED PATIENTS	0	0	0	0	5'376	9'095	12'000	14'054	15'216	15'927	16'656
COST OF THERAPY PER YEAR (EUR)	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650	3'650
<b>SALES (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>20</b>	<b>33</b>	<b>44</b>	<b>51</b>	<b>56</b>	<b>58</b>	<b>61</b>
CHANGE (%)						69%	32%	17%	8%	5%	5%
ROYALTY (%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
ROYALTIES (EUR MN)	0	0	0	0	3	5	7	8	8	9	9
UPFRONT & MILESTONE PAYMENTS (EUR MN)		5		5				5			
R&D COSTS	-1	-2	-2	0	0	0	0	0	0	0	0
<b>PROFIT BEFORE TAX (EUR MN)</b>	<b>-1</b>	<b>3</b>	<b>-2</b>	<b>5</b>	<b>3</b>	<b>5</b>	<b>7</b>	<b>13</b>	<b>8</b>	<b>9</b>	<b>9</b>
TAXES (EUR MN)	0	0	0	-1	-1	-2	-2	-4	-3	-3	-3
<b>PROFIT (EUR MN)</b>	<b>-1</b>	<b>3</b>	<b>-2</b>	<b>4</b>	<b>2</b>	<b>3</b>	<b>5</b>	<b>9</b>	<b>6</b>	<b>6</b>	<b>6</b>
<b>UNITED STATES (NEWRON SPECIALIST SALES FORCE)</b>											
NUMBER OF PATIENTS (MN)	2.7	2.7	2.8	2.8	2.8	2.9	2.9	3.0	3.0	3.1	3.1
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PERCENTAGE WITH POSITIVE SYMPTOMS (%)	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
PATIENTS WITH POSITIVE SYMPTOMS (MN)	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.2
TREATMENT-RESISTANT (%)	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
TREATMENT-RESISTANT SCHIZOPHRENIA	654'105	663'916	673'875	683'983	694'243	704'657	715'226	725'955	736'844	747'897	759'115
PATIENTS ON CLOZAPINE (%)	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%
PATIENTS ON CLOZAPINE	76'541	77'689	78'854	80'037	81'238	82'456	83'693	84'949	86'223	87'516	88'829
CLOZAPINE-RESISTANT SCHIZOPHRENIA (%)	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
CLOZAPINE-RESISTANT SCHIZOPHRENIA PATIENTS	22'962	23'307	23'656	24'011	24'371	24'737	25'108	25'485	25'867	26'255	26'649
PENETRATION (%)	0%	0%	0%	0%	20%	32%	42%	50%	56%	60%	18%
NUMBER OF TREATED PATIENTS	0	0	0	0	4'874	7'916	10'545	12'742	14'485	15'753	17'017
COST OF THERAPY PER YEAR (EUR)	5'113	5'086	5'106	5'106	5'106	5'106	5'106	5'106	5'106	5'106	5'106
<b>SALES (EUR MN) - BOOKED BY NEWRON</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>25</b>	<b>40</b>	<b>54</b>	<b>65</b>	<b>74</b>	<b>80</b>	<b>24</b>
CHANGE (%)						62%	33%	21%	14%	9%	-70%
COGS (%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
COGS (EUR MN)	0	0	0	0	-4	-6	-8	-10	-11	-12	-4
S,G&A (EUR MN)	0	0	0	0	-7	-8	-9	-11	-13	-14	-4
<b>PROFIT BEFORE TAX (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>14</b>	<b>26</b>	<b>37</b>	<b>44</b>	<b>50</b>	<b>55</b>	<b>17</b>
TAXES (EUR MN)	0	0	0	0	-5	-8	-11	-14	-16	-17	-5
<b>PROFIT (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10</b>	<b>18</b>	<b>25</b>	<b>30</b>	<b>35</b>	<b>38</b>	<b>11</b>
<b>GLOBAL SALES (EUR MN)</b>											
<b>GLOBAL SALES (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>45</b>	<b>74</b>	<b>98</b>	<b>116</b>	<b>130</b>	<b>139</b>	<b>85</b>
CHANGE (%)						65%	33%	19%	11%	7%	-38%
<b>GLOBAL PROFIT (EUR MN)</b>											
<b>GLOBAL PROFIT (EUR MN)</b>	<b>-1</b>	<b>3</b>	<b>-2</b>	<b>4</b>	<b>12</b>	<b>21</b>	<b>30</b>	<b>39</b>	<b>40</b>	<b>44</b>	<b>18</b>
CHANGE (%)	476%	-347%	-157%	-360%	183%	80%	38%	32%	3%	8%	-59%
WACC (%)	10%										
<b>NPV TOTAL PROFIT (CHF MN)</b>	<b>125</b>										
NUMBER OF SHARES (MN)	17.8										
NPV PER SHARE (CHF)	7										
SUCCESS PROBABILITY	35% (PROOF-OF-CONCEPT ESTABLISHED)										
<b>RISK ADJUSTED NPV PER SHARE (CHF)</b>	<b>2.4</b>										

	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
<b>GLOBAL SALES (EUR MN)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>45</b>	<b>74</b>	<b>98</b>	<b>116</b>	<b>130</b>	<b>139</b>	<b>85</b>
CHANGE (%)						65%	33%	19%	11%	7%	-38%
<b>GLOBAL PROFIT (EUR MN)</b>	<b>-1</b>	<b>3</b>	<b>-2</b>	<b>4</b>	<b>12</b>	<b>21</b>	<b>30</b>	<b>39</b>	<b>40</b>	<b>44</b>	<b>18</b>
CHANGE (%)	476%	-347%	-157%	-360%	183%	80%	38%	32%	3%	8%	-59%
WACC (%)	10%										
<b>NPV TOTAL PROFIT (CHF MN)</b>	<b>125</b>										
NUMBER OF SHARES (MN)	17.8										
NPV PER SHARE (CHF)	7										
SUCCESS PROBABILITY	35% (PROOF-OF-CONCEPT ESTABLISHED)										
<b>RISK ADJUSTED NPV PER SHARE (CHF)</b>	<b>2.4</b>										

		WACC (%)				
		8	9	10	11	12
<b>SUCCESS PROBABILITY</b>	100%	7.8	7.3	6.9	6.4	6.1
	80%	6.2	5.8	5.5	5.2	4.8
	65%	5.1	4.8	4.5	4.2	3.9
	50%	3.9	3.7	3.4	3.2	3.0
	35%	2.7	2.6	2.4	2.3	2.1
	25%	1.9	1.8	1.7	1.6	1.5
	15%	1.2	1.1	1.0	1.0	0.9

ESTIMATES AS OF 1 MAY 2024 SOURCE: VALUATIONLAB ESTIMATES

# Income Statement

NEWRON PHARMACEUTICALS											SHARE PRICE (CHF)	8.21
IFRS												
INCOME STATEMENT (EUR MN)	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
<b>PRODUCT SALES (INCLUDING PARTNERS)</b>	64	70	77	84	474	710	856	923	997	1'057	827	
CHANGE (%)	-3%	10%	10%	9%	463%	50%	21%	8%	8%	6%	-22%	
<b>PRODUCT SALES (BY NEWRON)</b>	0	0	0	0	25	40	54	65	74	80	24	
CHANGE (%)						62%	33%	21%	14%	9%	-70%	
<b>ROYALTIES</b>	7	7	8	9	63	97	118	127	138	146	120	
CHANGE (%)	13%	9%	9%	8%	630%	55%	21%	8%	8%	6%	-18%	
<b>LICENCE, UPFRONT &amp; MILESTONE INCOME</b>	0	44	10	44	34	53	28	45	37	50	0	
<b>OTHER INCOME &amp; GRANTS</b>	2	0	0	0	0	0	0	0	0	0	0	
<b>REVENUES (EXCL. PARTNER SALES)</b>	9	51	18	52	122	191	200	237	249	277	145	
CHANGE (%)	49%	463%	-65%	190%	132%	57%	4%	19%	5%	11%	-48%	
<b>COGS</b>	0	0	0	0	-4	-6	-8	-10	-11	-12	-4	
<b>GROSS PROFIT</b>	9	51	18	52	118	185	192	227	238	265	141	
CHANGE (%)	49%	463%	-65%	190%	125%	57%	4%	19%	5%	11%	-47%	
MARGIN	100%	100%	100%	100%	97%	97%	96%	96%	96%	96%	97%	
<b>R&amp;D</b>	-13	-10	-8	-8	-8	-9	-9	-10	-10	-11	-11	
CHANGE (%)	10%	-24%	-20%	0%	5%	5%	5%	5%	5%	5%	5%	
<b>S,G&amp;A</b>	-8	-8	-8	-8	-14	-16	-17	-19	-20	-21	-12	
CHANGE (%)	2%	0%	0%	0%	89%	10%	7%	11%	8%	5%	-45%	
<b>OPERATING EXPENSES</b>	-21	-18	-16	-16	-26	-31	-34	-38	-41	-44	-27	
CHANGE (%)	7%	-15%	-11%	0%	70%	16%	12%	12%	9%	6%	-39%	
AS % REVENUES	228%	34%	86%	30%	22%	16%	17%	16%	17%	16%	18%	
<b>EBITDA</b>	-11	34	3	37	95	161	166	199	208	233	118	
CHANGE (%)	-13%	-395%	-92%	1244%	157%	69%	3%	20%	4%	12%	-49%	
MARGIN (%)	-126%	66%	15%	71%	78%	84%	83%	84%	83%	84%	82%	
<b>DEPRECIATION &amp; AMORTIZATION</b>	0	0	0	0	0	0	0	0	0	0	0	
AS % REVENUES	2%	0%	1%	0%	0%	0%	0%	0%	0%	0%	0%	
<b>EBIT</b>	-12	33	3	37	95	161	166	199	208	233	118	
CHANGE (%)	-13%	-388%	-92%	1353%	158%	69%	3%	20%	4%	12%	-49%	
MARGIN (%)	-128%	66%	14%	70%	78%	84%	83%	84%	83%	84%	82%	
<b>NET FINANCIAL INCOME/(EXPENSE)</b>	-5	-4	-4	-2	0	1	1	2	3	3	4	
<b>PROFIT BEFORE TAXES</b>	-16	29	-2	35	95	161	167	201	210	236	122	
MARGIN	-179%	57%	-10%	67%	78%	84%	84%	85%	84%	85%	85%	
<b>TAXES</b>	0	-2	-3	-8	-35	-56	-57	-68	-71	-79	-43	
TAX RATE (%)	0%	8%	-167%	23%	37%	34%	34%	34%	34%	33%	35%	
<b>NET PROFIT/LOSS</b>	-16	27	-5	27	60	106	110	133	139	157	79	
CHANGE (%)	-7%	-264%	-118%	-654%	123%	76%	4%	21%	5%	13%	-49%	
MARGIN (%)	-179%	52%	-27%	51%	49%	55%	55%	56%	56%	57%	55%	
<b>PROFIT/(LOSS) PER SHARE (IN EUR)</b>	-0.91	1.49	-0.27	1.51	3.36	5.92	6.14	7.45	7.81	8.81	4.45	
<b>PROFIT/(LOSS) PER SHARE (IN CHF)</b>	-0.88	1.45	-0.27	1.47	3.28	5.78	6.00	7.28	7.62	8.60	4.35	

ESTIMATES AS OF 1 MAY 2024

SOURCE: VALUATIONLAB ESTIMATES

**NOTE:** At the end of FY 2023, Newron had a total of EUR 299 mn tax loss carryforwards, which the company can use on current and future profits.

# Ratios & Balance Sheet

NEWRON PHARMACEUTICALS											SHARE PRICE (CHF)	8.21
<b>RATIOS</b>												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
P/E		5.7x	-30.9x	5.6x	2.5x	1.4x	1.4x	1.1x	1.1x	1.0x	1.9x	
P/S		3.0x	8.3x	2.9x	1.2x	0.8x	0.8x	0.6x	0.6x	0.5x	1.0x	
P/NAV		-46.1x	-18.5x	8.0x	1.9x	0.8x	0.5x	0.4x	0.3x	0.2x	0.2x	
EV/EBITDA		4.1x	49.9x	3.7x	1.4x	0.9x	0.8x	0.7x	0.7x	0.6x	1.2x	
<b>PER SHARE DATA (CHF)</b>												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
<b>EARNINGS</b>	-0.88	1.45	-0.27	1.47	3.28	5.78	6.00	7.28	7.62	8.60	4.35	
CHANGE (%)	-14%	-265%	-118%	-654%	123%	76%	4%	21%	5%	13%	-49%	
<b>CASH</b>	0.68	2.67	2.34	2.71	8.33	17.58	27.14	38.58	50.52	63.89	71.05	
CHANGE (%)	-49%	291%	-12%	16%	207%	111%	54%	42%	31%	26%	11%	
<b>DIVIDENDS</b>	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
PAYOUT RATIO (%)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	
<b>NET ASSET VALUE</b>	-1.62	-0.18	-0.44	1.03	4.31	10.09	16.08	23.36	30.98	39.58	43.92	
CHANGE (%)	98%	-89%	149%	-331%	320%	134%	59%	45%	33%	28%	11%	
<b>BALANCE SHEET (EUR MN)</b>												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
<b>NET LIQUID FUNDS</b>	13	49	43	50	152	321	496	705	923	1'168	1'299	
<b>TOTAL ASSETS</b>	30	67	60	67	170	339	514	723	941	1'185	1'316	
<b>SHAREHOLDERS' EQUITY</b>	-30	-3	-8	19	79	184	294	427	566	723	803	
CHANGE (%)	113%	-89%	148%	-331%	320%	134%	59%	45%	33%	28%	11%	
RETURN ON EQUITY (%)	54%	-814%	60%	143%	76%	57%	37%	31%	25%	22%	10%	
<b>FINANCIAL DEBT</b>	26	48	36	0	0	0	0	0	0	0	0	
FINANCIAL DEBT AS % OF TOTAL ASSETS	86%	72%	60%	0%	0%	0%	0%	0%	0%	0%	0%	
<b>EMPLOYEES</b>	22	22	23	23	24	24	25	25	26	26	27	
CHANGE (%)	0%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	
<b>CASH FLOW STATEMENT (EUR MN)</b>												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
<b>NET PROFIT / (LOSS) BEFORE TAX</b>	-16	29	-2	35	95	161	167	201	210	236	122	
DEPRECIATION & AMORTIZATION	0	0	0	0	0	0	0	0	0	0	0	
OTHER NON-CASH ITEMS	4	6	6	6	6	6	6	6	6	6	6	
<b>CASH FLOW</b>	-12	35	4	41	101	167	173	207	216	242	128	
NET INCREASE/(DECREASE) IN WORKING CAPITAL	2	2	2	2	2	2	2	2	2	3	3	
<b>OPERATING FREE CASH FLOW</b>	-10	36	6	43	103	169	175	209	218	244	131	
NET CASH FLOWS FROM INVESTING ACTIVITIES	3	0	0	0	0	0	0	0	0.0	0.0	0.0	
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	-7	36	6	43	103	169	175	209	218	244	131	
NET CASH FLOWS FROM FINANCING ACTIVITIES	0	0	-12	-36	0	0	0	0	0	0	0	
<b>NET INCREASE/(DECREASE) CASH &amp; CASH EQUIVALENTS</b>	-7	36	-6	7	103	169	175	209	218	244	131	

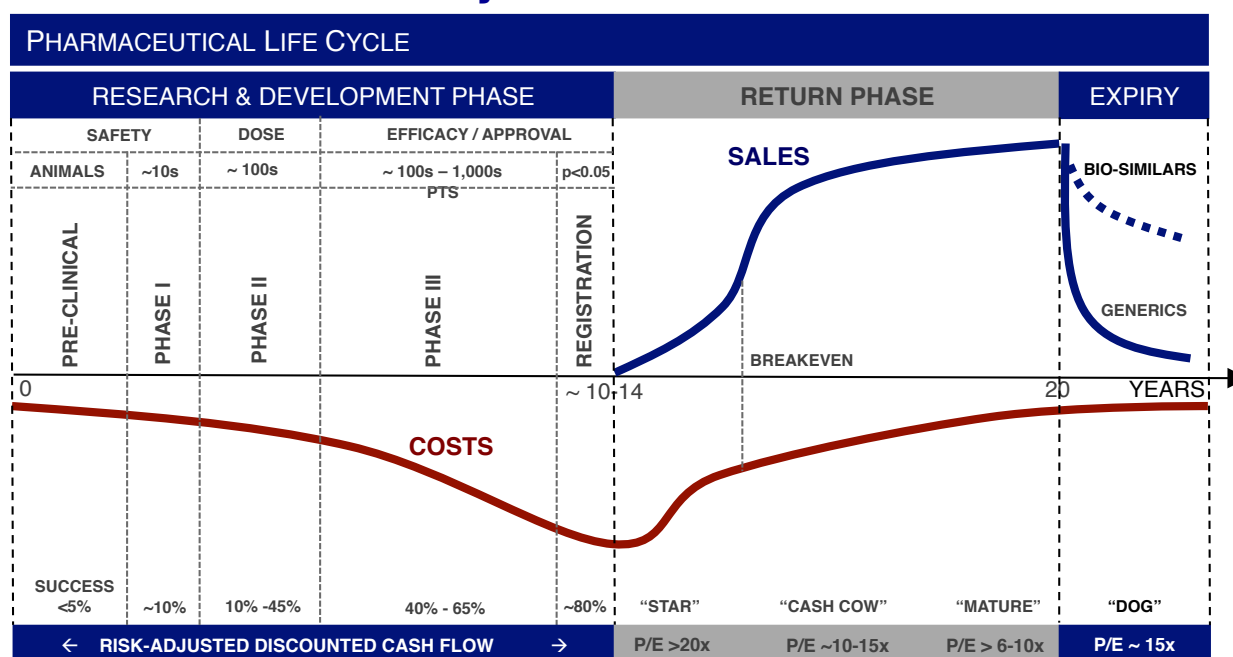
ESTIMATES AS OF 1 MAY 2024

SOURCE: VALUATIONLAB ESTIMATES

**NOTE:** Newron's total available cash resources, including EUR 12.6 mn in cash and cash equivalents (31 December 2023), royalty income from Xadago sales, Italian R&D tax credits, the recent share subscription agreement with an institutional healthcare investor with up to EUR 15 mn in funding, and the deferral of the first three tranche payments of the EUR 40 mn EIB loan by roughly 1 ½ year, will finance its planned development programs and operations well into 2025 and beyond key value inflection points.

# APPENDIX

## Pharmaceutical life cycle



SOURCE: VALUATIONLAB

To determine the value of a prescription (bio)pharmaceutical compound, it is critical to understand its life cycle. Fortunately, all compounds follow the same life cycle. The clock starts ticking after the compound is patented, providing 20 years of protection from generic competition. Market exclusivities can extend this protection period. The average Research & Development Phase takes 10-14 years, leading to an effective Return Phase of 6-10 years. The Development Phase has 3 distinct Phases, focused on safety (Phase I), dose (Phase II) and efficacy/clinical benefit (Phase III). The compound is filed for registration/approval at the FDA (US) or EMA (EU). The Return Phase is characterized by a star, cash cow, and mature phase. After patent expiry (or loss of market exclusivity) generic manufacturers may copycat the branded prescription drug, at significantly lower costs, leading to a sales and earnings implosion of the branded drug.

## Success probabilities and royalties

In our risk-adjusted NPV calculations, we use standardized success probabilities based on historical clinical success rates. The success rate increases as the project progresses through development. Sales and earnings forecasts are based on the clinical and competitive profile of the compound. The more advanced the compound is, the more accurate the forecasts become as the target market can be defined. We conservatively exclude projects that lack Phase IIa proof-of-concept data in our valuations.

### SUCCESS PROBABILITIES & ROYALTIES

DEVELOPMENT STAGE	AIM	WHAT / WHO	SUCCESS PROBABILITY (%)	COSTS (USD MN)	ROYALTIES (%)
PRE-CLINICAL	SAFETY & PHARMACOLOGY DATA	LAB TESTS / ANIMALS - NO HUMANS!	< 5	3	
PHASE I	SCREENING FOR SAFETY	HEALTHY VOLUNTEERS (10'S)	5-15	3	< 5
PHASE IIA	PROOF-OF-CONCEPT	PATIENTS WITH DISEASE (10'S)	10-20		
PHASE II	ESTABLISH THE TESTING PROTOCOL	PATIENTS WITH DISEASE (100'S)	15-35	5	5-15
PHASE IIB	OPTIMAL DOSAGE	PATIENTS WITH DISEASE (100'S)	20-45	5-10	
PHASE III	EVALUATE OVERALL BENEFIT/RISK	PATIENTS WITH DISEASE (1,000'S)	40-65	> 20-1,000	10-25
REGULATORY FILING	DETERMINE PHYSICIAN LABELING	CLINICAL BENEFIT ASSESSMENT	80-90		
APPROVAL	MARKETING AUTHORIZATION	PHYSICIANS FREE TO PRESCRIBE	100		15-30

SOURCE: VALUATIONLAB, TUFTS, FDA, EMA, CLINICALTRIALS.GOV



# Important Research Disclosures

valuationLAB AG is an independent life science research boutique with no securities or banking services. The company does not hold any positions in the securities mentioned in this report.

**Our financial analyses are based on the "Directives on the Independence of Financial Research" issued by the Swiss Bankers Association in January 2008.**

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## Risk Qualification

Speculative	less than 1 year cash and breakeven beyond 1 year
High Risk	profitable within 2 years and 1 approved product/key indication (patent expiry > 5 years)
Medium Risk	profitable and/or sales from at least 2 marketed products/key indications (patent expiry > 5 years)
Low Risk	profitable and sales from >2 marketed products/key indications (patent expiry > 5 years)

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