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

KEY DATA			SIX: NWRN
MARKET CAPITALIZATION (CHF MN)	147	PRICE ON 27 JUNE 2024	8.3
ENTERPRISE VALUE (CHF MN)	135	RISK-ADJUSTED NPV PER SHARE (CHF)	17.3
CASH (31 DECEMBER 2023) (CHF MN)	12	UPSIDE/DOWNSIDE (%)	109%
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)	122'864
UPCOMING CATALYSTS:	DATE	ANALYST(S):	BOB POOLER
- EVENAMIDE - PARTNERING AGREEMENT	BEFORE START "STUDY 017"		BP@VALUATIONLAB.COM
- PUBLICATION OF H1 2024 RESULTS	19 SEPTMEBER 2024		+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
 ESTIMATES AS OF 27 JUNE 2024

SOURCE: VALUATIONLAB ESTIMATES, NEWRON PHARMACEUTICALS

A pivotal year

KOLs highlight evenamide's potential at Investor Day

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:

- **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.
- **Publication of H1 2024 results (19 September 2024):** These results may coincide or follow shortly after the announcement of a global or regional partner for evenamide, providing more information on the development and commercialization plans.
- **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

NYC Investor Day highlights evenamide's unique positioning in schizophrenia

On June 25th, 2024, Newron hosted an Investor Day event in New York City, USA, highlighting the unique positioning of its key late-stage schizophrenia drug, evenamide, including clinical, scientific, registrational, and commercial plans for chronic and treatment-resistant schizophrenia. Three key opinion leaders (KOLs) in neuroscience and schizophrenia reviewed the company's clinical trials for evenamide and explored the high unmet needs, new concepts, and recent neurobiological findings for treating poor responders and patients with treatment-resistant schizophrenia (TRS). Evenamide's unique mechanism of action targets the core abnormalities in schizophrenia patients and should benefit poor-responding and TRS patients with a long-lasting effect and excellent tolerability, underlining its blockbuster sales potential.

The highlights of the Investor Day underlining evenamide's unique positioning in schizophrenia include:

- New insights into evenamide's novel MOA targeting the site of dysfunction
- Compelling phase III "Study 008A" trial results in poorly responding patients with schizophrenia
- Exciting POC "Study 014/015" trial results in treatment-resistant schizophrenia
- Outline of new phase III "Study 017" trial in TRS patients
- Partnering agreement expected in the next few months

Novel MOA targets site of dysfunction, normalizing activity without bad side effects

Dr. Anthony Grace, Ph.D., Editor-in-Chief of the International Journal of Neuropsychopharmacology, Distinguished Professor of Neuroscience, and Professor of Psychiatry and Psychology at the University of Pittsburgh, presented breakthrough preclinical data on treatment-resistant schizophrenia (TRS), which affects around 30% of patients. Most marketed antipsychotics act through the dopaminergic/serotonergic pathways. However, these antipsychotics appear to not act directly on the site of dysfunction in schizophrenia, leading to poor response, treatment resistance, early mortality, and tolerability issues. There is little evidence for a primary deficit in the dopaminergic system, and drugs that target this system do not impact the full spectrum of schizophrenia pathology.

It is now believed the dopaminergic system itself is normal but is likely to be dysregulated by other structures, such as the hippocampus, which is hyperactive in schizophrenia and the primary site of dysfunction. The hippocampus is a major component of the brain and part of the limbic system and plays an important role in memory, learning, and emotion. Dopamine agonists compensate for the dopaminergic system overactivity but are working five connections downstream from the site of dysfunction. This leads to significant side effects, which underly non-compliance and treatment resistance. This class of drugs is also ineffective in negative and cognitive symptoms and in treatment-resistant schizophrenia.

Evenamide acts at the site of dysfunction, the hippocampus. By selectively normalizing only hyperactive hippocampus neurons, it can normalize activity without introducing significant side effects. Because evenamide acts on the hippocampus, it can also normalize dysfunction not only regarding the dopamine system and psychosis but also impact negative

and cognitive symptoms. Evenamide's glutamate modulation has produced dramatic effects in the MAM model of schizophrenia, which closely mimics the changes observed in patients with schizophrenia. In this model, evenamide reversed abnormal hippocampal neuronal activity, normalized dopamine neuron population activity, improved cognition, and normalized social interactions. By acting on the glutamate system, evenamide can alleviate symptoms in patients who are treatment-resistant to dopaminergic-acting antipsychotic drugs. The effects of evenamide outlast its presence in the brain, suggesting that it impacts long-term plasticity changes and may help with neuronal repair in its extended therapeutic actions.

Unique “Study 008A” results provide hope for poorly responding patients

Dr. John Kane, M.D., Co-Director and Professor of the Institute of Behavioural Science, Feinstein Institutes for Medical Research, and Professor of Psychiatry, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, discussed the compelling positive results of the potentially pivotal phase III “Study 008A” trial results of evenamide, which offer new hope for poorly responding and treatment-resistant schizophrenia patients

More than 20 mn people worldwide are affected by schizophrenia. Despite over 60 different types of atypical and typical antipsychotics used for schizophrenia globally, a considerable number of patients remain severely ill and resistant to treatment. At the onset of illness, rates of primary treatment resistance have been shown up to 23%. Overall, 10-30% of patients have little or no response to current antipsychotics, and up to an additional 30% of patients have partial response to treatment. This may be because there are biological changes in the brains of patients that show reduced benefit and non-response to treatments compared to patients who respond adequately to treatment. First-episode patients (FEP) who show reduced or no response to their antipsychotics are highly likely to be diagnosed with TRS later. Significant neuro-anatomical and neurochemical differences can be detected in at-risk mental state (ARMS), FEP, and TRS compared to healthy controls and antipsychotic responders. Proton-MRI spectral studies indicate higher striatal glutamate levels in FEP and TRS patients compared to responders. Patients who are poor responders are likely to relapse significantly more than patients who respond to medication. To date, there are no studies that have demonstrated that the addition of one antipsychotic to another, or switching antipsychotics, has produced any benefit to poor responders and TRS patients.

Evenamide is the first drug to show benefit in this difficult-to-treat patient population, as seen in the potentially pivotal phase III “Study 008A” trial in 291 patients with chronic schizophrenia who respond poorly to second-generation antipsychotics. The primary endpoint, the Positive and Negative Syndrome Scale (PANSS), and the key secondary endpoint, the Clinical Global Impressions Scale - Severity (CGI-S), were met and showed statistical significance compared to placebo. The benefit of evenamide appears to be distributed equally among the seven second-generation antipsychotics, including clozapine, allowed in the trial. This therapeutic benefit may derive from evenamide's glutamate modulation activity. Evenamide was extremely well tolerated, without any of the usual side effects of available antipsychotics. The side effect profile is like a placebo with no increase in EPS, weight gain, blood glucose, metabolic syndrome, sexual dysfunction, CNS or cardiac effects, or laboratory abnormalities.

Exciting “Study 014/015” shows sustained and continuous improvement in TRS

Dr. Stephen R. Marder, M.D., a Distinguished Professor of Psychiatry at the Semel Institute of Neuroscience & Human Behavior and Director of the Section on Psychosis at UCLA Neuropsychiatric Institute, discussed the exciting results of the proof-of-concept open-label “Study 014/015” of evenamide in patients with treatment-resistant schizophrenia (TRS).

An estimated one-third of patients with schizophrenia are treatment-resistant. Patients may initially respond to treatments, but 30-60% become partially responsive or resistant to treatment. The use of higher doses (10-30% of patients), the addition of another antipsychotic (20-40% of patients), or switching to another drug is unsuccessful in patients with TRS. Clozapine remains the only drug approved for TRS, but for a variety of reasons (e.g., myocarditis, seizures, agranulocytosis) is grossly underutilized and used in less than 5% of patients. At least 50% of patients will improve substantially with clozapine. A high portion of patients – 30 to 50% - receiving both clozapine and other antipsychotics meet the criteria for TRS.

Evenamide, with its unique mechanism of action, has shown promising results as an add-on therapy to antipsychotics in the open-label 4-week proof-of-concept (POC) “Study 014” trial and its one-year extension “Study 015” trial, which can reduce the severity of psychosis symptoms that are resistant to treatment to with current antipsychotics including clozapine. The placebo-controlled “Study 014” trial showed effectiveness after only 4 weeks of treatment.

The “Study 015” extension trial suggests that evenamide has a unique property in that the TRS patients showed continuing improvement across all efficacy measures over a one-year treatment period. This has never been shown before in TRS patients. Similarly, the conversion of TRS patients to a non-resistant state and the finding that 25% of patients met criteria for remission are remarkable and unprecedented. This justifies further evaluation of evenamide in a new phase III, placebo-controlled, one-year global trial in TRS patients who are receiving other antipsychotics. Dr. Marder will be the Principal Investigator of this trial, dubbed “Study 017”.

An outline of the late-stage clinical development for evenamide in TRS

Newron’s Chief Medical Officer, Ravi Anand, MD, provided an update on evenamide’s clinical program, outlining that evenamide’s promising results will be evaluated in a global phase III, randomized, double-blind, one-year trial dubbed “Study 017”. The trial will be conducted in the US, Canada, and in several countries in Asia, Europe, and Latin America. More than 900 TRS patients are expected to be screened with more than 600 patients randomized 1:1 to evenamide 15-30 mg twice-daily (BID) or placebo. The primary efficacy endpoint will be the change from baseline in PANSS scores at 12 weeks. Following this initial period, subjects will continue on their assigned treatment until week 26, for the second maintenance efficacy endpoint, and then on to 1 year for read-out of the third (one-year, long-term) efficacy endpoint. The long-term extension will also serve to evaluate the long-term safety and tolerability of evenamide. For carcinogenicity, one study with a 6-month duration in genetically modified mice will be conducted in parallel to “Study 017”.

An agreement has been made with the regulatory authorities for approval of evenamide in TRS based upon positive “Study 017” trial results if supported by significant results from an additional positive phase III trial, namely, “Study 008A”. The registration dossier and new drug application (NDA) could be filed prior to completion of “Study 017” with 1,500 patients

Please see important research disclosures at the end of this document

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(an ICH requirement). Newron is confident that “Study 017” should meet its objectives and will be available as a treatment for schizophrenia patients based on the sustained and continuing improvement across all efficacy measure seen all clinical trials such as the POC trial “Study 014/015” and pivotal phase III “Study 008A” trial with a superior safety and tolerability profile.

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, Newron expects to sign a partnering agreement for evenamide in the next few months. This could be a global licensing agreement with a major CNS player or a licensing agreement for non-strategic regions, excluding the US in Japan, both in return for substantial upfront, regulatory, and sales milestones and royalties on sales.

This should substantially strengthen the company’s cash position 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. Following the partnering agreement, the company expects to start the second pivotal “Study 017” of evenamide in TRS in Q4 2024.

Investment case, strategy & cash

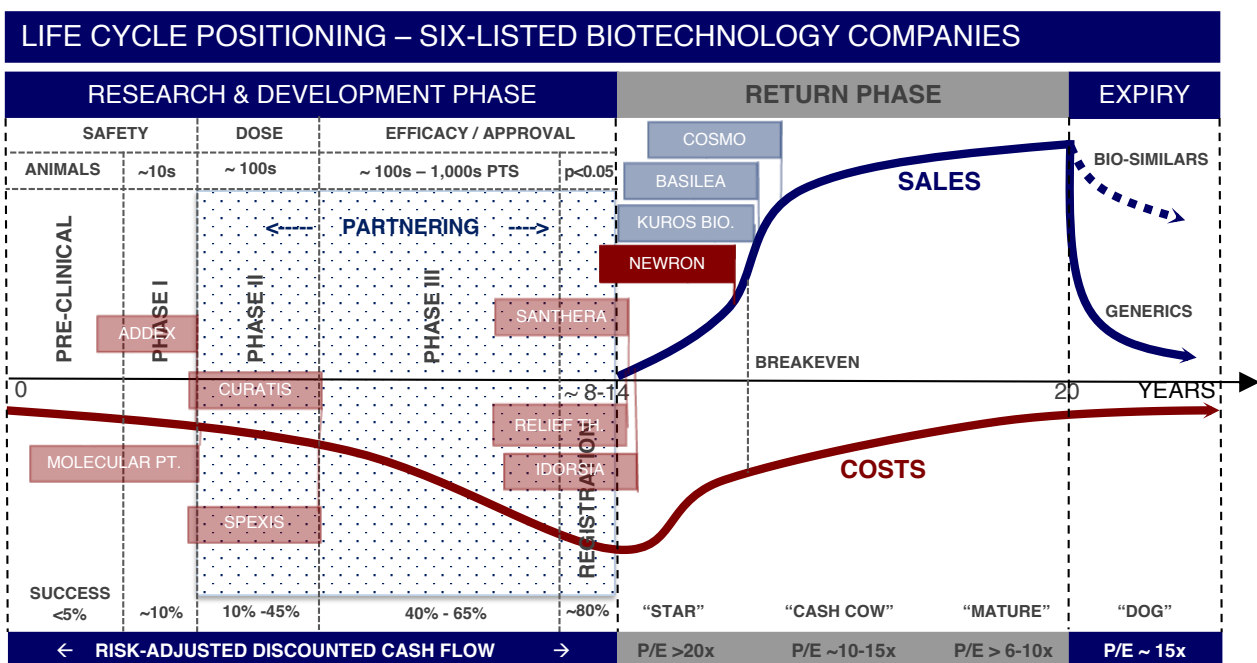
Investment case in a nutshell

Newron's key driver, evenamide for schizophrenia, continues to provide compelling data with "Study 008A", the first potentially pivotal phase II/III trial in chronic schizophrenia patients who inadequately respond to second-generation antipsychotics, meeting its primary endpoint and key secondary endpoint. This follows exciting one-year efficacy data in treatment-resistant schizophrenia (TRS) in the phase II "Study 014/015" trial. Newron will submit these results and the protocol for the second pivotal "Study 017" trial in TRS patients to the FDA. "Study 017" in TRS patients is now planned to start in Q4 2024. Both should add significantly to the value while substantially increasing the success rate and reducing the clinical development risk. On the back of the positive pivotal "Study 008A" results and the unprecedented results of "Study 014/015", a (global) partnering deal with a major CNS player is expected to be signed before the start of "Study 017" in Q4 2024, providing further equity upside. Hence, we believe substantial equity upside should be unlocked in 2024.

Based on our detailed bottom-up forecasts for Newron's key drivers, which have ample patent life and market exclusivity and target blockbuster markets, we conservatively calculate a sum-of-the-parts risk-adjusted NPV of CHF 308 mn or CHF 17.3 per share, providing equity upside of 109% from the current share price.

Life Cycle Positioning – High Risk

We qualify Newron's risk profile as High Risk as the company still makes losses, and revenues depend solely on Xadago in Parkinson's disease. On reaching breakeven in 2024 (assuming a significant agreement for evenamide in schizophrenia with substantial upfront payments) and the successful completion of the pivotal development of evenamide in schizophrenia and CTRS, the company should see a re-rating of the risk profile to Medium Risk. (See Important Disclosures for our Risk Qualification).



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%
TOTAL ASSETS				39.0		24.2	100%
OVERHEAD EXPENSES (INCLUDING REPAYMENT OF THE EUR 40 MN EIB LOAN)				-6.9		-6.9	
NPV/SHARE (CHF)				32.1		17.3	
PRICE ON 27 JUNE 2024						8.3	
PERCENTAGE UPSIDE / (DOWNSIDE)						109%	
* TRS - TREATMENT RESISTANT SCHIZOPHRENIA							
ESTIMATES AS OF 27 JUNE 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
2024					
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)	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 PRIMARY END POINT MET WITH A STATISTICALLY SIGNIFICANT (P-VALUE = 0.006) REDUCTION IN THE PANSS TOTAL SCORE OF 10.2 POINTS VS. 7.6 FOR PLACEBO KEY SECONDARY END POINT MET 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	
25 JUN	EVENAMIDE	SCHIZOPHRENIA	INVESTOR DAY	NEWRON HOSTED AN INVESTOR DAY IN NEW YORK CITY FOCUSED ON ITS CLINICAL, SCIENTIFIC AND COMMERCIAL PLANS FOR EVENAMIDE. THREE LEADING SCHIZOPHRENIA EXPERTS PRESENTED ON THE UNMET MEDICAL NEEDS IN SCHIZOPHRENIA AND NEW CONCEPTS AND RECENT NEUROBIOLOGICAL FINDINGS FOR TREATING POOR RESPONDERS AND TRS PATIENTS. AN OUTLINE OF THE PHASE III DEVELOPMENT PLAN OF EVENAMIDE IN TRS WAS PRESENTED. THE COMPANY EXPECTS TO ANNOUNCE EITHER A GLOBAL OR REGIONAL PARTNERSHIP FOR EVENAMIDE IN THE NEXT FEW MONTHS BEFORE STARTING THE PIVOTAL PHASE III "STUDY 017" TRIAL IN TRS PATIENTS.	
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 04	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 27 JUNE 2024

SOURCE: VALUATIONLAB ESTIMATES, NEWRON PHARMACEUTICALS

Forecasts & Sensitivity Analysis

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

EVENAMIDE - FINANCIAL FORECASTS FOR SCHIZOPHRENIA

INDICATION	ADD-ON THERAPY TO ANTIPSYCHOTICS FOR REDUCING POSITIVE SYMPTOMS AND PSYCHOTIC WORSENING IN PATIENTS WITH SCHIZOPHRENIA
DOSSAGE	30 MG TWICE DAILY (TBD)
PRICE	USA: USD 15/DAY, EU/ROW: EUR 10/DAY; PRICING MAY PROVE CONSERVATIVE IF EVENAMIDE BECOMES A NEW TREATMENT PARADIGM IN SCHIZOPHRENIA
STANDARD OF CARE	ATYPICAL (2ND GENERATION) ANTIPSYCHOTICS SUCH AS ZYPREXA, SEROQUEL, RISPERDAL, GEODON, ABILIFY
UNIQUE SELLING POINT	FIRST ADD-ON TO MAINSTAY ANTIPSYCHOTICS FOR SCHIZOPHRENIA WITH THE POTENTIAL TO PROLONG RESPONSE RATES AND REDUCE FREQUENT SWITCHING
7Ps ANALYSIS	
PATENT	US: PROTECTION UNTIL 2033 BASED ON COMPOSITION OF MATTER PATENT GRANTED UNTIL 2028 + 5 YEARS EXTENSION; EU: 10-YEARS DATA EXCLUSIVITY
PHASE	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
PATHWAY	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
PATIENT	POORLY RESPONDING PATIENTS CAN POTENTIALLY REGAIN A NORMAL SOCIAL AND PRODUCTIVE LIFE WITH A HIGHER LIFE EXPECTANCY
PHYSICIAN	POTENTIAL TO ADDRESS POORLY RESPONDING PATIENTS OR PATIENTS WITH BREAKTHROUGH SYMPTOMS ON CURRENT ANTIPSYCHOTIC TREATMENT
PAYER	SUBSTANTIAL REDUCTION OF ASSOCIATED COSTS SUCH AS UNEMPLOYMENT, LONG-TERM CARE, HOSPITALIZATION, SUICIDE RISK
PARTNER	PHASE IIA POC COMPLETED; NEXT STEPS: FUNDS SECURED TO START REGISTRATIONAL TRIALS; GLOBAL PARTNERING LIKELY ON POSITIVE "STUDY 008A" RESULTS

REVENUE MODEL

EUROPE / REST OF WORLD (PARTNER TBD)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
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
SALES (EUR MN)	0	0	0	0	186	302	383	428	474	501	529
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
PROFIT BEFORE TAX (EUR MN)	-12	18	10	20	43	75	57	104	71	125	79
TAXES (EUR MN)	0	-1	-2	-3	-13	-24	-18	-33	-22	-39	-25
PROFIT (EUR MN)	-12	17	8	17	29	52	39	71	49	86	54
UNITED STATES (PARTNER TBD)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
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
SALES (EUR MN)	0	0	0	0	152	257	313	344	376	409	208
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
PROFIT BEFORE TAX (USD MN)	0	20	0	20	44	66	80	55	101	66	33
TAXES (EUR MN)	0	-1	0	-3	-13	-19	-24	-16	-29	-19	-10
PROFIT (EUR MN)	0	18	0	16	28	42	51	35	64	42	21
GLOBAL SALES (EUR MN)	0	0	0	0	338	559	696	772	850	910	736
CHANGE (%)						65%	25%	11%	10%	7%	-19%
GLOBAL PROFIT (EUR MN)	-12	35	8	33	58	94	91	107	113	128	76
CHANGE (%)		-390%	-77%	301%	78%	63%	-3%	18%	6%	13%	-41%
WACC (%)											
NPV TOTAL PROFIT (CHF MN)	524										
NUMBER OF SHARES (MN)											
NPV PER SHARE (CHF)											
SUCCESS PROBABILITY											
RISK ADJUSTED NPV PER SHARE (CHF)	19.1										

SENSITIVITY ANALYSIS

	CHF/SHARE	WACC (%)				
		8	9	10	11	12
SUCCESS PROBABILITY	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 27 JUNE 2024

SOURCE: VALUATIONLAB ESTIMATES

Clozapine treatment-resistant schizophrenia (orphan-like indication)

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

INDICATION	ADD-ON THERAPY TO ANTIPSYCHOTICS FOR REDUCING POSITIVE SYMPTOMS & PSYCHOTIC WORSENING IN CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA (CTRS)
DOSAGE	15 OR 30 MG TWICE DAILY (TBD)
PRICE	USA: USD 15/DAY, EU/ROW: EUR 10/DAY; PRICING MAY PROVE CONSERVATIVE IF EVENAMIDE BECOMES A NEW TREATMENT PARADIGM IN SCHIZOPHRENIA
STANDARD OF CARE	CLOZAPINE AND OTHER ATYPICAL (2ND GENERATION) ANTIPSYCHOTICS SUCH AS ZYPREXA (OLANZAPINE), SEROQUEL (QUETIAPINE), RISPERDAL (RISPERIDONE)
UNIQUE SELLING POINT	POTENTIALLY FIRST ADD-ON THERAPY TO ANTIPSYCHOTICS IN PATIENTS WITH CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA (ORPHAN INDICATION)
7Ps ANALYSIS	
PATENT	US: PATENT PROTECTION UNTIL 2033 BASED ON COMPOSITION OF MATTER PATENT GRANTED UNTIL 2028 + 5 YEARS EXTENSION; EU: 10-YEAR DATA EXCLUSIVITY
PHASE	FILINGS RELATING TO ORPHAN/PRIME/FAST TRACT DESIGNATION; START PHASE III "STUDY 017" TRS TRIAL Q4 2024, RESULTS END 2025; LAUNCH H1 2027
PATHWAY	PHASE III TRIAL IN INADEQUATE RESPONDERS + PHASE III TRIAL IN TREATMENT-RESISTANT SCHIZOPHRENIA (INCL. CTRS); 18 MONTHS TO COMPLETION FOR EACH TRIAL
PATIENT	CLOZAPINE TREATMENT-RESISTANT SCHIZOPHRENIA PATIENTS CAN POTENTIALLY REGAIN A NORMAL SOCIAL AND PRODUCTIVE LIFE WITH A HIGHER LIFE EXPECTANCY
PHYSICIAN	POTENTIAL TO ADDRESS TREATMENT-RESISTANT PATIENTS WHERE CLOZAPINE NO LONGER WORKS OR OTHER ATYPICAL ANTIPSYCHOTICS
PAYER	TREATMENT-RESISTANT SCHIZOPHRENIA IS ASSOCIATED WITH SOME OF THE HIGHEST HOSPITALIZATION COSTS, COSTS TO SOCIETY AND RISK OF SUICIDE
PARTNER	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
EUROPE / REST OF WORLD (PARTNER TBD)											
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
SALES (EUR MN)	0	0	0	0	20	33	44	51	56	58	61
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
PROFIT BEFORE TAX (EUR MN)	-1	3	-2	5	3	5	7	13	8	9	9
TAXES (EUR MN)	0	0	0	-1	-1	-2	-2	-4	-3	-3	-3
PROFIT (EUR MN)	-1	3	-2	4	2	3	5	9	6	6	6
UNITED STATES (NEWRON SPECIALIST SALES FORCE)											
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
SALES (EUR MN) - BOOKED BY NEWRON	0	0	0	0	25	40	54	65	74	80	24
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
PROFIT BEFORE TAX (EUR MN)	0	0	0	0	14	26	37	44	50	55	17
TAXES (EUR MN)	0	0	0	0	-5	-8	-11	-14	-16	-17	-5
PROFIT (EUR MN)	0	0	0	0	10	18	25	30	35	38	11
GLOBAL SALES (EUR MN)											
GLOBAL SALES (EUR MN)	0	0	0	0	45	74	98	116	130	139	85
CHANGE (%)						65%	33%	19%	11%	7%	-38%
GLOBAL PROFIT (EUR MN)											
GLOBAL PROFIT (EUR MN)	-1	3	-2	4	12	21	30	39	40	44	18
CHANGE (%)	476%	-347%	-157%	-360%	183%	80%	38%	32%	3%	8%	-59%
WACC (%)	10%										
NPV TOTAL PROFIT (CHF MN)	125										
NUMBER OF SHARES (MN)	17.8										
NPV PER SHARE (CHF)	7										
SUCCESS PROBABILITY	35% (PROOF-OF-CONCEPT ESTABLISHED)										
RISK ADJUSTED NPV PER SHARE (CHF)	2.4										

SENSITIVITY ANALYSIS

	CHF/SHARE	WACC (%)				
		8	9	10	11	12
SUCCESS PROBABILITY	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 27 JUNE 2024

SOURCE: VALUATIONLAB ESTIMATES

Income Statement

NEWRON PHARMACEUTICALS											SHARE PRICE (CHF)	8.25
IFRS												
INCOME STATEMENT (EUR MN)	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
PRODUCT SALES (INCLUDING PARTNERS)	64	70	77	84	474	710	856	923	997	1'057	827	
CHANGE (%)	-3%	10%	10%	9%	463%	50%	21%	8%	8%	6%	-22%	
PRODUCT SALES (BY NEWRON)	0	0	0	0	25	40	54	65	74	80	24	
CHANGE (%)						62%	33%	21%	14%	9%	-70%	
ROYALTIES	7	7	8	9	63	97	118	127	138	146	120	
CHANGE (%)	13%	9%	9%	8%	630%	55%	21%	8%	8%	6%	-18%	
LICENCE, UPFRONT & MILESTONE INCOME	0	44	10	44	34	53	28	45	37	50	0	
OTHER INCOME & GRANTS	2	0	0	0	0	0	0	0	0	0	0	
REVENUES (EXCL. PARTNER SALES)	9	51	18	52	122	191	200	237	249	277	145	
CHANGE (%)	49%	463%	-65%	190%	132%	57%	4%	19%	5%	11%	-48%	
COGS	0	0	0	0	-4	-6	-8	-10	-11	-12	-4	
GROSS PROFIT	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%	
R&D	-13	-10	-8	-8	-8	-9	-9	-10	-10	-11	-11	
CHANGE (%)	10%	-24%	-20%	0%	5%	5%	5%	5%	5%	5%	5%	
S,G&A	-8	-8	-8	-8	-14	-16	-17	-19	-20	-21	-12	
CHANGE (%)	2%	0%	0%	0%	89%	10%	7%	11%	8%	5%	-45%	
OPERATING EXPENSES	-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%	
EBITDA	-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%	
DEPRECIATION & AMORTIZATION	0	0	0	0	0	0	0	0	0	0	0	
AS % REVENUES	2%	0%	1%	0%	0%	0%	0%	0%	0%	0%	0%	
EBIT	-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%	
NET FINANCIAL INCOME/(EXPENSE)	-5	-4	-4	-2	0	1	1	2	3	3	4	
PROFIT BEFORE TAXES	-16	29	-2	35	95	161	167	201	210	236	122	
MARGIN	-179%	57%	-10%	67%	78%	84%	84%	85%	84%	85%	85%	
TAXES	0	-2	-3	-8	-35	-56	-57	-68	-71	-79	-43	
TAX RATE (%)	0%	8%	-167%	23%	37%	34%	34%	34%	34%	33%	35%	
NET PROFIT/LOSS	-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%	
PROFIT/(LOSS) PER SHARE (IN EUR)	-0.91	1.49	-0.27	1.51	3.36	5.92	6.14	7.45	7.81	8.81	4.45	
PROFIT/(LOSS) PER SHARE (IN CHF)	-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 27 JUNE 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)	8.25
RATIOS												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
P/E		5.7x	-31.1x	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		-46.3x	-18.6x	8.0x	1.9x	0.8x	0.5x	0.4x	0.3x	0.2x	0.2x	
EV/EBITDA		4.1x	50.1x	3.7x	1.4x	0.9x	0.8x	0.7x	0.7x	0.6x	1.2x	
PER SHARE DATA (CHF)												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
EARNINGS	-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%	
CASH	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%	
DIVIDENDS	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%	
NET ASSET VALUE	-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%	
BALANCE SHEET (EUR MN)												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
NET LIQUID FUNDS	13	49	43	50	152	321	496	705	923	1'168	1'299	
TOTAL ASSETS	30	67	60	67	170	339	514	723	941	1'185	1'316	
SHAREHOLDERS' EQUITY	-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%	
FINANCIAL DEBT	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%	
EMPLOYEES	22	22	23	23	24	24	25	25	26	26	27	
CHANGE (%)	0%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	
CASH FLOW STATEMENT (EUR MN)												
	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
NET PROFIT / (LOSS) BEFORE TAX	-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	
CASH FLOW	-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	
OPERATING FREE CASH FLOW	-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	
NET CASH USED IN OPERATING ACTIVITIES	-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	
NET INCREASE/(DECREASE) CASH & CASH EQUIVALENTS	-7	36	-6	7	103	169	175	209	218	244	131	

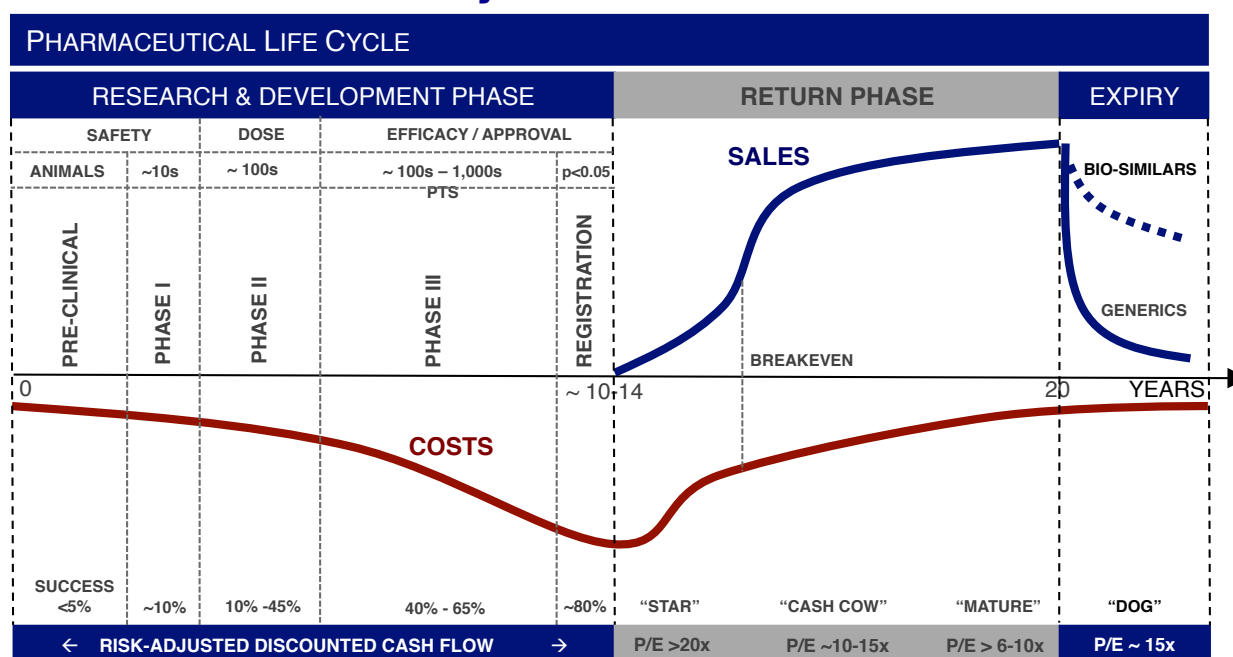
ESTIMATES AS OF 27 JUNE 2024

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

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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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