EDISON

Newron Pharmaceuticals

Interim results update

Evenamide validation underway

Pharma & biotech

Newron is developing evenamide (30mg twice per day) as an add-on to treat poorly managed and refractory schizophrenia. A potentially pivotal Phase II/III study is underway and could report by Q422. Newron hopes to partner evenamide for larger indications while selling the product directly to the targeted clozapine-resistant market. H121 results showed Xadago royalties of €2.65m, up 6.5% over H120. The additional Xadago dyskinesia study due to start in Q122 could eventually boost US sales, but there are potential generic challenges currently being legally contested. Newron had June cash plus loan facilities totalling €36.9m plus Xadago royalties to fund it into 2023. Our indicative value of CHF107m has been adjusted for lower Xadago royalty growth, core costs and higher debt.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	7.04	(18.04)	(1.01)	0.0	N/A	N/A
12/20	5.26	(18.16)	(1.09)	0.0	N/A	N/A
12/21e	5.49	(16.70)	(0.94)	0.0	N/A	N/A
12/22e	6.04	(29.86)	(1.67)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. 2019 accounts were restated.

Potentially pivotal study to provide validation

Evenamide selectively blocks sodium channels to prevent rapid bursts of the nerve depolarisation that carries electric signals. This may help to control schizophrenia. Study 008A (EudraCT 2020-006062-36) at a 30mg twice per day (*bid*) dose was previously viewed as a continuation of completed Study 008 (NCT04461119). It now has higher statistical power with 196 patients to become a potentially pivotal Phase II/III study run in Europe, Asia and Latin America. There are two day-29 primary endpoints: safety and efficacy. Completion is scheduled for late 2022. We expect further US-based studies, possibly in treatment-resistant patients once the US regulatory strategy has been agreed.

Xadago: Royalties, trials and possible generics

Xadago is a marketed product competing with established generic products like rasagiline. In the United States, generic companies have filed notice of their intention to enter the Xadago market; Newron is contesting these. Xadago's H120 royalties were €2.65m, up 6.5% over H120. A trial to extend Xadago's US label to cover relief of Parkinson's dyskinesia would add major value and might start by Q12022. Newron and Zambon agreed in March 2021 to fund this study on a 50:50 basis; the expected cost to Newron is under €10m. Newron will run the study.

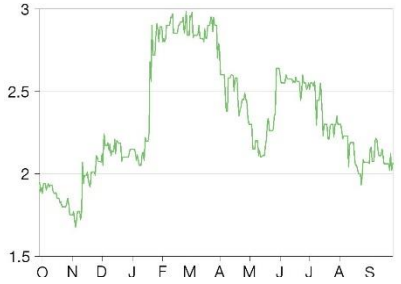
Valuation: Funding now into 2023

Newron had €21.9m cash on 30 June 2020 and added a further €7.5m EIB loan in September, so effectively had €29.4m cash. There is a remaining €7.5m EIB loan facility plus anticipated Xadago royalties to support planned developments into 2023. Our valuation model has been adjusted for lower than anticipated Xadago sales to about CHF107m (CHF6/share) and will be fully revised once Study 008A reports. Newron aims to acquire more products to boost its pipeline.

27 September 2021

Price	**CHF2.1**
Market cap	**CHF37m**
CHF1.09/€; CHF0.93/$; $1.017€	
Cash and investments (€m) at 30 June 2021	21.9
Shares in issue	17.845m
Free float	99.6%
Code	NWRN
Primary exchange	SIX
Secondary exchange	XETRA

Share price performance



%	1m	3m	12m
Abs	3.3	(20.6)	5.4
Rel (local)	8.7	(19.4)	(9.0)
52-week high/low	CHF3.0	CHF1.7	

Business description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease is sold in Europe, Japan and the US. Evenamide, a novel schizophrenia therapy, has started one Phase III and may start a further US trial in H122.

Next events

FY21 report	March 2022
Study 008A outcome	Q422

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Edison profile page

Xadago

Xadago is licensed, outside Japan and Asia, to Zambon, a private Italian company. Zambon is generally strong in Europe and Latin America with 20% of its sales in the home Italian market. It launched Xadago in Europe during H115, with Newron receiving double-digit royalties on sales. Our royalty rate estimate is about 12% in Europe.

In June 2020, the US Xadago sublicensee rights transferred to Supernus Pharma, a US company. Supernus cites that the US Parkinson's disease (PD) market is anticipated to grow from $1.5bn to $6.2bn by 2026. Under the sublicence, Newron shares 50% of Zambon's US royalties. Given the importance of the US market, this sharing arrangement might be a drag on royalty growth. The dyskinesia trial will increase Newron's royalty share slightly to give a return on the trial investment.

From 2017, Eisai has had the exclusive rights to market safinamide in Japan, as well as to develop and market safinamide in Asia. Safinamide (the generic name for Xadago but branded as Equfina) was approved in Japan in late 2019. Newron does not disclose sales by region, so detailed forecasting is not feasible.

Royalties and forecast revenues

Product royalties (including the United States and Japan) rose in H121 to €2.65m, up 6.5% over H120. Royalties were €5.24m in 2020 so we have revised our forecast to €5.5m for FY21, down from €6.7m. For 2022, we have trimmed our royalty forecast from €7.7m to €6.0m.

Current indication

Xadago is indicated for the treatment of adult patients with idiopathic PD as an add-on therapy to a stable dose of levodopa (L-DOPA) alone or in combination with other PD medicinal products in mid- to late-stage fluctuating patients. Dopamine is a major brain neurotransmitter. A symptom of the neurodegeneration seen in PD is lower levels of dopamine. Hence, boosting dopamine levels relieves PD symptoms. It does not stop the fundamental disease progression.

One of the issues with standard oral dosing of dopamine (given as the prodrug L-DOPA) is inconsistent blood levels, which lead to 'off' periods when PD symptoms return. MOA-B inhibitors are used as one of several possible therapeutics to limit off time. Xadago is a monoamine oxidase type B (MOA-B) inhibitor. MOA is the enzyme that breaks down dopamine, so reducing its MOA activity gives more consistent brain dopamine levels. Other treatments to deal with this include direct continuous delivery of L-DOPA gel to the small intestine via an external pump, but this is very expensive. Deep brain stimulation is also used.

In the MOA-B class, the leader is Azilect (rasagiline, Teva), approved by the FDA in 2006 and EMA in 2005. Rasagiline is an irreversible MOA-B inhibitor, which means it destroys the enzyme activity after it binds. Other MOA-B drugs like Xadago and Zelapar (selegiline) are reversible. Rasagiline started to become generic in 2016. It has a wide label for use alone or in combination with other PD medications. Azilect had peak sales in 2014 of $519m (EvaluatePharma) but due to generic versions, the market value is now about $50m in Europe and the US combined. Due to a late approval, it is a branded product in Japan (Takeda), accounting for about half of global sales. Selegiline seems never to have gained a significant market share with very low sales.

Label extension

A noted complication of L-DOPA treatment, the main PD therapy, is dyskinesia: uncontrolled tremors that can occur both when treatment is working ('on') and in 'off' periods. Dyskinesia is a

very complex condition and medical opinion is still uncertain about why it occurs and how to treat it. It develops progressively in many patients after several years of L-DOPA therapy. This is called LID and is the subject of further Xadago development by Newron.

Under an agreement reached in March 2021, Newron and its partner Zambon agreed to run a trial to formally gain an indication in LID. This is particularly important for US marketing and could lead to a significant rise in sales as it could provide a validated therapeutic gain over standard generics. Newron notes that anecdotally, doctors observe less dyskinesia in Xadago treated patients, but this effect needs to be validated and quantified. If successful, Newron would receive a €4m milestone on approval and a marginally enhanced royalty rate on all Xadago sales.

The trial will be funded 50:50 by Newron and Zambon; Newron will run the study and expects its share of costs to be under €10m. The trial is stated by Newron to be a six-month, double-blind, placebo-controlled study now planned to enrol about 400 patients. Patients will have pre-existing dyskinesia and will complete daily diaries to record dyskinesia using a Dyskinesia Rating Scale.

This study will take about two years to recruit, run and analyse and involve 30–40 centres. It is expected to start in Q122 so could announce data by mid-2024. Any dyskinesia label extension might be promoted from 2025.

Generic threat

The FDA has notified Newron that several applications for generic safinamide (Xadago) have been filed. Xadago has new chemical entity (NCE) exclusivity until 27 March 2022. Xadago is then protected to December 2028 by three patents that have potential extensions to 2031. If a generic is launched in the next few years, it would severely reduce our expectations of Xadago's US sales potential. Current sales growth with the new US sales licensee is not spectacular although the exact numbers are not disclosed by Newron.

Orange book patents

The FDA granted Xadago standard New Chemical Entity protection for five years, which expires on 27 March 2022. Safinamide's strongest (form of matter) patent has already expired. Newron lists three active US patents in the FDA Orange Book (the list of approved pharmaceuticals). The FDA does not enforce patents (courts do) or rule on patent validity (US Patent Office). The active patents are a production method expiring 10 December 2028 (US8076515B2); a process patent expiring 8 June 2027 (US8278485B2); and a use patent covering safinamide co-administration with other PD therapies (US8278485B2) expiring 1 September 2027. In our experience, it can be complex to try to enforce production and use patents; we do not comment on this case.

Abbreviated new drug application (ANDA)

To make an Abbreviated New Drug Application[1] (ANDA), a generic manufacturer must state that any active patents are invalid or not infringed. Under Paragraph IV of the FDA rules, as Newron has filed legal actions against the ANDA (Newron interim report), the FDA will suspend the ANDA for up to 30 months (to September 2024) as its regulations require. But, if future court rulings agree that the ANDAs are valid, the FDA could still authorise a generic sometime after April 2022. This would reduce our US royalty expectations.

Europe has regulatory protection for up to 10 years ending 21 February 2025. Patents could extend this protection.

Typically, the entry of generics leads to an 80–90% fall in revenues but this market may be slightly protected if patients and doctors prefer not to take any perceived risk of transferring patients to a different brand.

[1] An ANDA uses the filed data for the existing, approved chemical entity so no new trials need to be run if the product is chemically identical with the same formulation. This makes generics easy and cheap to launch.

Evenamide on track to enter pivotal trials in H221

Evenamide reduces the firing rate of neurons, preventing rapid bursts of the nerve depolarisation that carries electric signals. This gives it a potentially useful adjuvant role in controlling schizophrenia.

The clinical development plan for evenamide has evolved over 2021. At the start of the year, it was anticipated that the FDA required safety study (008) at 7.5mg bid and 15mg bid doses could lead to two pivotal studies. However, a further continuation study, 008A, to test a 30mg *bid* dose was then required. This could have delayed the programme.

Study 008A has now been turned, after a strategic revaluation, from a continuation safety study into a separate study that will form one of the two required pivotal studies. Study 008 is therefore now complete. The numbering (008A) is still used as this registered with the regulatory authorities.

Study 008A will be performed in Europe, Asia and Latin America. After reaching an agreement with the FDA on a larger US study, Newron expects study 008A to become part of the global registration package.

Study 008 outcome

As neuronal signalling is how the brain and heart function, the FDA required key safety evidence. Study 008 in 138 patients reported on 1 April and showed that evenamide was safe with no abnormal brain wave activity. A further 58-volunteer heart study (Study 010) showed no effects on heart electrical activity, indicating no risk of arrythmias.

In study 008, chronic schizophrenia patients were assessed on the widely used Positive and Negative Syndrome Scale (PANSS) for efficacy. There was no statistical difference compared to placebo at the 15mg *bid* dose; 7.5mg *bid* was sub-therapeutic. The data did indicate that due to the short half-life[2] of evenamide a bigger dose will provide a higher therapeutic level for longer.

Pivotal study 008A at 30mg *bid* for inadequate responders

The study (EudraCT 2020-006062-36) aims to enrol at least 196 patients in Europe, Asia and Latin America of whom at least 105 will be in Europe. (The EMA now insists that candidates for European approval should have enough EU-based patients included in the trial.) This gives Study 008A the statistical power to be a potentially pivotal Phase II/III study. It is placebo controlled. Patients will be treated with second-generation anti-psychotic medications, like clozapine,[3] but with an inadequate response and mild to moderate symptoms. This enables the effect of adding Evenamide to be measured. Patients will not be hospitalised or be a suicide risk. Treatment resistant patients[4] are excluded although patients on clozapine for at least six months will be permitted if they show minimal improvement.

The evenamide dose will be titrated from 15mg *bid* in the first week to 30mg *bid*. There are two day-29 primary endpoints: safety and tolerability and, for efficacy, the improvement in the PANSS.

We expect further US-based pivotal studies once the strategy has been agreed with the FDA.

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[2] That is, as Newron has discussed with us, the evenamide concentration in the blood peaks within a few hours of dosing then falls quickly. As with any therapeutic, the agent needs to be over a threshold concentration to have the required effect. A higher dose means that the efficacy threshold is exceeded for a longer time. Note that we have not seen any actual pharmacokinetic data.

[3] Patient will be stable on their medication but with mild to moderate symptoms, Medications are listed as aripiprazole, clozapine, quetiapine, olanzapine, paliperidone, or risperidone (2mg equivalent).

[4] Resistance is defined as “significant persistent symptoms of schizophrenia after adequate doses of two standard antipsychotic medications (from two different chemical classes, including at least one atypical antipsychotic) following 6 weeks of treatment with each at adequate doses” (source EudraCT record).

A 25mg *bid* dose was evaluated in a previous 89-patient, four-week study with positive efficacy. A 30mg dose single dose has already been safely tested. Study 008 showed a clean safety profile.

Timelines and cost

Of the timelines, 008A is now due to end in late 2022 implying the announcement of the outcome in Q123. This could lead to a 2023 partnering deal. The core patent expires in 2028 but patent extensions and data protection (requiring any generics to run a trial) will give an extended protection period in Europe of up to 10 years.

The timeline on further US studies is not yet established. In the United States, half the time in active US clinical development plus the FDA review period can be added to the patent protection duration. The FDA also gives separate five-year protection for new chemical entities. There are built in delays on generic competitor submission dates, depending on circumstances.

Newron expects EU and US patent-based market exclusivity to last until 2033.

The pivotal trials have been estimated by Newron to cost €30m. This means that we expect 2022 R&D costs to rise significantly as recruitment rises and as and possibly more studies, start.

Commercial strategy

Newron is seeking a partner for the more general indication of inadequate response to current atypical antipsychotic agents. This is a general schizophrenia indication for patients who are not well controlled on their current anti-psychotic medicine, about 70% of cases. In Newron's estimates, this could have a market potential of over US$1bn a year. In the general anti-psychotic market, the leading agents are now generic, but evenamide will add onto current therapy not replace it.

Newron is considering direct marketing of evenamide in certain territories, like the US, for the adjuvant treatment in patients resistant to clozapine. Clozapine is currently the most effective antipsychotic agent, but about 30–50% of patients become resistant, giving no further options. Newron estimates there are 20,000 clozapine-refractory patients in the United States. Clozapine treatment-resistant patients are registered and the clozapine prescribers are easy to identify. Newron management estimates that this niche market has a c $200m sales potential.

H121 financials, loans and cash

Revenues and costs

Reported royalties in H121 rose to €2.65m, up 6.5% over H120. Total royalties were €5.24m in 2020. We have revised our forecast to €5.5m for FY21, down from €6.7m. For FY22, we have trimmed our royalty forecast from €7.7m to €6m.

R&D costs in H121 were €6.78m versus €7.78m in H120, a decline, but this is not a good comparison as a third clinical project, now cancelled, was running for most of H120. Although no tax credit for the period was claimed (this will be assessed at the year-end), the cash flow shows that previous tax credits of €2.20m (versus €0.54m) were used to offset various employment taxes. Admin costs fell to €3.75m from €4.37m. There was an interest charge (some non-cash) of €1.39m, incurred on the European Investment Bank (EIB) loan and associated warrants.

Cash flows and cash need

Operating cash outflow was €8.75m but this included a large €3.93m decrease in trade payables. Financial assets of net €7.04m were realised in H1 giving a net cash outflow of €1.78m. The effective cash use was €8.82m.

Newron had cash of €11.43m on 30 June, plus financial assets of €10.48m making €21.91m. A further EIB loan of €7.5m was drawn in September and €7.5m can still be drawn in 2022. Assuming at least a further €8m of royalties until 31 December 2022, Newron therefore has about €45m available. Management is confident that this is adequate to fund Study 008A to completion and commerce other studies.

Balance sheet

The outstanding EIB loan on the balance sheet as of 30 June 2021 was €26.37m (€25.67m as of 31 December 2020) but will be about €33.9m by 31 December 2021 after a further €7.5m EIB loan. We expect the remaining tranche will be drawn in H122 taking the loan (plus warrants) to around €41m by 30 June 2022.

We do not now expect any evenamide deal until 2023 as any partner would want to reduce risk by analysing Study 008A data. On the positive side, positive pivotal data would increase a deal value.

Italian tax credits are used to offset taxes due on personnel. Newron holds €11.36m (down from €12.58m) of non-current tax credit receivables. It can now claim up to €4m per year. No credits were claimed in H121 but €2.2m were used.

There are 17.8m shares in issue (unchanged) plus 1.85m employee options and 0.5m warrants held by the EIB as part of the loan as of 30 June.

Valuation: Adjusted to CHF107m

Our current model (dated 30 June 2021) indicates an adjusted value of about CHF107m (CHF6/share), as shown in Exhibit 1, formerly CHF121m (CHF6.8/share), This is because of low Xadago growth and the increased debt level. We now expect Xadago royalties to peak at about €12m; this includes the dyskinesia indication. Note that this does not take into account any generic competition. We expect FY21 year-end debt to be about CHF37m (€33.9m). We have extrapolated the operating costs based on H121. A revision of the indicative value is difficult before study 008A data given uncertainties over the timing of US evenamide trials. In addition, we do not feel able to increase the success probability of evenamide as there is no efficacy data at the 30mg bid dose.

Exhibit 1: Revised Newron valuation

Item	Value
Value of product cashflows (CHFm)	222.6
Direct costs to 2033 less tax (CHFm)	(111.1)
Cash at June 2021 (CHFm)	32.0
Loans (estimated current value, CHFm)	(36.9)
Net value (CHFm)	**106.7**
Shares in issue (m)	17.85
Value per share (CHF)	**5.98**

Source: Edison Investment Research. Note: Exchange rate: CHF1.09/€.

Exhibit 2: Financial summary

€000s	2019	2020	2021e	2022e
Year end December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	7,038	5,258	5,489	6,036
Cost of Sales	0	0	0	0
Gross Profit	7,038	5,258	5,489	6,036
EBITDA	(18,567)	(16,386)	(13,689)	(26,292)
Depreciation	(206)	(219)	(219)	(219)
Share option adjustments	(2,126)	(1,461)	0	0
Operating Profit	(20,899)	(18,066)	(13,908)	(26,511)
Net Interest	737	(1,552)	(2,788)	(3,346)
Profit Before Tax (norm)	(18,036)	(18,157)	(16,696)	(29,857)
Profit Before Tax (reported)	(20,162)	(19,618)	(16,696)	(29,857)
Tax	(45)	(1,380)	0	0
Profit After Tax (norm)	(18,081)	(19,537)	(16,696)	(29,857)
Profit After Tax (reported)	(20,207)	(20,998)	(16,696)	(29,857)
Average Number of Shares Outstanding (m)	17.8	17.8	17.8	17.8
EPS - normalised (c)	(101)	(109)	(94)	(167)
EPS - (reported) (€)	(1.13)	(1.18)	(0.94)	(1.67)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	14,797	13,324	12,024	11,934
Intangible Assets	20	11	11	11
Tangible Assets	252	734	647	557
Investments	14,525	12,579	11,366	11,366
Current Assets	45,491	37,874	28,370	7,604
Stocks	0	0	0	0
Debtors	6,328	6,624	5,967	6,324
Cash	39,163	31,250	22,403	1,280
Current Liabilities	(5,595)	(6,892)	(7,151)	(7,651)
Creditors	(5,595)	(6,892)	(7,151)	(7,651)
Short term borrowings	0	0	0	0
Long Term Liabilities	(17,895)	(27,060)	(35,260)	(42,760)
Long term borrowings	(16,749)	(25,674)	(33,874)	(41,374)
Other long term liabilities	(1,146)	(1,386)	(1,386)	(1,386)
Net Assets	36,798	17,246	(2,017)	(30,873)
CASH FLOW				
Operating Cash Flow	(22,668)	(12,656)	(13,449)	(25,168)
Net Interest	737	(1,552)	(2,788)	(3,346)
Tax	(45)	(1,380)	0	0
Capex	(51)	(34)	25	25
Acquisitions/disposals	0	0	0	0
Financing	0	0	0	0
Other	17,337	7,365	7,365	7,365
Dividends	0	0	0	0
Net Cash Flow	(4,690)	(8,257)	(8,847)	(21,124)
Opening net debt/(cash)	(42,972)	(22,414)	(5,576)	11,471
HP finance leases initiated	0	0	0	0
Other	(15,868)	(8,581)	(8,200)	(7,500)
Closing net debt/(cash)	(22,414)	(5,576)	11,471	40,094

Source: Company accounts, Edison Investment Research

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