EDISON

ReNeuron Group

FY21 results and update

Extension trial back on track but with data delay

Pharma & biotech

The key news in the FY21 results statement was the restart of the Phase IIa (2m cell dose) extension study after a June safety halt due to a presumed intraocular eye infection (endophthalmitis). If some trial data is available by Q4 of CY21, this could open the way to a crucial partnering deal from probably mid-2022. The 12-month data from the first (1m dose) Phase IIa cohort showed stable responses with the two best patients seeing a doubling of their visual acuity. Preclinical projects in exosomes (drug targeting and delivery) and candidate cell lines (like a diabetes therapy) are progressing well but with no major partnerships as yet. FY21 (year ending 31 March) closed with £22.2m cash. Our valuation remains at £190m.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
03/20	6.2	(13.9)	(35.85)	0.0	N/A	N/A
03/21	0.3	(13.4)	(29.00)	0.0	N/A	N/A
03/22e	0.3	(13.1)	(19.12)	0.0	N/A	N/A
03/23e	0.4	(13.2)	(19.12)	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 trial underway, data Q4 2021

ReNeuron's portfolio is now refocused on the human retinal progenitor cell (hRPC) therapy for retinitis pigmentosa (RP), an inherited, degenerative genetic eye disease. The trial is now in a Phase IIa extension study using 2m cells (given as two injections (blebs) under the retina). The extended trial, which aims to recruit nine patients, is being tested in four centres: two in the US, one in the UK and one in Spain. ReNeuron had a setback in early June as a patient suffered a presumed bacterial infection (endophthalmitis) after a successful hRPC implantation. It is routine to halt trials to investigate if a possible safety signal emerges, but the review showed no fundamental issues. ReNeuron has announced that the US trial has restarted and that the centres in the UK and Spain should restart by August after regulatory sign off. ReNeuron now expects some three-month data in Q4 2021.

Broad portfolio creates partnering opportunities

ReNeuron is progressing a portfolio of preclinical exosome projects. In exosomes, small membrane particles able to carry various therapeutics, ReNeuron has shown penetration into the brain and has developed a peptide technology to give targeted drug delivery. In our view, these projects should generate partnering deals, four more commercial and two more academic collaborations started in FY21. There are also some cell lines in earlier research stages for indications such as diabetes.

Valuation: Maintained at £190m

ReNeuron raised £16.3m net in December 2020. With reduced costs after the cessation of the stroke study in mid-2020, cash at the FY21 year end rose to £22.2m. Management states that this cash will cover costs for at least 12 months; we estimate that till Q4FY23 is possible (Q1 CY23). A deal from mid-2022 could be possible on good clinical data. Our indicative value is unchanged at £190m pending more clinical data and deals.

15 July 2021

Price	**102p**
Market cap	**£58m**
	$1.32/£
Gross cash (£m) at 31 March 2021	22.2
Shares in issue (30 June)	56.94m
Free float	99.7%
Code	RENE
Primary exchange	LSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(13.2)	(27.7)	(27.8)
Rel (local)	(12.7)	(29.2)	(39.0)
52-week high/low	148.5p		72.5p

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 and cell therapies.

Next events

Continuation Phase II data	Q421
hRPC pivotal study start	Late 2022

Analyst

Dr John Savin +44 (0)20 3077 2500

healthcare@edisongroup.com

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ReNeuron portfolio

The main project uses hRPC (see Exhibit 1) to treat the degenerative eye condition RP. This might enter a pivotal study in H2 2022.

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 exosome applications all require partnering.

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 and development there is progressing.

ReNeuron is incorporated in the UK with offices in the UK and the US and the main laboratory in Bridgend, South Wales. A potential US share quotation is being considered alongside the current UK quotation, but probably requires further portfolio development and partnering.

Exhibit 1: ReNeuron portfolio (July 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 expected Q4 2021 • 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 2021 • Additional collaborations expected
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 8 July 2021

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 for RP 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 an allogeneic cell line. The cells can be produced in standardised batches and stored and shipped frozen. This avoids the complex, very expensive, customised manufacturing needed for autologous cell therapies.

Our August 2020 outlook note discussed the science background in more detail. Theoretically, it is likely that hRPC cells secrete trophic factors: hormone-like proteins that encourage retinal cell survival. It is also possible but unproven that some hRPC grow and differentiate into functional light-sensitive cells. Practically, clinicians, payors and patients need to know how much visual acuity (VA) can be preserved and recovered, and the duration of action of a single dose per eye. Currently, the duration appears to be at least one year.

ReNeuron's hRPC need to be injected close to the site required. This will be close to the centre of the retina, where most photoreceptors are situated. This subretinal injection is a precise procedure and temporarily distorts the retinal structure. The three- and six-month data from the extension Phase IIa study will pave the way for a pivotal trial.

Eye infection risk and protocol updates

As the eye cannot be sterilised, infection from bacteria naturally present on the patient's eye surface is an inherent risk. Prophylactic eye drops can be used. There are low levels of intraocular eye infection post-surgery (endophthalmitis) in procedures like cataract operations, up to 0.7%. Even simple injections, as of Eylea or Lucentis (for neovascular retinal diseases), carry a risk (0.03%).

In terms of the June safety event, the investigation found no obvious cause of the infection and the trial has restarted in the US, with regulatory submissions currently underway to restart in the UK and Spain. ReNeuron has now specified the use of prophylactic antibiotics in the protocol. Additional measures to improve handling of the cell preparation in the hospital have been added.

Visual acuity (VA): What has been seen so far?

The updated data, published on 6 January 2021 and updated in July, from the US Phase I/IIa trial (NCT02464436) is based on VA data from up to nine patients, depending on the time point. [1] 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.

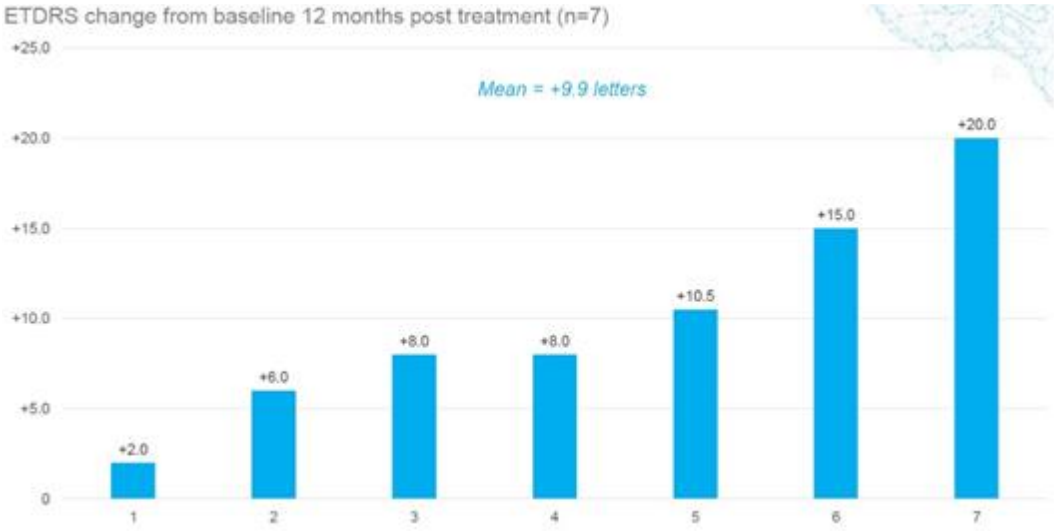
VA in the trial is measured using the ETDRS[2] chart. If a patient correctly reads three extra lines, (15 letters) their VA has doubled. This has been the historical FDA benchmark. Patient variability means that a one-line ETDRS chart difference (five letters) is not regarded as clinically significant, whereas a two-line difference is significant. The measure 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 measured in additional letters seen by the 1m cell dose cohort of Phase IIa patients at one year (seven evaluable cases). Of these seven, four showed VA gains of less than 10 letters, three of whom had gains of over five letters. One had a problem following the surgical procedure but recovered baseline level sight. Of the other three patients, one gained 10.5 letters and two patients gained the equivalent of three or more lines (15+ letters). The one year duration shows that the single hRPC injection efficacy has been maintained.

[1] In the initial Phase IIa, the single bleb of 1m cells was under the functional retina, but this caused problems for two patients. One recovered and is now included in the data set. This has reduced the average response. The other patient did not recover sight in the treated eye and is not in the reported data set.

[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. As lines is a blunt measurement, most trials measure the number of additional letters resolved.

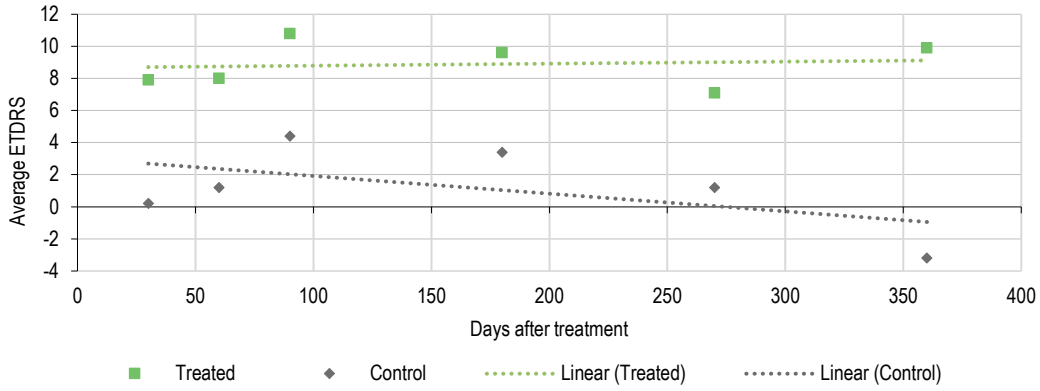
Exhibit 2: 12-month net gains in VA in seven patients



Source: ReNeuron

The untreated eyes, in contrast, showed steady deterioration, Exhibit 3. This data has been slightly revised since January. The untreated eye now shows an average decline of 3.2 letters after one year, giving an average net gain in the treated eye of 13.1 letters. Using a simple linear regression plot, it can be seen that vision in the treated eye data on average is stable (for at least one-year post-implantation), whereas there is a gradual decline in the untreated eye.

Exhibit 3: Mean letters gained in successfully treated patients over time



Source: ReNeuron (data updated as of July 2021), Edison Investment Research (lines of linear regression).

Steadily extending the hRPC Phase IIa

The extension study aims to recruit a further nine patients. As of 8 July, four in total had been recruited and treated. 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 1m hRPC (2m cells in total) will be used on either side of the functional retinal area being treated. The aim is to retain the contact of the retina with vision with its blood supply to avoid the issues seen in two patients in the initial cohort (described in the January note and August Outlook report). The design also enables a doubling of the dose to try and gain additional efficacy. 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 secondary vision

endpoints in the formal protocol are at six months. However, ReNeuron plans to release data on the three-month vision by late 2021. It is possible that not all the intended nine patients will have competed three months by that date; to do this would need all of the five remaining patients to be treated by early September.

Pivotal study design

Whether a Phase IIb or Phase III designation, this is planned to be a single pivotal study. As the treatment involves invasive surgery, there is no placebo control as it is unethical to ask patients to undergo such surgery to receive saline. The design is for about 100 patients randomised into three arms:

- no treatment,
- low dose,
- intended therapeutic dose – probably the 2m cell two bleb protocol.

This could start in the second half of 2022.

Competitors: Limited and mostly highly targeted

There is one direct cell therapy competitor identified by ReNeuron and five indirect gene therapy competitors, one using an RNA approach. Exhibit 4 shows the competitor space.

Exhibit 4: Competitors in Cell and Gene Therapy for RP

Company	Technology	Stage	Comment
ReNeuron (AIM, market cap: £63m*)	Cell therapy	Phase 1/2a	Cryopreserved formulation
jCyte Inc (US, private)	Cell therapy	Phase 2b	Not cryopreserved at drug product level
Spark Therapeutics (acquired by Roche in 2019 for $4.3bn)	Gene therapy	Approved and marketed, Luxturna for RPE65	Addresses only about 2%** of RP patients
Nightstar Therapeutics (acquired by Biogen in 2019 for $800 million)	Gene therapy	Phase 2/3	UK company co-founded by Prof Robert MacLaren
MeiraGTx (Nasdaq, market cap $712m*)	Gene therapy	Phase 1/2	-
ProQR therapeutics (Nasdaq, market cap $424m*)	RNA therapy	Phase 1/2 & Phase 2/3	-
AGTC (Nasdaq, market cap $176m*)	Gene therapy	Phase 1/2	-

Source: ReNeuron 8 July 2021

The only cell competitor, 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 6m (n=23) was seen, but with little effect at the 3m cell dose (+3.0 letters, n=25). Untreated patients (n=23) gained 2.80 letters. Hence the 3m dose had no net effect and the net 6m gain was +4.6 letters. jCyte has started a pivotal study based on a subgroup.

We are cautious about data comparisons with hRPC. jCyte's 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 6m cells per eye are required. The jCell formulation is also prepared fresh and cannot be cryopreserved. This means patients need to go to a centre next to the manufacturing site, which might limit its market.

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 expect that ReNeuron could get better terms on good continuation data.

Spark Therapeutics (acquired by 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 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). Unfortunately, in May 2021 the Phase II/III XIRIUS study reported that it did not meet its primary endpoint.

MeiraGTx, a UK and Ireland based company, has programmes against X-linked gene defects and an RPE65 project. The X-linked project is licensed to Jansen. Both projects are scheduled for progression into Phase III in the second half of 2021. The X-linked RP reported data in July 2020, finding statistically significant improvements in mean retinal sensitivity and central visual field progression rate. A mobility measure is also used.

ProQR uses an innovative RNA approach, QR-421a, to target exon 13 mutations by exon skipping in the *USH2A* gene. This is clearly highly targeted. ProQR reports good Phase I/II data and a Phase II/III is planned.

AGTC is developing AGTC-501 as an RP X-linked gene therapy. It has completed a 28-patient Phase I and is running two further studies: SKYLINE and VISTA, to evaluate safety and efficacy.

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). ReNeuron also has early-stage induced pluripotent stem cell (iPSC) projects, not further discussed as it is in an earlier research phase.

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

ReNeuron, over FY21, entered additional collaboration agreements with four major pharmaceutical and biotechnology companies and a further two with leading academic institutions. These are exploring multiple methods of loading exosomes. Exosomes could be the delivery component of a genetic or protein therapeutic. The technology can potentially generate royalties and milestones. We expect that at least one project might generate a formal deal within the forecast period. Proof of concept data is expected in late 2021. ReNeuron noted that the efficacy, probably delivery efficiency, of its exosomes was still lower than the desired specification. ReNeuron did note that it is optimising the use of specific peptides to sit on the surface of the exosomes to target them to specific tissues.

There are some exosome-focused 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 to stimulate anti-tumour responses.

Newsflow stronger in 2022

With the delays to the extended Phase IIa, we do not expect much clinical newsflow this year. ReNeuron has committed to a three-month snapshot of the data as is by Q4 of 2021. This might be limited. The key events will be completion of the six-month endpoints in the extension Phase IIa now due in the first half of 2022 and potential partnering, not in our view before mid-2022. Progress on exosomes is expected by Q4 of 2021 and this could generate significant revenues.

Valuation: Waiting for data

For valuation purposes, we assume an RP prevalence of one in 4,500. On our estimate, there are 75,000 diagnosed and treatable cases in total across the US and Europe; ReNeuron estimates the number of cases could be up to 250,000. 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, have been treated, the market becomes treatments of new cases (incidence).

As hRPC targets 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 Outlook note.

We expect the potential hPRC approval (unchanged probability of 30%) around H2 of 2025. The immunotherapy and diabetes cell therapy projects (see August note) have good deal potential but are in their preclinical stages. Exosome projects to deliver RNA drugs are promising but require early licensing. Our indicative value remains at £190m pending more clinical data. With 56.94m shares outstanding, this equates to 334p per share. We note high deal values in the retinal therapy area, with one totalling $250m plus royalties in June 2020. Codiak, a pure exosome company with two Phase I clinical projects, is now valued at about $400m, down 44% from its late 2020 high.

Financials: Solid cash and reduced burn rate

The loss before interest and tax to 31 March 2021 was £13.4m, a drop from the £13.8m FY20 loss after the mid-2020 restructuring. The tax credit also fell to £2.1m from £2.4m. There was a currency adjustment in FY21 of £0.5m; this is non-cash as the currency is needed to cover largely US expenses.

The effect of restructuring is seen in expenses where R&D fell to £9.5m from £16.3 in FY20. Admin costs fell to £3.7m from £4.2m in FY20. The overall loss of £11.3m (FY20 loss: £11.4m) was unaffected after restructuring as there was a £6m milestone in FY20 and low revenues of £0.3m in FY21 (plus £0.1m of COVID-19 furlough grants). Cash flows were boosted by the December 2020 capital raise, which yielded £16.3m net of costs. Cash rose from £12.6m at FY20 to £22.2m (including £7.5m of short-term investments) at 31 March 2021.

Based on our updated two-year forecast, we expect ReNeuron to have cash into early CY23 (that is Q4 of FY23). Management notes that there is cash for at least 12 months. Although the cash position is strong at the current expenditure level, either a deal or further capital will be needed to initiate the expected pivotal study. Investors should consider further funding needs, as given the strength of the hRPC product on current data, avoiding a partnership until there is positive pivotal data would likely maximise value.

Exhibit 5: Financial summary

£'000s	2020	2021e	2022e	2023e
Year end 31 March	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	6,165	335	300	350
Cost of Sales	0	0	0	0
Gross Profit	6,165	335	300	350
R&D expenses	(16,335)	(9,503)	(10,500)	(10,600)
SG&A expenses	(4,239)	(3,746)	(2,933)	(2,900)
EBITDA	(13,997)	(12,534)	(12,773)	(12,810)
Operating Profit (before amort. and except.)	(14,409)	(12,914)	(13,133)	(13,150)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(14,409)	(12,914)	(13,133)	(13,150)
Other	0	0	0	0
Net Interest	551	(496)	(13)	(18)
Profit Before Tax (norm)	(13,858)	(13,410)	(13,146)	(13,168)
Profit Before Tax (FRS 3)	(13,858)	(13,410)	(13,146)	(13,168)
Tax	2,446	2,063	2,276	2,298
Profit After Tax (norm)	(11,412)	(11,347)	(10,870)	(10,870)
Profit After Tax (FRS 3)	(11,412)	(11,347)	(10,870)	(10,870)
Average Number of Shares Outstanding (m)	31.8	39.1	56.8	56.9
EPS - normalised (p)	(35.85)	(29.00)	(19.12)	(19.12)
EPS - FRS 3 (p)	(35.85)	(29.00)	(19.12)	(19.12)
Dividend per share (p)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	1,229	872	629	436
Intangible Assets	186	186	186	186
Tangible Assets	452	213	88	13
Other	591	473	355	237
Current Assets	19,147	24,479	13,695	2,861
Stocks	0	0	0	0
Debtors	696	444	444	444
Cash and deposits	12,625	22,203	11,206	350
Other	5,826	1,832	2,045	2,067
Current Liabilities	(6,446)	(5,884)	(5,884)	(5,884)
Creditors	(6,280)	(5,727)	(5,727)	(5,727)
Short term borrowings	0	0	0	0
Short term leases	(166)	(157)	(157)	(157)
Other	0	0	0	0
Long Term Liabilities	(707)	(562)	(405)	(248)
Long term borrowings	0	0	0	0
Long term leases	0	0	0	0
Other long term liabilities	(707)	(562)	(405)	(248)
Net Assets	13,223	18,905	8,035	(2,835)
CASH FLOW				
Operating Cash Flow	(13,651)	(12,075)	(12,865)	(12,932)
Net Interest	258	(6)	(13)	(18)
Tax	(611)	6,056	2,063	2,276
Capex	(119)	(25)	(25)	(25)
Acquisitions/disposals	0	0	0	0
Financing	188	17,502	0	0
Dividends	0	0	0	0
Other	6,242	(1,865)	(157)	(157)
Net Cash Flow	(7,693)	9,587	(10,997)	(10,856)
Opening net debt/(cash)	(20,152)	(12,459)	(22,046)	(11,049)
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(12,459)	(22,046)	(11,049)	(193)

Source: ReNeuron accounts, Edison Investment Research

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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