EDISON

ReNeuron Group

New year update

Continuing to gain clinical data in eye disease

Pharma & biotech

After an eventful 2020, ReNeuron released updated 12-month Phase II data in January on its lead human retinal progenitor cell (hRPC) project. This continues to show a consistent and robust, sustained average gain in visual acuity in retinitis pigmentosa (RP). A continuation study in nine patients using two million cells is underway with three- and six-month data due over H2 CY21 and the first three patients treated. This will facilitate partnering negotiations. A pivotal hRPC study may start in 2022. Deals are possible in CY21 on the exosome genetic drug delivery platform, which could be very valuable. The valuation remains at £190m with strong cash.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
03/19	2.7	(17.2)	(45.34)	0.0	N/A	N/A
03/20	6.2	(13.9)	(35.85)	0.0	N/A	N/A
03/21e	0.2	(14.4)	(32.85)	0.0	N/A	N/A
03/22e	0.2	(13.3)	(20.55)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. Shares in issue increased by 25m in December 2020.

hRPC in a strong competitive position

ReNeuron's portfolio is now refocused on the hRPC therapy for RP, an inherited, degenerative eye disease caused by one of more than 100 different gene mutations. The newly released 12-month data in seven patients (up from four in June 2020) show that visual acuity gains continue and appear stable. hRPC therapy could potentially treat any RP patient, giving a big potential commercial advantage; competing gene therapies each target specific, rare mutations. There is only one cell-based competitor which is at a similar development stage. ReNeuron should be in a good position to start a pivotal study in 2022 and to look at possible partnering in a high-value deal, depending on the continuation study data due in H2 CY21.

Broad portfolio creates partnering opportunities

ReNeuron is progressing a portfolio of preclinical exosome projects. In our view, these should generate a number of partnering deals in 2021; exosome-based therapeutics have aroused a lot of recent investor interest. There are also earlier stem cell projects (in immunotherapy and diabetes), which could generate further deals from 2021 to 2022. Fosun continues to develop the CTX stroke indication in China; CTX will only progress through partnering in other territories.

Valuation: Maintained at £190m

ReNeuron conducted a placing of £15m and open offer of £2.5m in late 2020, giving £17.5m gross. Management states that this cash will cover costs for at least 18 months. Our indicative value is unchanged at £190m. We note current high deal values in the gene and cell retinal therapy area, with one totalling $250m plus royalties in June. Exosome projects are promising but are preclinical and need partners to progress into development; many deals have been at high values. In October 2020, Codiak, a pure exosome company with two clinical projects, completed a US IPO and is now valued at about $590m.

15 January 2021

Price	**114p**
Market cap	**£65m**
	$1.32/£
Gross cash (£m) at 30 September 2020	9.8
Shares in issue	56.85m
Free float	99.7%
Code	RENE
Primary exchange	LSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	47.1	25.2	(15.5)
Rel (local)	40.9	8.9	(6.9)
52-week high/low	270.0p		75.5p

Business description

ReNeuron Group is a UK biotech company developing allogeneic cell therapies. Human retinal progenitor cells are the lead Phase I/IIa project for retinitis pigmentosa. There is a strong preclinical technology base in exosomes.

Next events

Further hRPC Phase I/IIa data	Ongoing
Continuation Phase II data	H221
hRPC pivotal study start	H222

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ReNeuron portfolio

The main project uses hRPC (see Exhibit 1) to treat the degenerative eye condition RP. The exosome set of projects are for the delivery of high-value pharmaceuticals, probably genetic therapies like siRNA, to the brain, but also have potential as vaccine vectors. These applications all require partnering and there are three evaluation projects underway. There are some very early-stage projects in progenitor cells. These could mature into valuable projects from 2021–22 onwards. The CTX project in stroke disability requires one or more partners to progress further; in China, the partner is Fosun.

ReNeuron is incorporated in the UK with offices in the UK and the US and the main laboratory in Bridgend, South Wales. The company has around 35 employees.

Exhibit 1: ReNeuron portfolio (January 2021)

Programme	Indication	Pre-clinical	Phase 1	Phase 2	Next Milestones
Human Retinal Progenitor Cells	Retinitis Pigmentosa				• Further data read-outs from expanded Phase 2a study over next twelve months • Pivotal trial to commence in H2 2022, subject to Phase 2a data
Exosome platform	Neurodegeneration, Oncology, Vaccines (e.g. COVID-19)				• Proof of concept data from current research collaborations expected in H1 2021 • Additional collaborations expected over the next 12 months
iPSC platform	Oncology, Diabetes				• Validation of technology and publication of pre-clinical proof-of-concept data
CTX cell line	Stroke Disability				• Currently partnered in China with FOSUN • Open for partnerships outside China

Source: ReNeuron

hRPC: A strong lead project

The hRPC project is the critical lead project for ReNeuron. It is one of two cell therapy companies tackling RP. RP is a very diverse group of degenerative genetic eye diseases where photoreceptor cells progressively die. RP manifests through progressive night blindness (low light vision) with loss of peripheral vision. Eventually, high-resolution acuity and colour vision is lost. Gene therapies only treat specific mutations, meaning that the patient pool for each is very small. Cell therapies can potentially treat many patient types.

hRPC scientific and clinical rationale

ReNeuron's approach is very different to gene therapy as it uses genetically healthy hRPC. The cells are allogeneic based on an immortalised cell line. This means they can be produced in standardised batches, and stored and shipped frozen. This avoids the complex, very expensive, customised manufacturing needed for autologous cell therapies. The only other RP cell therapy in development, jCyte, uses fresh cells which will be a serious problem in commercial use if approved.

Our August outlook note discussed the science background in more detail. Theoretically, it is likely that hRP cells secrete trophic factors: hormone-like proteins that encourage retinal cell survival. It is

also possible that some hRPC grow and differentiate into functional light-sensitive cells. Practically, clinicians, payors and patients need to know how much visual acuity can be preserved and recovered, and the duration of action of a single dose per eye.

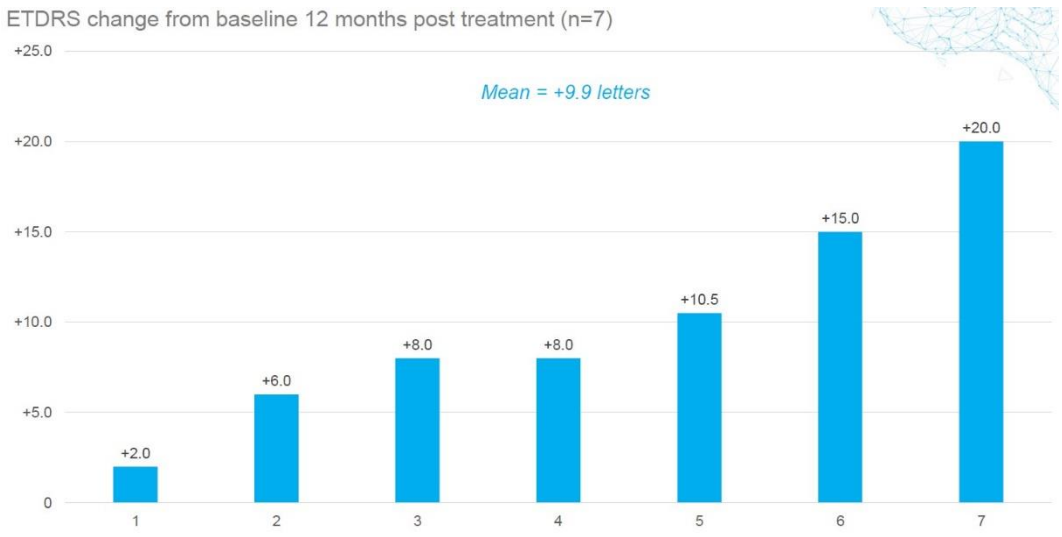
ReNeuron's hRPC need to be injected close to the site required, usually the centre of the eye, where most photoreceptors are situated. This involves depositing a small drop (a bleb) with one million hRPC as a subretinal injection. The subretinal injection is a precise operation and temporarily distorts the retinal structure. In the continuation Phase II, two blebs will be given near to functional retinal areas but not under them.[1] This could support, by trophic factors, the nearby functional retina and potentially help to restore some function to the overlying degraded retina. The three- and six-month data, due in H221, will indicate how successful this revised strategy might be and pave the way for the Phase III trial design.

Visual acuity (VA) – what has been seen so far?

Here we summarise the updated data, published on 6 January 2021, from the US Phase I/IIa trial (NCT02464436) based on data from up to nine patients. VA is critically important to patients as it provides the ability to resolve details and perform day-to-day tasks – but it is a variable parameter. VA is measured using the ETDRS[2] chart. If a patient correctly reads three extra lines, their VA has doubled. This has been the historic FDA benchmark. Patient variability means that a one-line ETDRS chart difference (five letters) is not regarded as clinically significant whereas a two-line difference is significant. The term often used is best corrected visual acuity (BCVA), which means that the patients wear spectacles or contact lenses for the readings.

Exhibit 2 shows the individual VA gains seen by the Phase II patients at one year (seven cases). ReNeuron notes that gains of 10 letters or more would be a benefit and if a proportion of patients gained three lines (15 letters) or more, that should suffice for regulatory approval.

Exhibit 2: 12-month net gains in VA in seven patients



Source: ReNeuron

Of these seven, four showed VA gains of less than 10 letters, three of whom had clinically significant gains of over five letters. Of the other three patients, one in effect gained two lines (10+

[1] In Phase IIa, the single bleb of one million cells was under the functional retina but this caused problems for two patients who experienced a loss of sight; one recovered and is now included in the data set but this has reduced the average response as a result.

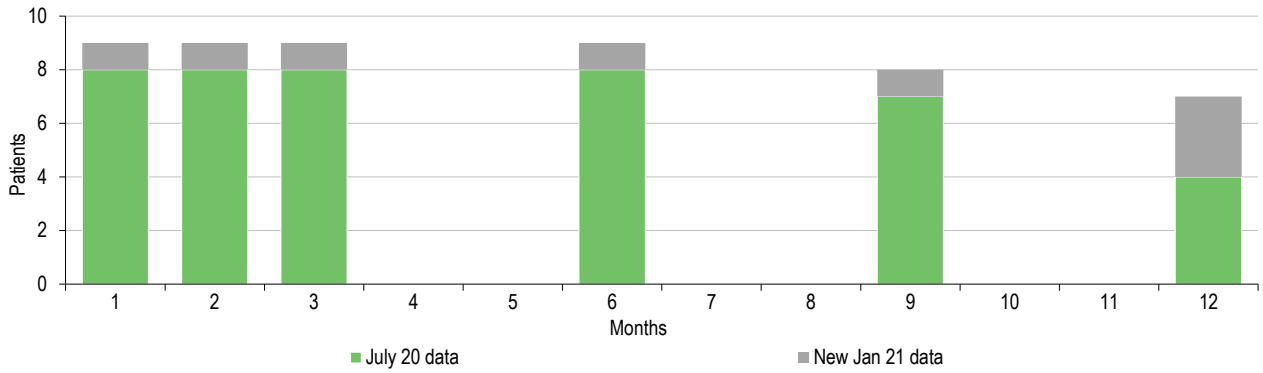
[2] Early Treatment Diabetic Retinopathy Study. This is a letter chart whose lines are based on visual resolution angle with five letters of identical size per line in a geometric size progression. Three lines is a doubling in visual acuity.

letters) and two patients gained the equivalent of three lines (15+ letters), so a potential doubling of their VA. This is also after 12 months, so the effect of the single hRPC injection has been maintained.

In our August note, we commented that the therapy appears to give a clear benefit quickly and then appears stable on average. The further data strengthen this impression. However, the data now include one patient who had a surgical complication on bleb implantation but subsequently recovered to baseline. This has reduced the reported averages. Another patient who experienced a surgical complication is not included as they have not recovered any sight in the treated eye.

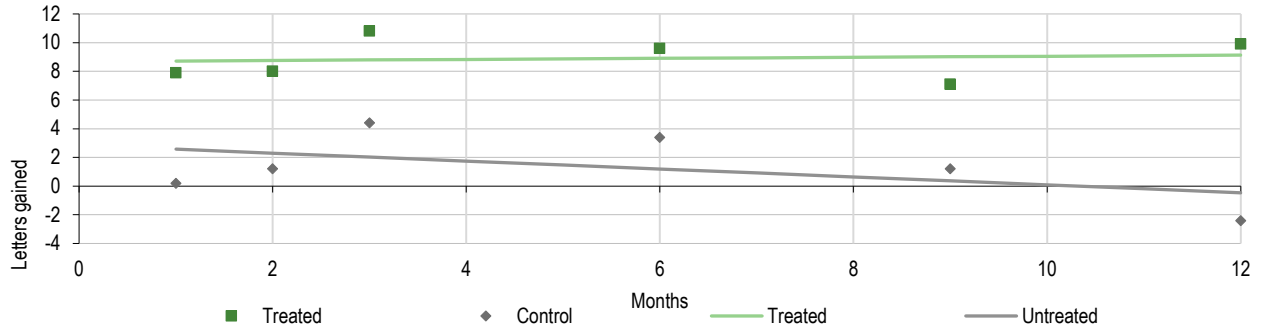
Of interest is that at the nine- and 12-month points, there are now additional patients reported. The untreated eye now shows, with seven patients, a decline of -2.4 letters at a year giving an average gain in the treated eye of 12.3 letters. Exhibit 3 shows the patients at each time point, Exhibit 4 shows the data per time point. Using a simple linear regression plot, it can be seen that the treated eye data on average is stable, whereas there is a gradual decline in the untreated eye.

Exhibit 3: Patient data at various timepoints



Source: ReNeuron data, Edison Investment Research

Exhibit 4: Mean letters gained in successfully treated patients over time



Source: ReNeuron (data), Edison Investment Research (lines of linear regression)

US and UK extension of hRPC Phase II

The FDA-approved amended protocol plus the UK regulatory go-ahead has enabled the dose to be raised to two million cells for a further nine patients in an extension of the current trial. These new patients will add to the 10 Phase IIa patients already treated (of whom nine reported as above).

In the extension study, two blebs of one million hRPC (two million cells in total) will be used on either side of the functional retinal area being treated. A wider range of pre-treatment baseline VA in patients will be eligible and the trial endpoints will be expanded to include VA (as before), microperimetry, visual field, retinal sensitivity and retinal structure. The primary endpoint remains safety.

The other company, jCyte, developing an RP cell therapy, jCell, uses an intravitreal injection – into the vitreous jelly filling the inner eye. This is technically simpler to administer but the cells are then dispersed across a large volume. Hence, at least six million cells per eye are required.

The continuation study recruited its first patient in the US in late 2020 and on 15 January 2021 reported that the first three-patient cohort had been treated. These patients will undergo a safety review before the next cohort, as is standard practice. There are now two US centres enrolling patients. The Oxford Eye Hospital (UK) site is not yet recruiting, probably due to COIVID-19 restrictions.[3] A further European site might be added.

Pivotal progression in 2022

According to management, a regulatory discussion is now anticipated around late H2CY21 in preparation for the planned pivotal study application, enabling a possible Phase III to start in mid-2022. Management states that a small Phase III could enable a regulatory filing in 2024; the size of any Phase III depends on the visual acuity gain seen in the continuation study. If there is a large relative gain in VA, a small number of patients in Phase III could yield data that have strong statistical significance. The Chinese timeline with Fosun still assumes a 2024 approval in China.

Competitors – limited and mostly highly targeted

There is one direct cell therapy competitor and four indirect gene therapy competitors. The cell competitor, jCyte, has been referred to above. jCyte is a private academic company. In summer 2020, it reported data from a Phase IIb RP trial (NCT0307373). In 74 patients, a net mean 7.4 letter gain at the higher cell dose of six million (n=23) was seen but with little effect at the three million cell dose (+3.0 letters, n=25). Untreated patients (n=23) gained 2.80 letters. Hence the three million dose had no effect and the net six million gain was +4.6 letters. jCyte plans to start a pivotal study in 2021 based on a subgroup. We are cautious about data comparisons with hRPC.

Japanese eye specialist company Santen licensed the rights to jCell for $50m in cash, $12m in a convertible note offering and up to an additional $190m in milestones based on approval and initial sales plus a sales royalty. This provides a basic benchmark for any ReNeuron partnering deal, but we anticipate that ReNeuron could get better terms on good continuation data.

Spark Therapeutics (Roche) has the one approved (2018) product, Luxturna. It sells for £613,410 per treatment (ex-tax) in the UK and treats both eyes in patients with recessive RPE65-associated Leber congenital amaurosis mutations. The mutation is rare, about 2% of RP cases. Spark sold $21.2m of Luxturna (net of rebates) in H119 before its acquisition by Roche for $4.3bn. The high deal value was due to the potential of Spark's technology in conditions such as haemophilia.

Biogen is developing BIIB112 to treat X-linked RP (X chromosome linked disease is only in males of course). Data from 2020 reported sight improvements in six of 18 patients with good tolerability.

MeiraGTx has programmes against X-linked gene defects and an RPE65 project. It reported early X-linked RP data in July 2020, finding statistically significant improvements in mean retinal sensitivity and central visual field progression rate.

[3] Professor Robert MacLaren, a recognised leader in the treatment of retinal diseases, will be the principal investigator in Oxford. The new US centre is the prestigious Casey Eye Institute, Oregon Health & Science University. The two other US sites listed on the clinical trial record are the Retinal Research Institute in Phoenix, Arizona and the Massachusetts Eye and Ear Infirmary, Boston.

Exosomes – deals possible in 2021

Exosomes are tiny lipid (oil) vesicles about 100nm in diameter that are secreted by cells, particularly mesenchymal stem cells (MSCs), the basis of ReNeuron's CTX platform. ReNeuron also has early-stage induced pluripotent stem cell (iPSC) projects, not further discussed.

Exosomes can be isolated and loaded with short RNA sequences and/or small therapeutic proteins or drugs. Exosomes also appear to pass though the blood/brain barrier, as shown by literature reports of down-regulation of brain proteins by exosomes injected into mice.

ReNeuron has several promising projects and three collaborations running. Its exosomes could be the delivery component of a gene therapeutic and generate royalties and milestones. We anticipate that at least one project might generate a formal deal during 2021.

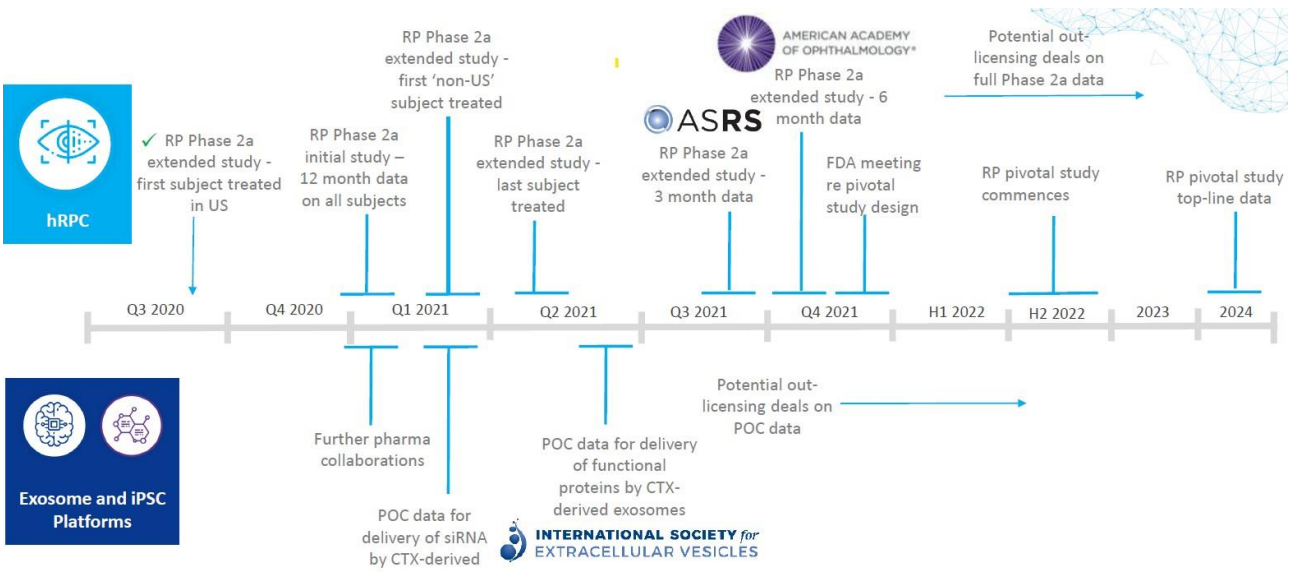
There are some specialist companies such as Evox Therapeutics, based in Oxford, UK. Evox announced a deal with Takeda in 2020 worth up to €803m.

The US company Codiak has two clinical projects designed to stimulate anti-tumour responses. One of these, exoIL-12, produced positive safety data from an ascending dose Phase I/II study in December 2020 of an IL-12-displaying exosome therapy designed to stimulate anti-tumour responses. Codiak completed an IPO in October 2020, raising $82m, and has a market cap of about $590m. This shows the magnitude of the potential upside form ReNeuron's exosome portfolio.

Newsflow

The updated newsflow projected by ReNeuron management up until a possible hRPC filing in 2024 is shown in Exhibit 5. Apart from anticipated exosome deals, the major event in 2021 will be the first three months of continuation hRPC trial data, probably at a conference in Q321. Six-month data could be available in Q421. This may allow a potential high-value partnering deal to be concluded from 2022 onwards. The data should also enable ReNeuron to finalise the Phase III design with regulatory agencies. This then leads to Phase III potentially starting in H222, with possible regulatory filings from 2024.

Exhibit 5: ReNeuron potential newsflow



Source: ReNeuron

Valuation: Maintained at £190m

For valuation purposes, we assume an RP prevalence of one in 4,500. On our estimate, there are about 75,000 diagnosed cases in total across the US and Europe. There are then about 1,100–2,500 new diagnoses per year (incidence) in the US and about 3,200 in Europe. Consequently, once all known (prevalence) patients with disease who can be treated, are treated, sales are based on new cases (incidence). There are no data on retreatment, so we have not assumed that this happens, but it seems a plausible additional scenario.

As hRPC target a bigger market than Luxturna, we have assumed a lower price of $275,000 – this is to be more acceptable to payors and to achieve good levels of uptake. Our forecast has 2030 US sales of $428m, European sales of $367m and Japanese sales (through a partner) of $120m. This results in total forecast world sales of $915m. The background assumptions and rationale are unchanged from our August 2020 note.

The potential hPRC approval (unchanged probability of 30%) is expected around H2 CY25. The immunotherapy and diabetes cell therapy projects have good deal potential but are in their preclinical stages. Exosome evaluation projects to deliver RNA drugs are promising and require early licensing. Our indicative value on 1 January 2021 remains £190m. With 56.85m shares outstanding, this equates to 334p per share. We note current high deal values in the gene and cell retinal therapy area, with one totalling $250m plus royalties in June 2020. Codiak, a pure exosome company with two Phase I clinical projects, is valued at about $590m.

Financials – H1 cash and December 2020 funding

In H121 to 30 September 2020, the loss (after a £0.9m tax credit) was £7.1m. Operating cash outflow was £5.5m, offset by receipt of the £2.9m FY19 tax credit. This gave a cash outflow of £2.6m. For FY21, we expect operating cash use to be c £13.8m. with FY21 year-end cash (30 March) of about £16m. FY22 costs are expected to be lower after the June CY20 restructuring. With £17.5m gross raised in December 2020, management has stated that ReNeuron has cash for at least 18 months, that is until the start of a potential Phase III study. This excludes any exosome deal values. Financial estimates are shown in Exhibit 6.

Exhibit 6: Financial summary

£'000s	2019	2020	2021e	2022e
Year end 31 March	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	2,720	6,165	238	182
Cost of Sales	0	0	0	0
Gross Profit	2,720	6,165	238	182
R&D expenses	(16,246)	(16,335)	(10,618)	(10,500)
SG&A expenses	(4,773)	(4,239)	(3,836)	(3,028)
EBITDA	(18,129)	(13,997)	(13,811)	(12,941)
Operating Profit (before amort. and except.)	(18,299)	(14,409)	(14,216)	(13,346)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(18,299)	(14,409)	(14,216)	(13,346)
Other	0	0	0	0
Net Interest	1,064	551	(211)	64
Profit Before Tax (norm)	(17,235)	(13,858)	(14,427)	(13,282)
Profit Before Tax (FRS 3)	(17,235)	(13,858)	(14,427)	(13,282)
Tax	2,887	2,446	1,600	1,600
Profit After Tax (norm)	(14,348)	(11,412)	(12,827)	(11,682)
Profit After Tax (FRS 3)	(14,348)	(11,412)	(12,827)	(11,682)
Average Number of Shares Outstanding (m)	31.6	31.8	39.0	56.8
EPS - normalised (p)	(45.34)	(35.85)	(32.85)	(20.55)
EPS - FRS 3 (p)	(45.34)	(35.85)	(32.85)	(20.55)
Dividend per share (p)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	1,522	1,229	1,104	979
Intangible Assets	186	186	186	186
Tangible Assets	632	452	452	452
Other	704	591	466	341
Current Assets	29,988	19,147	21,374	9,853
Stocks	0	0	0	0
Debtors	834	696	696	696
Cash and deposits	26,386	12,625	16,178	4,657
Other	2,768	5,826	4,500	4,500
Current Liabilities	(7,402)	(6,446)	(4,446)	(4,446)
Creditors	(7,261)	(6,280)	(4,280)	(4,280)
Short term borrowings	0	0	0	0
Short term leases	(141)	(166)	(166)	(166)
Other	0	0	0	0
Long Term Liabilities	(864)	(707)	(541)	(375)
Long term borrowings	0	0	0	0
Long term leases	0	0	0	0
Other long-term liabilities	(864)	(707)	(541)	(375)
Net Assets	23,244	13,223	17,491	6,011
CASH FLOW				
Operating Cash Flow	(15,037)	(13,651)	(15,328)	(12,941)
Net Interest	303	258	14	64
Tax	3,129	(611)	2,923	1,600
Capex	(239)	(119)	(100)	(100)
Acquisitions/disposals	0	0	0	0
Financing	0	188	17,500	0
Dividends	0	0	0	0
Other	4,365	6,128	(1,457)	(144)
Net Cash Flow	(7,479)	(7,807)	3,553	(11,521)
Opening net debt/(cash)	(27,911)	(26,245)	(12,459)	(16,012)
HP finance leases initiated	0	0	0	0
Other	5,813	(5,979)	0	0
Closing net debt/(cash)	(26,245)	(12,459)	(16,012)	(4,491)

Source: ReNeuron accounts, Edison Investment Research

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