

ReNeuron Group

Exciting positive data in retinitis pigmentosa (RP)

Early clinical results

Pharma & biotech

22 February 2019

Price **56.50p**
Market cap **£18m**

Net cash (£m) at 30 September 2018 30.7
 Shares in issue 31.6m
 Free float 100%
 Code RENE
 Primary exchange AIM
 Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	11.9	(3.4)	(38.9)
Rel (local)	8.9	(5.2)	(37.7)
52-week high/low	99.00p 47.50p		

Business description

ReNeuron is a UK biotech company developing allogeneic cell therapies. The first pivotal Phase IIb trial for CTX neural stem cells for chronic stroke disability is underway. Human retinal progenitor cells (hRPCs) are also being studied for RP (in Phase I/IIa).

Next events

Full-year results	June 2019
Phase I/IIa hRPC additional data	H119
Phase I/IIa hRPC study readout	H119
Chronic stroke readout	Early 2020

Analyst

Andy Smith +44 (0)20 3077 5700

healthcare@edisongroup.com

[Edison profile page](#)

ReNeuron Group is a research client of Edison Investment Research Limited

ReNeuron's announcement of early but exciting data on three patients in the clinical study of its human retinal progenitor cell (hRPC) product was well received. Although the patient numbers are small and the follow-up time points are short (two months and 18 days), the improvements in visual acuity are striking and may enable an earlier start to the pivotal programme.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
03/17	0.9	(18.2)	(0.49)**	0.0	N/A	N/A
03/18	0.9	(21.0)	(55.66)	0.0	N/A	N/A
03/19e	0.0	(22.0)	(55.17)	0.0	N/A	N/A
03/20e	0.0	(27.2)	(70.94)	0.0	N/A	N/A

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

Positive preliminary data in RP

ReNeuron has announced positive data on the first three RP patients in the Phase I/IIa clinical study of its hRPC cell therapy product. At this early stage in the study our expectations were limited as we had anticipated that more time would be required for efficacy to be seen. A surprising and dramatic improvement in visual acuity was observed – a 20-letter improvement at two months, 15- and 14-letter improvements at 18 days – in the first three patients forming the first cohort dosed with the new cryopreserved, commercially ready formulation. Investors will be familiar with the letters on an ETDRS eye chart from their regular eye tests. As a comparison, albeit in different indications, the best-selling drug, Eylea, for wet age-related macular degeneration (wAMD) and diabetic macular oedema (DME), has only shown maintenance (rather than improvement) of visual acuity in [94% of wAMD patients](#) and a [9.6- to 18.8-letter gain](#) in DME depending on the severity of disease. These data from ReNeuron's study are measured from baseline but also use the patient's untreated eye as a placebo.

What came before and what comes after?

In the first Phase I portion of the study, ReNeuron had already dosed 12 patients with more severe disease (lower baseline acuity) with an earlier formulation that was not optimised for shelf life or subretinal implantation. This gave regulators a safety baseline to allow study progression to less severe patients (where visual acuity improvements should be more obvious) and higher doses. With another three patients expected to start in March, again at the top dose from the Phase I study portion, if efficacy is also demonstrated in this cohort and acuity gains in the first cohort are maintained, ReNeuron will be in a good position to approach regulators and potential partners to discuss an accelerated path to market.

Valuation: No changes for now

We have made no changes to our valuation or probabilities at this stage. However, we recognise that early evidence of efficacy may enable ReNeuron to advance to a pivotal study more quickly, subject to discussions with regulators. This is because, for many RP patients, no therapeutic options exist. Our forecasts and valuation are unchanged at £192m or 608p per share.

Exhibit 1: Financial summary

	£'000s	2017	2018	2019e	2020e
Year end 31 March		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		900	897	43	43
Cost of Sales		0	0	0	0
Gross Profit		900	897	43	43
R&D expenses		(16,648)	(16,657)	(22,656)	(23,788)
SG&A expenses		(4,139)	(4,616)	(5,078)	(5,585)
EBITDA		(19,814)	(20,222)	(23,561)	(27,158)
Operating Profit (before amort. and except.)		(19,887)	(20,376)	(23,706)	(27,331)
Intangible Amortisation		0	0	0	0
Exceptionals		0	0	0	0
Operating Profit		(19,887)	(20,376)	(23,706)	(27,331)
Other		0	0	0	0
Net Interest		1,722	(591)	1,693	99
Profit Before Tax (norm)		(18,165)	(20,967)	(22,013)	(27,232)
Profit Before Tax (FRS 3)		(18,165)	(20,967)	(22,013)	(27,232)
Tax		2,592	3,352	4,554	4,781
Profit After Tax (norm)		(15,573)	(17,615)	(17,459)	(22,451)
Profit After Tax (FRS 3)		(15,573)	(17,615)	(17,459)	(22,451)
Average Number of Shares Outstanding (m)		3,164.6	31.6	31.6	31.6
EPS - normalised (p)		(0.49)	(55.66)	(55.17)	(70.94)
EPS - FRS 3 (p)		(0.49)	(55.66)	(55.17)	(70.94)
Dividend per share (p)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets		724	912	1,050	1,215
Intangible Assets		0	186	186	186
Tangible Assets		724	726	864	1,029
Other		0	0	0	0
Current Assets		58,136	41,706	25,580	14,114
Stocks		0	0	0	0
Debtors		1,060	1,285	1,285	1,285
Cash		53,061	37,411	19,741	8,048
Other		4,015	3,010	4,554	4,781
Current Liabilities		(5,703)	(5,949)	(5,949)	(5,949)
Creditors		(5,703)	(5,949)	(5,949)	(5,949)
Short term borrowings		0	0	0	0
Short term leases		0	0	0	0
Other		0	0	0	0
Long Term Liabilities		0	0	0	(10,000)
Long term borrowings		0	0	0	(10,000)
Long term leases		0	0	0	0
Other long term liabilities		0	0	0	0
Net Assets		53,157	36,669	20,681	(619)
CASH FLOW					
Operating Cash Flow		(13,976)	(19,244)	(22,433)	(26,007)
Net Interest		520	383	1,693	99
Tax		1,340	4,357	3,352	4,554
Capex		(532)	(235)	(282)	(338)
Acquisitions/disposals		0	0	0	0
Financing		0	0	0	0
Dividends		0	0	0	0
Other		0	0	0	0
Net Cash Flow		(12,648)	(14,739)	(17,670)	(21,693)
Opening net debt/(cash)		(65,708)	(53,060)	(37,410)	(19,740)
HP finance leases initiated		0	0	0	0
Other		(0)	(911)	0	0
Closing net debt/(cash)		(53,060)	(37,410)	(19,740)	1,953

Source: ReNeuron accounts, Edison Investment Research

General disclaimer and copyright

This report has been commissioned ReNeuron Group and prepared and issued by Edison, in consideration of a fee payable by ReNeuron Group. Edison Investment Research standard fees are £49,500 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 Edison analyst 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 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 2019 Edison Investment Research Limited (Edison). All rights reserved FTSE International Limited ("FTSE") © FTSE 2019. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd who holds an Australian Financial Services Licence (Number: 427484). 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

Neither this document and associated email (together, the "Communication") constitutes or form part of any offer for sale or subscription of, or solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it form the basis of, or be relied on in connection with, any contract or commitment whatsoever. Any decision to purchase shares in the Company in the proposed placing should be made solely on the basis of the information to be contained in the admission document to be published in connection therewith.

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 (nor will such persons be able to purchase shares in the placing).

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

The Investment Research is a publication distributed in the United States by Edison Investment Research, Inc. Edison Investment Research, Inc. is registered as an investment adviser with the Securities and Exchange Commission. 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 general 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
1,185 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