EDISON

ReNeuron Group

Biblical aspirations

Interim results update

Pharma & biotech

ReNeuron's interim results for the six months to 30 September 2017 showcased a crucial juncture in the company's history. With the first of two US placebo-controlled, late-stage studies in chronic stroke starting in 2018 and dosing ongoing in the US Phase I/II study in retinitis pigmentosa, ReNeuron's stem cell therapies are aimed at helping the disabled walk and the blind see. ReNeuron reported a loss of £9.6m for the six months (vs £7.7m in H117). In 2018 ReNeuron's profile will increase further as it conducts two clinical studies and opens an operational base in the US.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
03/16	0.0	(12.8)	(0.44)	0.0	N/A	N/A
03/17	0.0	(10.2)	(0.24)	0.0	N/A	N/A
03/18e	0.0	(14.2)	(0.42)	0.0	N/A	N/A
03/19e	0.0	(15.4)	(0.46)	0.0	N/A	N/A

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

First late-stage study in chronic stroke starts

ReNeuron will start dosing chronic stroke patients in a randomized, placebo-controlled study of its CTX cells in early 2018. An open investigational new drug (IND) application brings ReNeuron unprecedented exposure in the US, which will be aided by its recently announced opening of a US office. When the FDA allows a biotechnology company to start a US clinical study, it has already been through considerable scrutiny by the regulator and the progress of its studies can be followed on www.clinicaltrials.gov. This means that potential partners can keep a close eye on ReNeuron's progress and determine when the PISCES III study has completed enrolment, for example.

Biblical, rather than trivial indications

ReNeuron's innovative therapies for chronic stroke and retinopathies are for indications with few, if any, available treatments. While this makes a new intervention for chronic ischaemic stroke a high-risk endeavour – no other treatments have been approved in stroke disability – the return on a successful clinical study would be significant. Investors will have to weigh these risks in the next year as a fund-raising or partnership to enable the completion of the clinical programmes will be necessary before the end of ReNeuron's cash runway later in FY19.

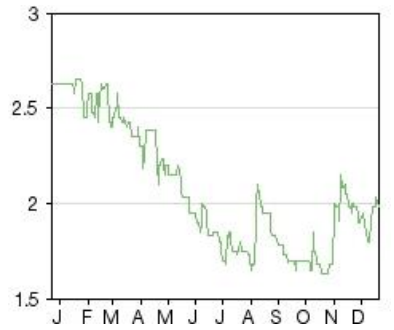
Valuation: Largely unchanged at £286m

We have updated our valuation to £286m (previously £291m) for the revised cash figure at 30 September, R&D spend phasing and further strength of the US dollar. The translation effect may increase in 2018 as ReNeuron's US clinical trial costs and the opening of its US office increase these expenses. ReNeuron is making a hugely positive step in inviting the scrutiny of the FDA for its US clinical programmes and the dosing of the first US patient in 2018 will be an important milestone. We forecast a cash runway later into FY19, before which it may either raise money and/or partner some of its programmes.

21 December 2017

Price	**1.98p**
Market cap	**£63m**
	£/$1.34
Net cash and deposits (£m) at 30 September 2017	45.3
Shares in issue	3,164.6m
Free float	60.5%
Code	RENE
Primary exchange	AIM
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	1.3	16.2	(28.2)
Rel (local)	(0.6)	12.2	(33.7)
52-week high/low		2.6p	1.6p

Business description

ReNeuron is a UK biotech company developing allogeneic cell therapies. CTX neural stem cells are in development for ischaemic stroke disability (Phase III planned) and human retinal progenitor cells (hRPCs) are being studied for retinitis pigmentosa (Phase I/II).

Next events

Initiation of the first US late-stage controlled stroke study	Q118
Phase I/II readout for hRPC in RP	Q218
Start Phase IIb hRPC in RP	Q218

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Updated financial and clinical pipeline overview

ReNeuron has a broad clinical pipeline with multiple data readouts anticipated in the next two years. As it advances into the pivotal clinical study stage, spend will increase in advance of, and during, the later stages of clinical trials. Thus ReNeuron reported a loss of £9.6m for the six months to September 2017 (compared with £7.7m in H117).

Phase III chronic stroke study – H118

Longer-term data from ReNeuron's PISCES II Phase II clinical study of its CTX neural stem cell-derived therapy demonstrated better activity at 12 months than was previously reported at three months. While in different therapeutic areas and patients, the recent data on Novartis's and Gilead Sciences' approved CAR-T cell therapies presented at the American Society of Hematology (ASH) meeting also demonstrated better responses at 12 months than the initial early data at six months. This improving response rate over time for cellular therapies may have, in part, given ReNeuron the validation and confidence to open a US IND and commence the 110-patient PISCES III late-stage clinical study. This is one of two studies required for approval by the FDA. The first patient dosed under a US IND is no mean feat for even the largest of pharmaceutical companies since the FDA reviews thousands of pages of preclinical, clinical, manufacturing and toxicology data before it allows the first US patient to be dosed. It is also necessary for the FDA to agree the protocol, endpoints and the statistical analysis plan before the study can start. Therefore, when ReNeuron doses its first patient in the randomized, placebo-controlled study of an engineered stem cell therapy for chronic stroke, it will be treading a path that few have trodden before.

ReNeuron has taken many years to get to this point and, with a cash runway of about 18 months and a PISCES III study readout in late 2019, investors will need to bear in mind that either a fund-raising in order to see the final results of the study, or a partnering event facilitated by ReNeuron's new US office will need to occur. By that time, we estimate that full enrolment in the PISCES III study will have occurred (one of the two required for the biologics license application [BLA]) and the US profile of the company could be significantly enhanced.

hRPC to be pursued in two indications

ReNeuron's second stem cell-derived product, hRPC, is being investigated in a Phase I/II study in retinitis pigmentosa (RP) in the US. The Phase I trial has three dose cohorts with three patients in each and all three safety dose cohorts have completed. Dosing has started in the Phase II portion of the study. The subsequent expansion of the RP programme into Phase IIb is expected by mid-2018, followed by an additional Phase II study in cone-rod dystrophy.

Once again, ReNeuron seems to be at the right place at the right time, as Spark Therapeutics' gene therapy (voretigene neparvovec) for a much narrower patient population with inherited retinal diseases was approved by the FDA on 19 December 2017. In this case, Spark has done some of the heavy lifting for ReNeuron since the typical visual acuity endpoints used in other, more common ophthalmic clinical studies do not apply to these retinopathies and Spark's approval will lend ReNeuron a helping hand in pivotal clinical trial design, as well as raising the profile of experimental therapies to treat inherited degenerative eye diseases.

Exosome nanomedicine platform potentially in clinic in H119

ReNeuron's third platform in exosome nanomedicine is at a much earlier stage than its stem cell programmes in the clinic. There is also the potential for ReNeuron to partner with this programme,

as exosomes could be a target vehicle for drug delivery in oncology. However, we expect the clinical and business development focus at ReNeuron to be on the later-stage programmes.

Valuation: Largely unchanged at £286m

We have adjusted our valuation to £286m to take account of the last six months of cash burn, and have not included any contribution for the preclinical exosome nanomedicine platform. We have reduced the cash in our valuation to £45.3m at end-September and adjusted the cable rate to reflect the recent strength in the US dollar (£/$ from 1.28 to 1.34). We have changed the estimates of R&D expenses in our model to anticipate a slower, measured start to late-stage clinical trial recruitment in chronic stroke and therefore a longer cash runway. This phasing of R&D spend has the effect of slightly increasing the valuation, as while the same amounts are spent, the time value of those negative cash flows is lower. We will revisit the rate of R&D expense after the first patients have been dosed at the next results announcement. We have maintained our forecast price of CTX in chronic stroke at $50,000, but admit this may be an underestimate with the first two recently approved CAR-T cellular therapies, albeit less comparable since they are indicated in a much smaller patient population, have priced at c $400,000.

We maintain our financial forecasts, although we expect more visibility on the increasing spend on the clinical programmes at the full-year results and will update our model at that time. ReNeuron has a strong cash position (we forecast a cash runway in FY19), which should allow the company to significantly advance its clinical trial programme, resulting in a number of potential key inflection points over the next 24 months, including:

- completion of the PISCES III study for CTX in stroke (H219);
- Phase II hRPC safety data in 2018; and
- further preclinical data from the exosome nanomedicine platform (efficacy and toxicity).

Exhibit 1: Financial summary

£'000s	2013	2014	2015	2016	2017	2018e	2019e
Year end 31 March	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue	17	22	30	29	46	46	46
Cost of Sales	0	0	0	0	0	0	0
Gross Profit	17	22	30	29	46	46	46
R&D expenses	(4,786)	(5,829)	(7,250)	(10,272)	(8,648)	(11,220)	(11,782)
SG&A expenses	(2,319)	(2,824)	(3,693)	(4,015)	(4,139)	(4,346)	(4,781)
EBITDA	(6,966)	(7,857)	(10,269)	(13,632)	(11,717)	(14,522)	(15,014)
Operating Profit (before GW and except)	(7,088)	(7,969)	(10,394)	(13,724)	(11,887)	(14,666)	(15,662)
Intangible Amortisation	0	0	0	0	0	0	0
Exceptionals	0	0	0	0	0	0	0
Operating Profit	(7,088)	(7,969)	(10,394)	(13,724)	(11,887)	(14,666)	(15,662)
Other	0	0	0	0	0	0	0
Net Interest	29	149	91	878	1,722	458	237
Profit Before Tax (norm)	(7,059)	(7,820)	(10,303)	(12,846)	(10,165)	(14,208)	(15,425)
Profit Before Tax (FRS 3)	(7,059)	(7,820)	(10,303)	(12,846)	(10,165)	(14,208)	(15,425)
Tax	714	754	1,397	1,492	2,592	853	925
Profit After Tax (norm)	(6,345)	(7,066)	(8,906)	(11,354)	(7,573)	(13,356)	(14,499)
Profit After Tax (FRS 3)	(6,345)	(7,066)	(8,906)	(11,354)	(7,573)	(13,356)	(14,499)
Average Number of Shares Outstanding (m)	748.7	1,425.0	1,788.8	2,609.3	3,164.6	3,164.6	3,164.6
EPS - normalised (p)	(0.85)	(0.50)	(0.50)	(0.44)	(0.24)	(0.42)	(0.46)
EPS - FRS 3 (p)	(0.85)	(0.50)	(0.50)	(0.44)	(0.24)	(0.42)	(0.46)
Dividend per share (p)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed Assets	1,620	1,772	2,033	6,963	724	3,239	5,783
Intangible Assets	1,272	1,272	1,591	1,591	0	0	0
Tangible Assets	213	225	161	361	724	3,239	5,783
Other	135	275	281	5,011	0	0	0
Current Assets	4,602	22,347	14,054	64,894	65,888	49,110	43,182
Stocks	0	0	0	0	0	0	0
Debtors	341	676	400	1,421	812	812	812
Cash	3,547	20,917	12,382	60,709	61,061	47,446	41,444
Other	714	754	1,272	2,764	4,015	853	925
Current Liabilities	(1,164)	(2,036)	(2,345)	(4,199)	(5,702)	(3,702)	(13,702)
Creditors	(539)	(1,234)	(1,150)	(3,700)	(5,701)	(3,701)	(3,701)
Short term borrowings	0	0	0	0	0	0	(10,000)
Short term leases	(1)	(1)	(1)	(1)	(1)	(1)	(1)
Other	(624)	(801)	(1,194)	(498)	0	0	0
Long Term Liabilities	(150)	(366)	(606)	0	(1)	(1)	(1)
Long term borrowings	0	0	0	0	0	0	0
Long term leases	0	(2)	(1)	0	(1)	(1)	(1)
Other long term liabilities	(150)	(364)	(605)	0	0	0	0
Net Assets	4,908	21,717	13,136	67,658	60,909	48,646	35,262
CASH FLOW							
Operating Cash Flow	(6,637)	(6,718)	(9,124)	(11,920)	(5,976)	(15,428)	(13,899)
Net Interest	(1)	0	0	0	0	0	0
Tax	616	714	879	0	1,340	4,015	853
Capex	(37)	(121)	(380)	(293)	(532)	(2,660)	(3,192)
Acquisitions/disposals	0	0	0	0	0	0	0
Financing	5,601	23,435	0	65,195	0	0	0
Dividends	0	0	0	0	0	0	0
Other	30	61	91	345	520	458	122
Net Cash Flow	(428)	17,371	(8,534)	53,327	(4,648)	(13,615)	(16,116)
Opening net debt/(cash)	(3,974)	(3,546)	(20,914)	(12,380)	(65,708)	(61,059)	(47,444)
HP finance leases initiated	0	(3)	0	1	(1)	0	0
Other	0	0	0	0	0	0	0
Closing net debt/(cash)	(3,546)	(20,914)	(12,380)	(65,708)	(61,059)	(47,444)	(31,327)

Source: ReNeuron accounts, Edison Investment Research

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