EDISON

ReNeuron Group

FY18 results

US exclusivity deal - more than non-dilutive cash

Pharma & biotech

ReNeuron ended FY18 with a healthy cash balance and the 11 July announcement of an exclusivity agreement worth up to US$5m with a US specialty pharmaceutical company for the evaluation of ReNeuron's hRPC platform now leaves it well-funded through to FY20. A key milestone is the imminent start of the US Phase IIb PISCES III placebo-controlled study in chronic stroke disability, which heralds the later stages of clinical development for ReNeuron.

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	3.9	(25.6)	(71.21)	0.0	N/A	N/A
03/20e	1.0	(30.4)	(84.40)	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.

FY18 results: Strong cash balance

ReNeuron's end-year cash balance was £37.4m (vs £53.1m at end FY17), about £5m higher than our estimate. Net losses in FY18 were £17.6m, better than the £20.1m we had forecast. These incorporated R&D expenses of £16.7m, up £1.6m on a comparable basis, and were distorted by material FX losses (£0.9m vs a gain of £1.7m in FY17). Net cash outflows were £14.9m (£12.6m in FY17) and we estimate net outflows of £21.2m in FY19.

Funded for a busy programme

ReNeuron is pushing forward on a number of fronts this year and next that will increase cash its requirements. The first pivotal US Phase IIb study in chronic stroke disability and the Phase I/IIa study in retinitis pigmentosa (RP) will have both started expanded studies. A new base in Boston was opened in 2018. Funding this activity will be the end-March 2018 cash, supplemented by three therapeutic development grants already announced of around £5m, and up to $5m from an undisclosed US specialty pharmaceutical company for the exclusive evaluation of the hRPC platform. Additionally, management states that it is in active discussions with third parties with a view to eventual collaboration and outsourcing deals relating to other technologies and platforms. ReNeuron is currently well-financed but, subject to further business development, we anticipate that further funds will be required to complete the clinical programmes in FY20.

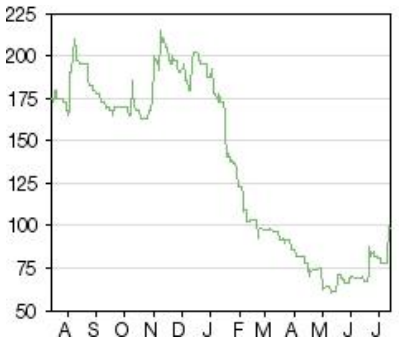
Valuation: Minor but useful changes

We have updated our model for the FY18 results, and incorporated the recent grants and US fee agreement. Our valuation moves to £280m or 8.9p per share from £276m or 8.7p per share, but does not yet include the second $2.5m (£1.9m) payment in evaluation fees, which could be received in the next three months.

13 July 2018

Price	**98.50p**
Market cap	**£31m**
Net cash at 31 March 2018	37.4
Shares in issue	31.6m
Free float	100%
Code	RENE
Primary exchange	AIM
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	40.7	27.1	(43.7)
Rel (local)	42.1	20.7	(45.9)

52-week high/low 215.0p 60.0p

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 imminent. Human retinal progenitor cells (hRPCs) are also being studied for RP (in Phase I/IIa).

Next events

Interim 2019 results	December 2018
Chronic stroke pivotal Phase IIb study start	Q318
Phase I/IIa hRPC study readout	Mid-2019
Chronic stroke pivotal study readout	End 2019

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Clinical pipeline updates: Pivotal Ph IIb study imminent

ReNeuron's FY18 results included pipeline updates on its three product candidates/platforms and noted the partnering interest in those products. The first of two pivotal, US placebo-controlled, Phase IIb clinical studies of the CTX stem cell therapy in chronic stroke disability is due to dose the first patient imminently. Top-line results are expected at the end of 2019. This study has expanded the number of trial sites to 40 from 25 to ensure that patient recruitment targets are met. The US open-label, hRPC cell therapy Phase I/IIa study in retinitis pigmentosa (RP) is ongoing and recruitment is being expanded to bolster the safety database in patients with less impaired vision. The hRPC cell therapy product was the highlight of the results announcement, with the evaluation agreement and associated cash inflows discussed below. The interest in RP is logical as a recent GlobalData analysis listed 16 products in Phase II and three products in Phase III, including jCyte's stem cell product, like ReNeuron's CTX product, in Phase II in the US.

Platforms attract partnering interest

A welcome proof of external interest in ReNeuron's products was demonstrated by the 11 July announcement of the exclusivity agreement signed with an undisclosed US-based specialty pharmaceutical company on the potential out-licensing of the hRPC technology platform. While the initial $2.5m for the three-month exclusivity period and subsequent $2.5m are useful cash inflows, they could potentially lead to the substantial milestones and royalties of a full licensing transaction. The second $2.5m payment is contingent on the due diligence progress and the evaluation period lasts for three months. We have currently excluded the second payment from our FY19 revenue forecast, but even the $5m total will have a much smaller impact on ReNeuron than either the full licensing transaction or the external validation of its technology.

FY18 financials: Strong cash balance

ReNeuron's end-year cash balance was £37.4m (vs £53.1m at end FY17), about £5m higher than our estimate. Net losses in FY18 were £17.6m, better than the £20.1m we had forecast. These incorporated R&D expenses of £16.7m, up £1.6m on a comparable basis, and were distorted by material FX losses (£0.9m vs a gain of £1.7m in FY17). Net cash outflows were £14.9m (company definition; £12.6m in FY17) and we estimate net outflows of £21.2m in FY19. This net cash outflow includes the grant and evaluation fee inflows subject in part to their tax treatment. We have made some assumptions on the £5.0m in grant funding including its recognition over 36 months and the payment of £1.0m of the grants to collaborators. In terms of costs, FY18 R&D and SG&A combined costs were £21.3m. We estimate these to rise to £29.7m in FY19 and £31.5m in FY20.

Funded into FY20

Our forecasts point to ReNeuron being funded into 2020, which should enable significant advancement of the two clinical studies (the first US pivotal chronic stroke Phase IIb and RP Phase I/IIa) and possibly a Phase I exosome study in an oncology indication. With £37.4m in cash at the end of March 2018, our assumption of £4m out of the £5m in research grants over the next 36 months, and at least $2.5m from the exclusivity assessment for hRPC, ReNeuron has the resources to progress to potential valuation inflection points and continue to develop its broad portfolio. We expect the company to accelerate its investment in operating activities, particularly within R&D, in line with the progression of its clinical pipeline.

Valuation

We have rolled our model forward to FY20 and updated our valuation to reflect the lower cash burn in FY18, expected grant inflows and the hRPC platform evaluation deal just announced. We also take into account of the increased cash requirements of the expanded CTX cell therapy in chronic stroke disability Phase IIb PISCES III trial. This results in a valuation of £280m (vs £276m) or 8.9p per share. This does not include any contribution for the recently presented exosome nanomedicine platform as it is currently preclinical, but has the potential to generate both oncology products, and/or further licensing revenues. We expect to revisit this when the first exosome target is taken into the clinic. ReNeuron is funded into FY20 on our revised forecasts, which should enable it to execute on an expanding clinical trial programme, resulting in a number of potential key inflection points over the next 24 months, including the pivotal Phase IIb study for CTX in chronic stroke (with data expected at the end of 2019; Phase I/IIa hRPC data in mid-2019; and further preclinical data from the exosome nanomedicine platform (efficacy and toxicity).

Prudent cash management results in modest valuation change

We have maintained the probability of success for CTX cells in chronic stroke disability at 25% as it is in Phase IIb. The revised cash balance at end FY18, updated FX rates (we use spot FX) and a £5.5m increase in R&D spend in FY19 (to reflect running two Phase II studies) are the three main changes we have made to our model. We have also incorporated the exclusivity fee ($2.5m) and grant (£4.0m net) cash inflows, recognising them in FY19 and over 36 months respectively, as revenue in the income statement. As a result, our rNPV valuation increases slightly to £282m or 8.90p per share from £276m or 8.74p per share and is detailed in Exhibit 1 below. Our valuation does not include the second tranche of $2.5m (£1.9m) in potential evaluation fees, which could be received in the next three months.

Exhibit 1: rNPV valuation

Product	Setting	Status	Launch	NPV (£m)	Peak sales ($m)	Probability of success	Royalty rate	rNPV (£m)	rNPV per share (p)
CTX	Stroke disability	Phase II/III	2020	677	1,633	25%	30%	157	4.96
hRPC	CRD	Phase I/II	2020	100	147	20%	30%	15	0.49
hRPC	RP	Phase I/II	2020	357	629	20%	30%	70	2.21
Portfolio total				1,134				244	7.67
Cash (end March 2018)								37.4	1.18
Overall valuation								280	8.85

Source: Edison Investment Research, Company announcements. Note: Number of shares in issue is 31.6m

Exhibit 2: Financial summary

£'000s	2016	2017	2018	2019e	2020e
Year end 31 March	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	563	900	897	3,937	1,043
Cost of Sales	0	0	0	0	0
Gross Profit	563	900	897	3,937	1,043
R&D expenses	(10,272)	(16,648)	(16,657)	(24,656)	(25,888)
SG&A expenses	(4,015)	(4,139)	(4,616)	(5,078)	(5,585)
EBITDA	(13,632)	(19,814)	(20,231)	(25,651)	(30,258)
Operating Profit (before amort. and except.)	(13,724)	(19,887)	(20,376)	(25,796)	(30,431)
Intangible Amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Operating Profit	(13,724)	(19,887)	(20,376)	(25,796)	(30,431)
Other	0	0	0	0	0
Net Interest	878	1,722	(591)	187	81
Profit Before Tax (norm)	(12,846)	(18,165)	(20,967)	(25,609)	(30,350)
Profit Before Tax (FRS 3)	(12,846)	(18,165)	(20,967)	(25,609)	(30,350)
Tax	1,492	2,592	3,352	3,073	3,642
Profit After Tax (norm)	(11,354)	(15,573)	(17,615)	(22,536)	(26,708)
Profit After Tax (FRS 3)	(11,354)	(15,573)	(17,615)	(22,536)	(26,708)
Average Number of Shares Outstanding (m)	2,609.3	3,164.6	31.6	31.6	31.6
EPS - normalised (p)	(0.44)	(0.49)	(55.66)	(71.21)	(84.40)
EPS - FRS 3 (p)	(0.44)	(0.49)	(55.66)	(71.21)	(84.40)
Dividend per share (p)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	6,963	724	912	1,049	1,215
Intangible Assets	1,591	0	186	186	186
Tangible Assets	361	724	726	863	1,029
Other	5,011	0	0	0	0
Current Assets	64,894	58,136	41,706	20,525	(5,177)
Stocks	0	0	0	0	0
Debtors	1,421	1,060	1,285	1,285	1,285
Cash	60,709	53,061	37,411	16,166	(10,104)
Other	2,764	4,015	3,010	3,073	3,642
Current Liabilities	(4,199)	(5,703)	(5,949)	(5,949)	(5,949)
Creditors	(3,700)	(5,703)	(5,949)	(5,949)	(5,949)
Short term borrowings	0	0	0	0	0
Short term leases	(1)	0	0	0	0
Other	(498)	0	0	0	0
Long Term Liabilities	0	0	0	0	0
Long term borrowings	0	0	0	0	0
Long term leases	0	0	0	0	0
Other long term liabilities	0	0	0	0	0
Net Assets	67,658	53,157	36,669	15,624	(9,911)
CASH FLOW					
Operating Cash Flow	(11,920)	(13,976)	(19,244)	(24,501)	(29,086)
Net Interest	345	520	383	187	81
Tax	0	1,340	4,357	3,352	3,073
Capex	(293)	(532)	(235)	(282)	(338)
Acquisitions/disposals	0	0	0	0	0
Financing	65,195	0	0	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	53,327	(12,648)	(14,739)	(21,244)	(26,270)
Opening net debt/(cash)	(12,380)	(65,708)	(53,061)	(37,411)	(16,166)
HP finance leases initiated	1	0	0	0	0
Other	(0)	(0)	(911)	0	0
Closing net debt/(cash)	(65,708)	(53,060)	(37,411)	(16,167)	10,104

Source: Company accounts, Edison Investment Research. Note 100:1 share consolidation with effect from January 2018.

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