

Newron Pharmaceuticals

Pharma & biotech

1 November 2021

Pivotal progress on schizophrenia therapy

Newron, a Switzerland-quoted Italian company, is developing evenamide (30mg twice per day) to meet the major unmet need for new therapies to help both poorly managed and refractory schizophrenia patients. Evenamide would add on to existing treatments. A potentially pivotal study is due to report by Q422. Newron hopes to partner evenamide for the larger market of patients no longer gaining the full benefit of current anti-psychotic therapies. Newron may directly sell evenamide to treat identified clozapine-resistant patients. The company now gains royalties from Xadago, a Parkinson's disease therapy. A further Xadago dyskinesia study, starting in Q122, could boost sales. Newron had cash plus loan facilities at end June totalling €36.9m plus Xadago royalties to fund it into 2023.

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 (at a 30mg twice per day (bid) dose) has been boosted to give higher statistical power (196 patients) to become a potentially pivotal Phase II/III study. It is being run in Europe, Asia and Latin America. Completion is scheduled for late 2022. We expect mainly US studies, possibly in treatment-resistant schizophrenia patients, once the US regulatory strategy has been agreed with the FDA.

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 H121 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 Q122. 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 is running the study.

Valuation: Funding into 2023

Newron had €21.9m cash on 30 June 2021 and has since drawn the last €15m of the EIB loan facility so effectively had €36.9m in cash (pro forma) and €40m face value of debt. There are also anticipated Xadago royalties to support planned developments into 2023. Our valuation indicates about CHF107m (CHF6/share) based on Xadago royalties and probability adjusted evenamide sales. Our valuation will be revised once Study 008A reports and a full evenamide efficacy readout at a therapeutic dose is available. Newron aims to acquire products to boost its pipeline.

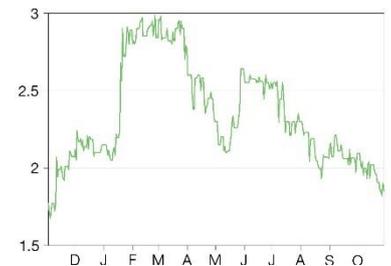
Edison estimates

Year end	Revenue (€m)	PBT (€m)	EPS (c)	DPS (c)	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

Source: Newron reports, Edison estimates

Price **CHF1.85**
Market cap **CHF33m**

Share price graph



Share details

Code **NWRN**
Shares in issue **17.85m**
Net debt at 30 June 2021 **€4.6m**

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 and generates royalties. Evenamide, a novel schizophrenia therapy, has started one Phase III and may start a further trial, mostly in the US, in H122.

Bull

- One approved product (Xadago) generating royalties with planned further indications.
- Evenamide could fit major needs to manage patients who are clozapine resistant plus those no longer gaining full benefit from their current therapies.
- Cash to fund the company well into 2023.

Bear

- Xadago faces competing generic products with potential generic direct competition.
- Evenamide dose of 30mg twice has uncertain efficacy but 25mg bid has shown responses.
- Partnering deal on evenamide unlikely until data for study 008A are available from late 2022.

Analyst

Dr John Savin MBA +44 (0)20 3077 57 00

healthcare@edisongroup.com

[Edison profile page](#)

Newron Pharmaceuticals is a research client of Edison Investment Research Limited

General disclaimer and copyright

This report has been commissioned by Newron Pharmaceuticals and prepared and issued by Edison, in consideration of a fee payable by Newron Pharmaceuticals. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out of or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2020 Edison Investment Research Limited (Edison).

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of the financial and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960

Schumannstrasse 34b

60325 Frankfurt

Germany

London +44 (0)20 3077 5700

280 High Holborn

London, WC1V 7EE

United Kingdom

New York +1 646 653 7026

1185 Avenue of the Americas

3rd Floor, New York, NY 10036

United States of America

Sydney +61 (0)2 8249 8342

Level 4, Office 1205

95 Pitt Street, Sydney

NSW 2000, Australia