

# ReNeuron Group

Trial update

## Stable 12-month vision

The first set of 12-month data from the ongoing retinitis pigmentosa (RP) eye study has been released showing a stable longer-term response, which is excellent. However, the 12-month data are only for three patients so far with mean numbers reported. ReNeuron aims to present more RP eye data over 2020. Stroke data from the CTX PISCES III trial are expected around mid-2021. We retain the indicative value of ReNeuron at £197m.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
03/18	0.9	(21.0)	(55.66)	0.0	N/A	N/A
03/19	2.7	(17.2)	(45.34)	0.0	N/A	N/A
03/20e	6.1	(22.8)	(60.33)	0.0	N/A	N/A
03/21e	3.1	(30.8)	(83.69)	0.0	N/A	N/A

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

## More data and some 12-month outcomes

The US trial ([NCT02464436](#)) has now reported data on eight patients to three months, six patients to six months and three at 12 months (Exhibit 1). All these patients had successful surgery, but two others experienced surgical complications and lost sight. The time course data are very supportive (Exhibit 2), with rapid gains in the treated eye followed by a stable mean [visual acuity](#) gain of 15 letters using EDTRS (we calculated between six and 12 months). It is interesting the acuity gain seen averages six letters in the untreated eye; this takes longer to develop, from two to three months after treatment. So far, these longer-term data are an average of a few patients (Exhibit 1) with no range or SD reported, but will become more robust as more patient data is gained. The 12-month data on six patients are due in Q320, with all eight currently reported by late 2020.

## hRPC cell-based therapy might treat any RP patient

RP is an inherited, degenerative eye disease caused by one of over 100 different gene mutations. ReNeuron's human retinal progenitor cell (hRPC) therapy could potentially treat any RP patient giving a big potential commercial advantage. Gene therapies can only treat specific mutations. As a next stage, the current Phase I/IIa US trial will be extended at a higher dose and a new site in the UK is planned. ReNeuron and its clinical advisers believe that the amended protocol will enable the efficacy signal observed so far to be both better delineated and magnified. A pivotal hRPC study is being planned with an application possible in H1 2021. The data so far supports running such a study. Running a larger US trial may require a US partner.

## Valuation: £197m with cash into 2021

We retain our indicative value of £197m or 624p per share. This uses a 25% probability of success for hRP therapy. It is possible that hRPC could become the major valuation contributor over 2020. The CTX stroke indication is a major unmet need, but the PISCES III trial cannot produce data before mid-2021 with our expected launch window being from 2024 onwards.

## Pharma & biotech

26 February 2020

**Price** **151.5p**
**Market cap** **£48m**

\$1.32/£

Cash (£m) at 30 September 2019 21.3

Shares in issue 31.6m

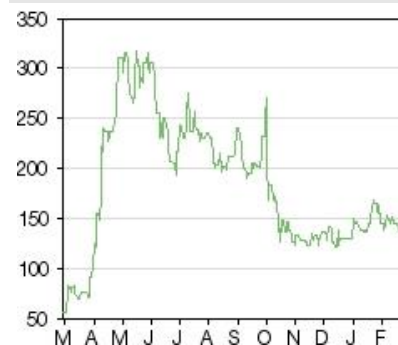
Free float 99.7%

Code RENE

Primary exchange LSE

Secondary exchange N/A

## Share price performance



%	1m	3m	12m
Abs	(8.5)	22.7	180.6
Rel (local)	(1.7)	27.8	181.9

52-week high/low 325.00p 56.00p

## Business description

ReNeuron Group 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 are also being studied for retinitis pigmentosa (in Phase I/IIa).

## Next events

Further hRPC Phase I/IIa data	Ongoing
Chronic stroke US Phase IIb study readout	Mid-2021
FY20 results	July 2020

## Analyst

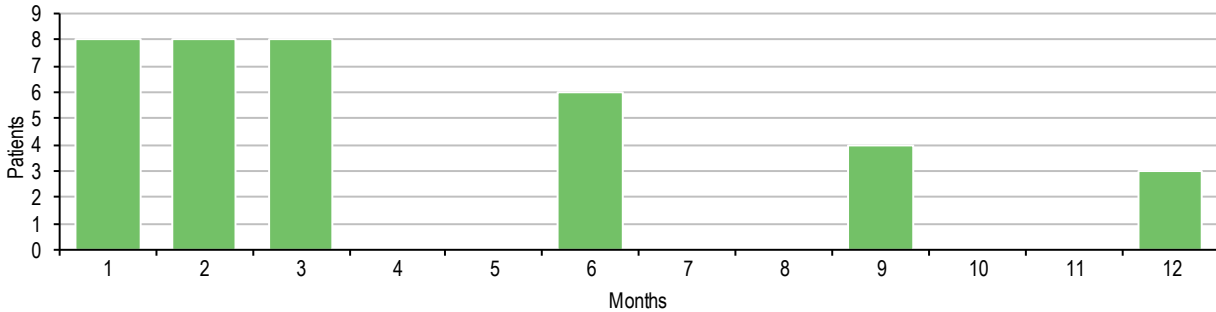
Dr John Savin +44 (0)20 3077 2500

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)
[Edison profile page](#)

**ReNeuron Group is a research client of Edison Investment Research Limited**

## Detailed data to 12 months, US and UK expansion

**Exhibit 1: Patient numbers reporting data by time point**

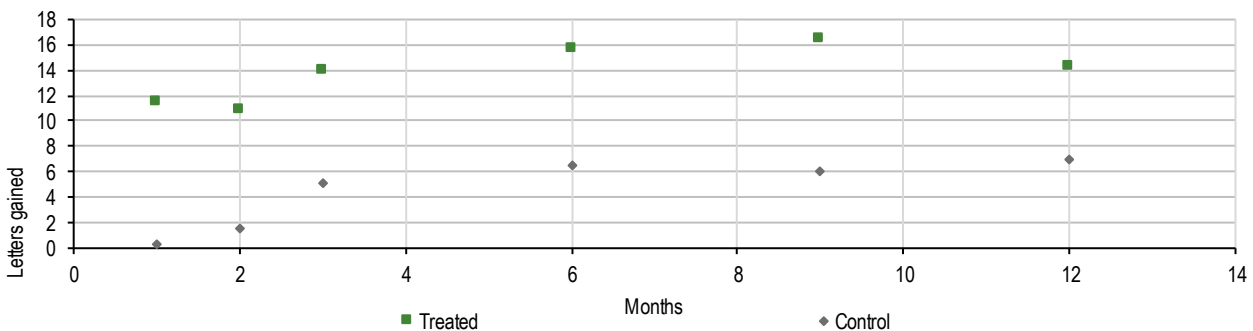


Source: ReNeuron (Edison graphic). NB there are eight patients overall

All eight of these patients will have 12-month data by late 2020. By then, we will also have some 18-month vision data. The trial has a two-year final endpoint. The reported patients were dosed with 1 million cells. In an amended protocol submitted to the FDA, nine extra patients will be added to the 21 planned and the dose will be raised to 2 million cells. In addition, a wider range of pre-treatment baseline visual acuity in patients will be eligible and the trial endpoint will be expanded to include microperimetry testing to measure and detect changes in retinal sensitivity

The current study is currently expected to run till November 2022, so needs to complete recruitment by Q4 2020. ReNeuron has also applied to the UK MHRA to open a UK site at the Oxford Eye Hospital. Professor Robert MacLaren, a world-renowned leader in the treatment of retinal diseases, will be Principal Investigator. The trial currently runs at two US centres.

**Exhibit 2: Visual mean acuity gain in treated and untreated eyes with hRPC**



Source: ReNeuron (Edison graphic)

The exact 12-month mean data are less important as the numbers will change when more patient data are acquired. The gains in the untreated eye seen in this study are interesting and appear stable. ReNeuron's hRPC therapy uses cells so inter-eye connectivity is very unlikely, making the outcome scientifically puzzling. If significant gains in the untreated eye are confirmed and consistent, this may require design changes to the planned pivotal study, due from 2021.

A clinically similar observation was reported by Gensight in May 2019, with two-year viral gene therapy data (against a different eye condition) showing improvements in the sham-treated eye, an unexplained and unexpected observation. Technically, the two products are very dissimilar (cells vs retrovirus virus), so this might be coincidental.

**Exhibit 3: Financial summary**

	£'000s	2018	2019	2020e	2021e
Year end 31 March		IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>					
Revenue		897	2,720	6,094	3,094
Cost of Sales		0	0	0	0
Gross Profit		897	2,720	6,094	3,094
R&D expenses		(16,657)	(16,240)	(24,685)	(28,634)
SG&A expenses		(4,616)	(4,779)	(5,078)	(5,586)
EBITDA		(20,222)	(17,915)	(23,448)	(30,965)
Operating Profit (before amort. and except.)		(20,376)	(18,299)	(23,575)	(31,032)
Intangible Amortisation		0	0	0	0
Exceptionals		0	0	0	0
Operating Profit		(20,376)	(18,299)	(23,575)	(31,032)
Other		0	0	0	0
Net Interest		(591)	1,064	792	240
Profit Before Tax (norm)		(20,967)	(17,235)	(22,783)	(30,792)
Profit Before Tax (FRS 3)		(20,967)	(17,235)	(22,783)	(30,792)
Tax		3,352	2,887	3,579	4,152
Profit After Tax (norm)		(17,615)	(14,348)	(19,204)	(26,640)
Profit After Tax (FRS 3)		(17,615)	(14,348)	(19,204)	(26,640)
Average Number of Shares Outstanding (m)		31.6	31.6	31.8	31.8
EPS - normalised (p)		(55.66)	(45.34)	(60.33)	(83.69)
EPS - FRS 3 (p)		(55.66)	(45.34)	(60.33)	(83.69)
Dividend per share (p)		0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>					
Fixed Assets		912	1,522	1,682	1,959
Intangible Assets		186	186	186	186
Tangible Assets		726	632	792	1,069
Other		0	704	704	704
Current Assets		41,706	29,988	11,684	15,849
Stocks		0	0	0	0
Debtors		1,285	834	834	834
Cash and deposits		37,411	26,386	8,082	12,247
Other		3,010	2,768	2,768	2,768
Current Liabilities		(5,949)	(7,402)	(7,402)	(7,402)
Creditors		(5,949)	(7,261)	(7,261)	(7,261)
Short term borrowings		0	0	0	0
Short term leases		0	(141)	(141)	(141)
Other		0	0	0	0
Long Term Liabilities		0	(864)	(864)	(30,864)
Long term borrowings		0	0	0	(30,000)
Long term leases		0	0	0	0
Other long term liabilities		0	0	0	0
Net Assets		36,669	24,108	5,965	(19,593)
<b>CASH FLOW</b>					
Operating Cash Flow		(14,887)	(11,947)	(18,808)	(25,733)
Net Interest		383	342	792	242
Tax		0	0	0	0
Capex		(235)	(239)	(287)	(344)
Acquisitions/disposals		0	0	0	0
Financing		0	0	0	0
Dividends		0	0	0	0
Other		0	0	0	0
Net Cash Flow		(14,739)	(11,844)	(18,304)	(25,835)
Opening net debt/(cash)		(53,061)	(37,411)	(26,380)	(8,076)
HP finance leases initiated		0	0	0	0
Other		(911)	813	0	0
Closing net debt/(cash)		(37,411)	(26,380)	(8,076)	17,759

Source: ReNeuron accounts, Edison Investment Research

---

## General disclaimer and copyright

This report has been commissioned by 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 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 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