EDISON

Newron Pharmaceuticals

FY22 results update

A year ahead of clinical milestones for evenamide

Pharma and biotech

Newron has released its annual report and provided an operational overview for evenamide as a potential schizophrenia therapy. Positive interim data for the Phase II (study 014/015, in treatment-resistant schizophrenia, TRS) was shared in Q123 with similar results demonstrated in the full/top-line six-week data for all enrolled patients (released on 20 March 2023). The Phase III (study 008A, for patients on antipsychotics but not with TRS) is ongoing; results are expected in H223. Newron is preparing another Phase III (study 003 in TRS), which it plans to initiate in 2023. We believe positive results from these trials would represent the most significant near-term catalysts. At end December 2022, Newron had a total cash and liquid asset position of €22.8m, which we estimate will provide a cash runway into 2024. We value Newron at CHF128.7m or CHF7.2/share (previously CHF113.9m or CHF6.4/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	5.76	(14.12)	(0.79)	0.0	N/A	N/A
12/22	6.09	(16.99)	(0.95)	0.0	N/A	N/A
12/23e	6.46	(17.11)	(0.96)	0.0	N/A	N/A
12/24e	6.85	(22.27)	(1.25)	0.0	N/A	N/A

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

Evenamide provides a significant near-term catalyst

In our view, the near-term value driver for Newron is clinical data for evenamide, with the need for improved schizophrenia therapies a significant opportunity because a lack of response to current therapies is a key challenge. Evenamide is involved in multiple studies as an adjunctive therapy, in schizophrenia and in patients with TRS. For the Phase II trials, encouraging full six-week data was reported on 20 March 2023 (study 014) and one-year results for the extension arm (study 015) are expected in Q124. For the Phase III trial (008A), results are expected in H223.

Cash runway into 2024

With a total cash and a current financial asset position of €22.8m, given our cash burn estimates, we believe Newron is sufficiently funded past the key study 008A readout in H223 and the initiation of the study 003 by H223. Assuming positive clinical results, we anticipate the company will look to find a partner in key regions with a potential launch in 2025. However, in the event of a delay in the anticipated launch timelines, the company would need to explore funding options to support its growing R&D pipeline.

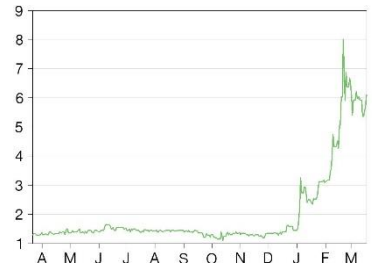
Valuation: CHF128.7m or CHF7.2 per share

We value Newron at CHF128.7m or CHF7.2 per share (vs CHF113.9m or CHF6.4 per share). We include a risk-adjusted NPV calculation for Xadago in Parkinson's disease (PD) and evenamide in schizophrenia and a net debt position of €22.4m. Value uplift comes from increasing the probability of success for evenamide to 60% (50% previously) and rolling our model forward by six months; however, these were partially offset by a higher net debt position and the impact of foreign exchange.

20 March 2023

Price	**CHF6.12**
Market cap	**CHF109m**
	CHF/€1.02
Net debt (€m) at end December 2022	22.4
Shares in issue	17.8m
Free float	99%
Code	NWRN
Primary exchange	SIX Swiss Exchange
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	1.3	341.9	360.2
Rel (local)	7.5	348.4	422.9
52-week high/low	CHF8.0		CHF1.1

Business description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease is sold in Europe, Japan and the United States. Evenamide, a novel schizophrenia add-on therapy, is involved in a Phase III trial programme targeting schizophrenia.

Next events

Evenamide Phase II study 014 read-outs	H123
Evenamide Phase III study 008A read-outs	H223
Evenamide Phase II study 015 read-outs	Q124

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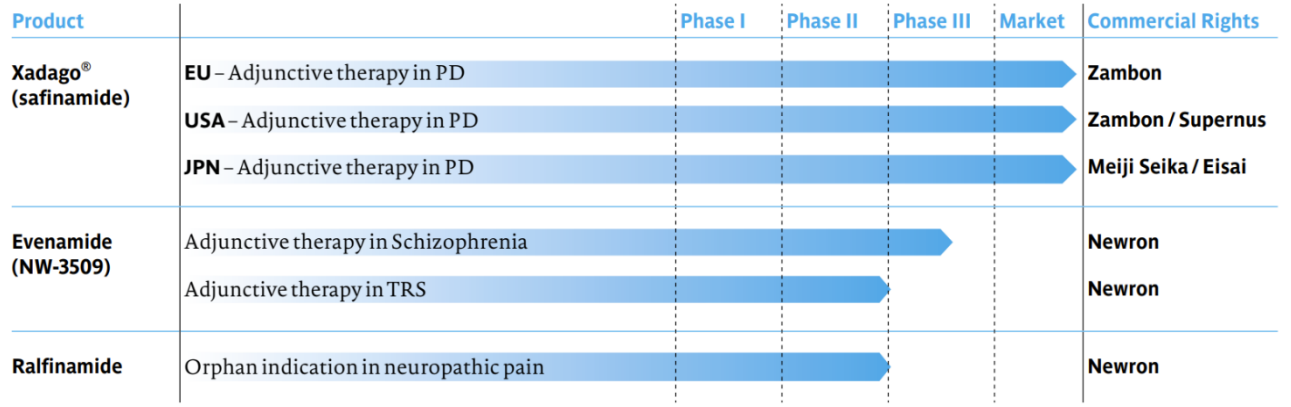
Edison profile page

An active pipeline with a focus on CNS and pain

Newron Pharmaceuticals is a biopharmaceutical company focused on developing innovative treatments for diseases of the central nervous system (CNS). Royalties for the company's marketed drug Xadago (€5.9m in FY22), an adjunctive therapy for PD, continue to contribute to the company's top-line revenues. Newron and its partners Zambon and Supernus are working to protect intellectual property rights associated with Xadago in the United States. Previously, the company was looking to expand Xadago's label with a second indication in levodopa-induced dyskinesia (LID), a major complication for PD patients involving uncontrolled involuntary movements. However, Newron and Zambon have since reached an agreement to discontinue these plans and do not intend to initiate further clinical studies.

The company's focus lies firmly with the clinical development of evenamide as an add-on therapy, for use in schizophrenia and in TRS. Phase II studies have demonstrated evidence of evenamide's efficacy, significantly improving symptoms of psychosis in patients with TRS. The company's evenamide pipeline includes two Phase III trials: one study, which is ongoing, in patients with schizophrenia who are taking antipsychotics but not classified as having TRS (study 008A), and one study, which is expected to start in 2023, with TRS patients who are not responding to clozapine, a commonly used antipsychotic drug (study 003).The company's pipeline also includes ralfinamide as a potential therapy for the orphan indication of neuropathic pain, but the programme has been deprioritized in recent years and is not included in our valuation of the company.

Exhibit 1: Newron's clinical development pipeline



Source: Newron annual report 2022

Evenamide: An overview of ongoing clinical activities

The near-term catalyst for the Newron revolves around the clinical development of evenamide, a glutamate modulator for the treatment of schizophrenia. While clozapine is a typical treatment for managing schizophrenia, over half of patients are unresponsive to the therapy, highlighting the opportunity for evenamide as an improved option. Evenamide is involved in several ongoing clinical programmes:

- The Phase II trial (study 014 – six weeks, and study 015 – extension study) is an international, randomised, open-label, rater-blinded assessment of evenamide (safety and efficacy) as an add-on to an antipsychotic (excluding clozapine) in patients with moderate to severe TRS. Six-week data for the first 100 patients randomised in study 014 (receiving either 7.5mg, 15mg or 30mg doses) was reported in June 2022. Of the 100, 90 continued with extension study 015 and updated data have been shared for 85 patients at the six-month read-out and for 77

patients at the one-year read-out. Encouragingly, the data across this duration showed a gradual and sustained pattern of improvement in key efficacy measurements (eg, Positive and Negative Syndrome Scale, Clinical Global Impression – Severity of illness and Change from Baseline), with the proportion of patients achieving significant improvements increasing over time. The enrolment of patients for study 014 has now been completed (n=161) and management released top-line six-week data for all enrolled patients on 20 March 2023, reporting similar safety and tolerability and clinical benefit to that noted in the first 100 patients. Interestingly, similar efficacy was observed irrespective of the different dosage strengths at six weeks (we note that later cohorts were administered the higher 15mg and 30mg doses versus 7.5mg and 15mg for the initial participants). We anticipate that the clinical benefit would continue to improve with treatment over a longer period (in line with the observed trend for the first 100 patients) and systematic differences between doses of evenamide, if observed, would become clearer with time. One-year data from all 161 patients in extension study 015 are expected in Q124.

- Evenamide is also involved in a pivotal Phase III trial (study 008A), which was initiated in September 2021; patient enrolment is ongoing. This is a four-week, randomised, double-blind, placebo-controlled study to assess the safety, efficacy and tolerability of evenamide (30mg twice daily as an add-on treatment for chronic schizophrenia in patients already receiving antipsychotics (who are not classed as having TRS). We expect results from this study in H223 and, in our view, this may represent a major near-term catalyst for Newron, if the data are positive.
- In addition, the company is planning a potentially pivotal Phase III trial (study 003) to investigate the safety, efficacy and tolerability of evenamide as an add-on treatment in patients with TRS not responding adequately to their monotherapy treatment with atypical antipsychotics (including clozapine). This will be a multinational, randomised, placebo-controlled, 10-week global study. Management expects to initiate this study in 2023.

These trials will make a critical contribution to the Phase II/III evenamide development programme data package, provided the results continue to be positive.

Financials

In FY22, Newron's total revenue recorded moderate growth of 5.8% y-o-y to €6.1m (7.7% below our FY22 revenue estimate of €6.6m), largely pertaining to royalty payments from partners on sales of Xadago. Total operating expenses increased 7.0% y-o-y to €19.4m in FY22, which mainly comprised R&D (62%) and general and administrative (G&A) expenses (38%). While G&A expenses remained largely unchanged during the year, R&D expenses (€12.0m) were up 11.9% y-o-y, due to the start of the Phase III evenamide study in Q421. The operating loss was €13.3m (vs €12.4m in FY21). The company reported a pre-tax loss in FY22 of €17.5m, compared to €14.9m in FY21, which incorporated €3.9m of interest expenses in FY22 related to accrual of the European Investment Bank (EIB) loan interest that Newron needs to pay from 28 June 2024. The cash used in operations was reported at €11.1m, slightly below €11.4m in FY21.

We note that the company has drawn down all five tranches of the EIB loan and we expect repayment of the first two tranches (total €17.5m) to be due in FY24. The EIB financing agreement has provided the company with a total of €40m in funding, with each tranche bearing an interest rate of 3% annually. An additional fixed rate (between 6.75% and 5.25% depending on the tranche) is also payable on expiry of the facility. As part of the agreement Newron issued 807,169 warrants to the EIB. At end FY22, the company had €45.2m in interest-bearing debt.

While our long-term assumptions for evenamide remain unchanged, we have made some adjustments to our FY23 forecasts based on the FY22 results and have introduced FY24 estimates.

We have adjusted our FY23 revenue to €6.5m from €7.9m previously assuming a c 6% y-o-y growth in royalty income for Xadago. We forecast FY24 revenue of €6.8m, assuming a similar 6.0% growth in revenues. We expect the evenamide Phase III trial will be the primary focus of R&D expenditures in FY23, but now anticipate the pivotal study 003 to start in H223 (Q223 previously) and have therefore deferred some of the previously estimated R&D expenditure from FY23 to FY24. Our revised estimate for R&D expenses in FY23 is €13.4m (€16.4m previously). As the trial progresses in FY24, we anticipate higher R&D expenses of €18.5m. We therefore estimate operating losses for FY23 and FY24 of €14.4m and €19.2m, respectively (vs our previous expectation of a €16.4m operating loss in FY23).

At end-FY22, Newron had a cash position of €13.4m, plus €9.4m in other current financial and liquid assets. Based on our forecasted operating cash burn, we estimate a cash runway for the company into 2024. Assuming a positive readout from study 008A in H223, we expect Newron will pursue a partnership deal for evenamide in schizophrenia, a payment from which may extend our runway estimate. In the absence of any partnership deal for evenamide in schizophrenia, we expect management would need to raise additional capital of €30m in FY24, modelled as illustrative debt. If the funding is realised through an equity issue instead (at the last closing trading price of CHF6.12 share at 17 March 2023), Newron would have to issue 4.8m shares, resulting in our per-share valuation reducing to CHF5.7/share from CHF7.2 currently (shares outstanding would increase from 17.8m to 22.6m). Our model assumes evenamide's commercial launch in FY25, which we estimate should provide sufficient cash inflows to support ongoing operational and working capital requirements from internally generated funds. However, if there is a delay in the anticipated launch timelines, the company would need to explore additional funding options to support its growing R&D pipeline.

Valuation

Our valuation for Newron increases to CHF128.7m or CHF7.2 per share (previously CHF113.9m or CHF6.4 per share). We include FY22 net debt of CHF21.9m (€22.4m). As mentioned above, we have revised our FY23 revenue estimate and underlying R&D costs corresponding to the Phase III development programme for evenamide. Based on the recent decision by Newron and Zambon to discontinue the planned Xadago/safinamide clinical study for PD patients with PD LID, we have excluded Xadago in PD LID from our valuation. Our valuation now is based on a risk-adjusted NPV calculation for Xadago in PD and evenamide in schizophrenia (Exhibit 2). Importantly, we have increased the probability of success for the evenamide in schizophrenia to 60% from 50% previously, based on recent encouraging interim results from its Phase II 014/015 clinical trial, which contributes the most to the value uplift. Other minor factors that contributed to the valuation increase were rolling our model forward six months and the impact of foreign exchange (CHF0.98/€, previously CHF0.96/€, and US$1.08/€, previously US$1.0/€).

Exhibit 2: Newron valuation breakdown

Product	Indication	Launch	Probability of success	rNPV (CHFm)	NPV/share (CHF/share)
Xadago	PD	2015	100%	32.8	1.8
Evenamide	Schizophrenia	2025	60%	240.9	13.5
Total direct product value				273.6	15.3
Direct costs to 2033 less tax				(123.0)	(6.9)
Cash at end-December 2022				22.3	1.3
Loans (fair value December)				(44.3)	(2.5)
Valuation				**128.7**	**7.2**

Source: Edison Investment Research. Note: Valuation figures are converted from to CHF from € (CHF0.98/€).

Exhibit 3: Financial summary

Accounts: IFRS, Yr end: December 31, €:000s	2020	2021	2022	2023e	2024e
PROFIT & LOSS					
Total revenues	5,258	5,762	6,094	6,456	6,847
Cost of sales	0	0	0	0	0
Gross profit	5,258	5,762	6,094	6,456	6,847
Total operating expenses	(23,324)	(18,119)	(19,396)	(20,881)	(26,043)
Research and development expenses	(14,853)	(10,725)	(12,005)	(13,434)	(18,521)
SG&A	(8,471)	(7,394)	(7,391)	(7,448)	(7,522)
EBITDA (normalized)	(16,386)	(11,386)	(12,620)	(14,238)	(19,078)
Operating income (reported)	(18,066)	(12,357)	(13,302)	(14,425)	(19,196)
Finance income/(expense)	(1,552)	(2,527)	(4,170)	(2,681)	(3,070)
Exceptionals and adjustments	0	0	0	0	0
Profit before tax (reported)	(19,618)	(14,884)	(17,472)	(17,106)	(22,266)
Profit before tax (normalised)	(18,157)	(14,122)	(16,992)	(17,106)	(22,266)
Income tax expense (includes exceptionals)	(1,380)	(17)	(21,000)	0	0
Net income (reported)	(20,998)	(14,901)	(17,493)	(17,106)	(22,266)
Net income (normalised)	(19,537)	(14,139)	(17,013)	(17,106)	(22,266)
Basic average number of shares, m	17,845.0	17,845.0	17,845.0	17,845.0	17,845.0
Basic EPS (€)	(1.18)	(0.84)	(0.98)	(0.96)	(1.25)
Adjusted EPS (€)	(1.09)	(0.79)	(0.95)	(0.96)	(1.25)
BALANCE SHEET					
Property, Plant and Equipment	105	87	72	72	72
Right of use assets (leases)	629	490	455	285	186
Intangible Assets	11	2	0	0	0
Non-current receivables (Tax credits)	12,579	10,480	8,175	5,774	3,087
Total non-current assets	13,324	11,059	8,702	6,131	3,345
Cash and equivalents	13,213	25,019	13,424	8,418	1,822
Current financial assets	18,037	9,575	9,350	0	0
Inventories	0	0	0	0	0
Trade Accounts Receivable	6,624	4,833	5,719	5,276	5,498
Total current assets	37,874	39,427	28,493	13,694	7,320
Trade Accounts Payable	6,741	3,504	4,869	4,605	5,211
Other Current Liabilities	151	150	172	172	172
Total current liabilities	6,892	3,654	5,041	4,777	5,383
Long-term Debt	25,674	42,542	45,165	45,165	57,665
Leasing Obligations	520	389	325	325	325
Share based liabilities	181	213	220	220	220
Long-term Provisions	685	581	474	474	474
Total non-current liabilities	27,060	43,725	46,184	46,184	58,684
Equity attributable to company	17,246	3,107	(14,030)	(31,136)	(53,402)
CASH FLOW STATEMENT					
Pre-tax profit	(19,618)	(14,884)	(17,472)	(17,106)	(22,266)
Net Financial Income	(531)	(792)	(1,183)	0	0
Depreciation and amortisation	219	209	202	188	118
Share based payments	1,461	762	480	0	0
Other adjustments	(842)	3,524	4,996	2,401	2,687
Movements in working capital	3,723	(264)	1,885	179	384
Cash from operations (CFO)	(15,588)	(11,445)	(11,092)	(14,338)	(19,077)
Capex	(34)	(20)	(18)	(18)	(18)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	(582)	8,440	(299)	9,350	0
Cash used in investing activities (CFIA)	(616)	8,420	(317)	9,332	(18)
Loans received	7,500	15,000	0	0	0
Illustrative debt	0	0	0	0	30,000
Loan repayments	0	0	0	0	0
Equity issued	0	0	0	0	0
Other Financing Cash Flows (leases)	(135)	(169)	(186)	0	0
Cash from financing activities (CFF)	7,365	14,831	(186)	0	30,000
Cash and equivalents at beginning of period	22,052	13,213	25,019	13,424	8,418
Increase/(decrease) in cash and equivalents	(8,839)	11,806	(11,595)	(5,006)	10,905
Effect of FX on cash and equivalents	0	0	0	0	0
Cash and equivalents at end of period	13,213	25,019	13,424	8,418	19,322
Net (debt)/cash (including liquid resources)	5,576	(7,948)	(22,391)	(36,747)	(38,343)

Source: Edison Investment Research

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