EDISON

Cell Therapy

Pioneering regenerative medicines

Initiation of coverage

Pharma & biotech

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Cell Therapy is developing potentially disruptive therapy for the treatment of severe chronic heart failure. Based on the pioneering work of Nobel Laureate Professor Sir Martin Evans, the company has isolated a novel line of allogenic immuno-Modulatory Progenitor Cells (iMP), which are suitable for injection directly into the myocardium during open heart surgery. The lead candidate, Heartcel, is on track to commence a pivotal Phase III trial in Europe by the end of this year and has recently been licensed to Daiichi Sankyo (DS) in Japan. The company anticipates that an H217 approval in these countries may be possible and potentially a 2019 launch in the US.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
07/14	0.0	(0.8)	N/A	N/A	N/A	N/A
07/15	0.0	(1.6)	N/A	N/A	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items.

Novel cell therapies for tissue regeneration

Cell Therapy is developing proprietary cellular therapies, which aim to repair or regenerate damaged tissue in diseases with high unmet medical need. The discovery process aims to select and isolate novel cell types that are not naturally occurring – which may therefore have the potential to generate defensible intellectual property – and are morphologically distinct from mesenchymal stem cells. The initial area of focus is chronic heart failure, although other possible indications (which are not factored into our valuation) include oncology and diabetes.

Heartcel Phase II study showed encouraging results

Heartcel showed encouraging results in a small (n=11) single cohort Phase II study in patients with heart failure undergoing coronary artery bypass grafts (CABG), with improvement in all parameters and no mortality or major adverse cardiac events (MACE) at 30 months after the surgery. This has helped the company to secure a Japanese marketing partner, DS, and facilitated discussions with the European Medicines Agency (EMA), which has given its authorisation to proceed to a Phase III pivotal trial.

Valuation: Risk-adjusted rNPV of £346m

We currently value Heartcel, together with Myocardion, the follow-on product for use in percutaneous coronary intervention (PCI), and Tendoncel, a non-core asset earmarked for out-licensing, at £346m on risk-adjusted net present value (rNPV). This is underpinned by the company's current net cash position of approximately £17m, which includes the upfront payment of £12.5m from DS. We are mindful of the fact that, although the Phase II data were presented at the European Society for Cardiovascular and Endovascular Surgery Congress in March 2015, they are yet to be published or subject to peer review and there is currently low scientific visibility on the precise mechanism of action of the iMPs.

Business description

Cell Therapy is a privately held Welsh biotech company developing allogeneic cell therapies. The cardiac programme consists of two lead products, Heartcel and Myocardion. A third product, Tendoncel, has completed a Phase II study in lateral epicondylitis.

Next events

Europe Phase III trial start for Heartcel	H216
Regulatory decisions on Breakthrough and Orphan designations for Heartcel	H216
Start of Tendoncel Phase III study	H216
US Phase III trial start for Heartcel	H216

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Investment summary

Company description: A leading player in tissue regeneration

Cell Therapy is a UK clinical-stage company developing a portfolio of cell-based regenerative therapies. The initial focus is on chronic heart failure patients undergoing open heart surgery and CABG and the lead candidate, Heartcel, is injected directly into the myocardium at the end of the procedure. It has been out-licensed to Daiichi in Japan and is about to enter Phase III pivotal trials in Europe. Myocardion, a similar treatment for patients who are suitable for PCI, is currently in Phase II and a third product, Tendoncel, which has completed a Phase II study in lateral epicondylitis (tennis elbow) and been designated non-core, is earmarked for out-licensing. The company was founded in 2009 by Nobel Laureate, Professor Sir Martin Evans and Ajan Reginald, ex-Global Head of Emerging Technologies, Roche. It is headquartered in Cardiff, with laboratories at the GE Cell and Gene Therapy Centre of Excellence, and has been supported by Welsh Government Grants.

Valuation: rNPV model suggests £346m

We value the above three projects, on which we have some visibility, at £346m using risk-adjusted NPV. This is based on our usual discount rate of 12.5% and a 33% probability of Heartcel successfully negotiating Phase III trials and reaching the market. The corresponding risk factors in our model for Myocardion and Tendoncel are 8% and 33% respectively. Although we recognise the significant market opportunity represented by Myocardion, there has been little visibility on data to date. Our valuation does not include a contribution from other early stage projects or the technology platform in general and we have made no allowance for overhead, or additional financing costs, should they become necessary. On that basis, Heartcel currently represents 84% of the current value of the company.

Risk versus reward

As an entity involved in drug discovery and development, Cell Therapy is subject to the usual risks associated with that area of activity which may include clinical development delays, unfavourable outcomes in clinical trials or regulatory reviews, competitor activity and pricing and re-imbursement.

Specifically with respect to Heartcel, the company is applying for Orphan Drug status (Europe and US) and Breakthrough Designation (US) and failure to secure this may affect the timelines in our model and delay approval in those jurisdictions. DS, Cell Therapy's marketing partner in Japan, is now responsible for clinical trials and the registration process in that country and any delay could affect our valuation. We have also assumed that a development and marketing partner will be sought for Heartcel in the US.

Financials

As Cell Therapy is a private company, we do not make financial forecasts. Cell Therapy reports current cash of £17.0m (vs £1.2m at end FY15) including the £12.5m upfront payment from DS and a recent increase in capital from existing shareholders and private investors. We estimate that the company has enough cash for the next two to three years and additional funding may be required to recruit a specialist salesforce to market Heartcel in Europe and for the continued development of Myocardion, although at this point the company may have started to receive significant income from DS in Japan.

Cell Therapy is a pioneer in cell-based repair

Cell Therapy is a clinical-stage regenerative medicine business. It is developing novel cell-based therapies that target areas of significant unmet or poorly met medical need. Lead product, Heartcel, uses immuno-Modulatory Progenitor cells (iMPs) to treat end-stage heart failure in patients with blockages in their coronary arteries, in conjunction with open heart surgery and CABG. It has completed a Phase II study, with US and European Phase III trials planned. Cell Therapy has been advised by the EMA Scientific Advice Working Party (SAWP) to conduct a small placebo controlled Phase III trial with interim readouts, which could allow the product to launch in Europe as early as H217. Cell Therapy intends to apply for Orphan Drug (Europe and US) and Breakthrough (US) designations. The second cardiac product, Myocardion, which uses a related but distinct cell, is being developed for a similar population of heart failure patients who are suitable for PCI – a far less invasive procedure than CABG. The Tendoncel programme, now considered to be non-core and earmarked for out-licensing, comprises a platelet-based therapy, and has potential in numerous tendinopathies. Efficient proprietary techniques are used to develop allogeneic (off the shelf) cells, which has both financial and commercial advantages. Exhibit 1 shows the current development pipeline.

Exhibit 1: Cell Therapy's R&D pipeline

Product	Indication	Status	Est. launch*	Notes
Heartcel	Orphan NYHA II-IV heart failure patients undergoing CABG at risk of incomplete revascularisation	Phase II	2017 (EU) 2019 (US) 2018 (Japan)	Uncontrolled Phase II (n=11) in patients with NYHA class III-IV undergoing CABG. Completed in Nov 2014. At >30 months no mortality or MACE. Statistically significant LVEF improvement, reduction in LV scar size and improved quality of life (by MLHF). European and US Phase III trial planning in progress.
	Kawasaki Disease	Preclinical		Paediatric Investigation Plan submitted to the EMA for paediatric Orphan indication Kawasaki Disease. Phase I/II planning.
Myocardion	Stage II-III heart failure undergoing PCI at risk of incomplete revascularisation	Pre-IND	2023	PML-derived cells, optimised for delivery by catheter during PCI for patients with NYHA class II-III. Phase II trial planning in progress.
Tendoncel	Tennis elbow and other tendinopathies	Phase II	2019 (EU) 2020 (US)	Phase IIb placebo controlled trial in lateral epicondylitis (n=34). Statistically significant improvement at day 21 in two functional questionnaires (DASH and PRTEE). No significant change in IgE levels. Ongoing phase II studies in other tendinopathies.
Skincel	Wound healing, cosmetic applications	Phase I/II	2020	Phase I safety study completed. Phase IIb planning in progress.
Other	Oncology; type 1 diabetes; liver fibrosis	Preclinical	N/A	Oncology Phase I initiation (in B-cell malignancies) due in H116.

Source: Cell Therapy and Edison Investment Research. Note: *These refer to Edison's estimated launch dates. NYHA = New York Heart Association; CABG = coronary artery bypass grafting; MACE = major adverse cardiac event; LVEF = left ventricular ejection fraction; MLHF = Minnesota Living with Heart Failure scale; PCI = percutaneous coronary intervention.

The appeal of successful regenerative therapy should not be underestimated, both from a clinical and commercial perspective. Where many therapies merely address the symptoms of a disease, cellular therapy offers the opportunity to address the underlying pathology of the condition, effecting repair or reversal of the disease through the regeneration of the affected tissue. The already fast-paced field of cellular therapy research has accelerated further in recent years, with a number of clinical studies producing encouraging early signs of the efficacy of different cell types in various indications, including cardiovascular disease.

The cardiac products, Heartcel and Myocardion, were developed using proprietary technologies based on the work of Nobel Laureate Professor Sir Martin Evans. The products derive from progenitor cells of mesodermal lineage (PMLs), a new class of progenitor cells discovered and isolated by Cell Therapy. Heartcel, centres on immuno-Modulatory Progenitor cells (iMP), which are cultured from PMLs. Although having similar properties to mesenchymal stem cells (MSC), iMPs possess a distinct phenotype that Cell Therapy believes is optimised for immune-modulation and

cardiac regeneration. It is developing these multi-potent cells specifically for allogeneic[1] (as opposed to autologous[2]) administration. The final product can be cryopreserved, stored and transported, with a simple procedure to prepare the cells for injection, so offering a genuine "off-the-shelf" cellular therapy. Heart failure affects c 26 million people worldwide and results in more than one million hospitalisations annually in the US and Europe. The cardiac programmes have the potential to be disruptive innovations and, if successful, the clinical and benefits of these therapies would translate into a highly attractive market opportunity.

Platelet therapies have been proposed to enhance wound healing and tissue regeneration through the secretion and action of growth factors.[3] Cell Therapy also has two further separate, and distinct, therapies, Tendoncel and Skincel. These allogeneic platelet-based therapies have been developed in a proprietary and novel topical formulation enabling ease of use; Cell Therapy also believes this will ensure consistent bioavailability and dosing for both tendon and skin regeneration.

Can a broken heart be mended?

In the US alone, heart failure affects 5.7m people, with 670,000 new cases per year.[4] Despite advances in medical management, the prognosis for heart failure is poor, with a five-year mortality rate of c 50% following diagnosis (Heart Failure Fact Sheet), comparable to that from breast or colon cancer.

When damaged, the heart has limited capacity for self-renewal and undergoes adverse remodelling with resulting diminished function. In response to poor oxygen supply (due to coronary artery disease, CAD), the heart may reduce the energy demands of contraction to prevent death of heart cells, resulting in areas of hibernating, but viable, myocardium (heart muscle). Heart failure, the final common stage of many diseases of the heart, is the clinical syndrome that results when the heart is unable to pump sufficient blood to meet the body's metabolic requirements. Currently, the mainstay of treatment for heart failure is with drugs and lifestyle changes. However, where heart failure is caused or exacerbated by CAD, treatment may also involve revascularisation procedures to restore blood flow to the myocardium and return function. The two principal procedures are coronary artery bypass grafting (CABG), using grafted vessels to circumvent blockages in the arteries, and Percutaneous Coronary Intervention (PCI), where a balloon-catheter is used to dilate the arteries, typically then deploying a stent to maintain patency.

Failure to completely restore the blood supply to the myocardium following these procedures, also known as incomplete revascularisation (ICR), has been shown to have a detrimental impact on long-term clinical outcomes, including major adverse cerebrovascular or cardiac events (MACCE) and all-cause mortality.[5] ICR occurs in 37% and 43% of CABG and PCI procedures respectively,[6] and treatment options thereafter are limited. Certain risk-factors for ICR are identifiable pre-operatively, such as complexity of coronary anatomy and disease, and clinical co-morbidities.

[1] **Allogeneic**, where culture expanded stem-cells originating from a single donor are used to provide treatments to large numbers of patients.

[2] **Autologous**, where stem cells are harvested from a patient and culture expanded ex vivo to large quantities over many weeks before then being returned to the patient.

[3] Moraes VY, *et al.* Platelet-rich therapies for musculoskeletal soft tissue injuries (Review). Cochrane Database Syst Rev 2014, Issue **4**, Art. No.: CD010071.

[4] Ambrosy AP, *et al*. The global health and economic burden of hospitalisations for heart failure: lessons learned from hospitalised heart failure registries. *Am Coll Cardiol.* **63**:1123-1133 (2014).

[5] Farooq V, *et al*. The negative impact if incomplete angiographic revascularization on clinical outcomes and its association with total occlusions. *J Am Coll Cardiol.* **61**(3):282-294 (2013).

[6] Head SJ, *et al*. Incidence, predictors and outcomes of incomplete revascularisation after percutaneous coronary intervention and coronary bypass grafting: a subgroup analysis of 3-year SYNTAX data. *Eur J Cardiothorac Surg.* **41**(3):535-541 (2012).

While current therapeutic approaches for heart failure do improve symptoms and prolong life, they do not address the underlying problem of damage to, and loss of, myocardium. The development of cellular therapies has offered the prospect of regenerating the myocardium and impeding adverse left ventricle (LV) remodelling. Numerous preclinical and clinical studies support the ability of various stem cell populations to improve cardiac function and attenuate adverse LV remodelling. Cell Therapy is targeting those patients identified as being at risk of ICR, delivering cellular therapies at the time of the revascularisation procedure to ameliorate the effects of ICR.

A Cochrane review evaluating autologous bone marrow‐derived stem cells therapy for chronic ischaemic heart disease and heart failure in more than 1,200 patients, showed a reduction in deaths and readmission to hospital in the long term as well as improvements in heart function. The treatments appeared safe, with no long-term adverse events reported. However, the review concluded that the quality of the evidence is relatively low because there were few deaths and hospital readmissions in the studies, and individual study results varied quite widely. It should also be noted that many of the trials were performed in conjunction with CABG or other LV assist device procedures, making it difficult to separate the effects of cell therapy from those of revascularisation.

Cell Therapy's myocardial regeneration programmes

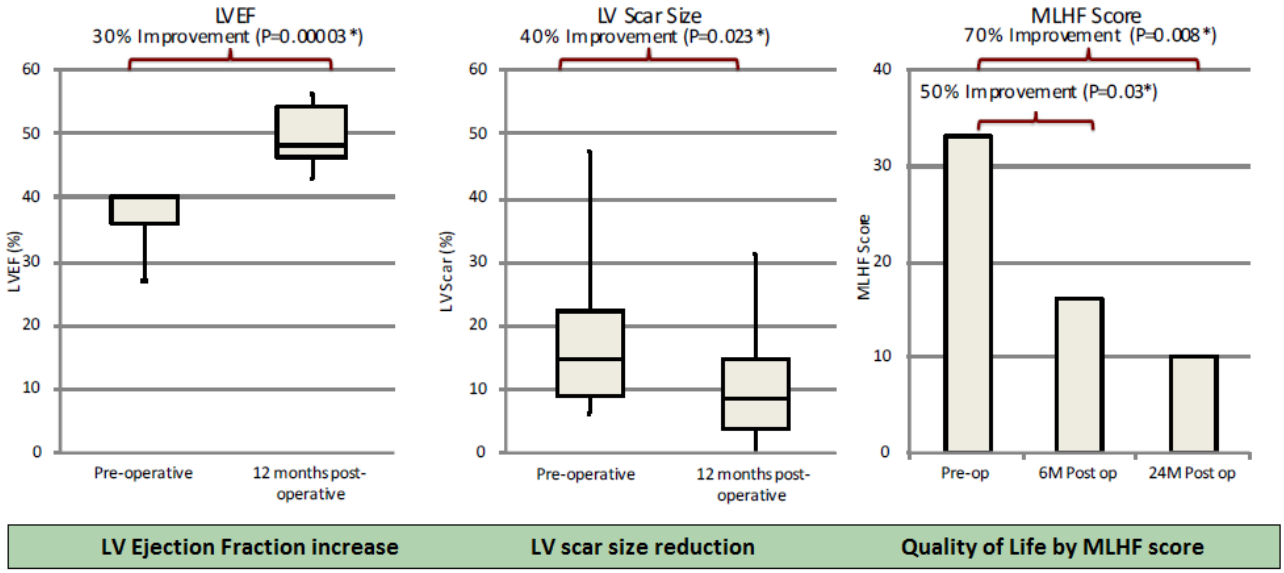
Heartcel and Myocardion can be used alongside CABG and PCI respectively, to mitigate the effects of ICR in patients with heart failure. Both are developed using Cell Therapy's proprietary PML cell line. The Heartcel treatment consists of a single application of 2.58 x 10^4 cells per kg (c 2-4m cells per patient). The Myocardion formulation is currently undergoing optimisation for the different mode of delivery.

Heartcel: Positive results across all key parameters in Phase II

Heartcel has completed an open-label Phase II study, with results presented at the ESCVS Congress in March 2015. The study evaluated 11 patients with advanced heart failure (NYHA III-IV, LV ejection fraction ≤40%) who were to undergo CABG and deemed to be at risk of ICR. All patients had pre-operative SPECT[7] imaging to identify non-functioning hibernating areas of the myocardium that would be at risk of ICR. During the surgery the iMPs were injected into these pre-identified areas in the myocardium; on average there were 6-8 injection sites per patient. The iMP cells were injected using a 22-guage needle after which a swab was used to occlude the injection site for several seconds to minimise any reflux of cell suspension.

[7] SPECT Scan: single photon emission computed tomography uses radioactive tracers and a scanner to record data that a computer constructs into two- or three-dimensional images. SPECT can give information about blood flow to tissues and chemical reactions in the body.

Exhibit 2: Heartcel: Phase II results



Source: Cell Therapy and Edison Investment Research. Note: *Statistically significant.

All patients were followed up with post-operative SPECT imaging to assess changes in functionality at the injection sites. SPECT imaging demonstrated increased functioning cells at 4- and 12-months post-CABG across all patients in the study. In addition to the SPECT findings, all Heartcel recipients have survived, MACE-free, to date (>30 months), despite one-year mortality rates in NYHA IV patients being estimated to be between 30-70%. Furthermore, patients were found to have a statistically significant improvement in LV ejection fraction (LVEF, a measure of heart function) and LV scar size sustained for at least 12 months.

Reassuringly, given that it is an allogeneic therapy, there was no evidence of immune response as measured by white blood cell count at the one month follow-up. Finally, and arguably most significant from the patient's perspective, there was a sustained improvement, beyond 18 months, in quality of life on the Minnesota Living with Heart Failure scale (MLHF), which assesses the burden of living with heart failure. Exhibit 2 illustrates the results.

However, there is a residual concern that this study did not include a control group of patients and the data is, as yet, unpublished. We do not know whether the patients had any significant co-morbidities of a kind that is often found in this group of patients such as diabetes, or renal failure, which could affect recovery and post-operative mortality. Nor can we separate out the effect of the operation from that of the iMP inject afterwards, although the company has cited independently published studies which suggest that the pre-operative NYHA group classification is one of the most important predictors of post-operative mortality (Marchenko et al. 2011) after isolated CABG in this group of patients and Ahmed et al found a 90% three year mortality rate in NYHA IV patients during long term follow up, which is not necessarily reflective of the sub-group of patients who would be suitable for CABG. These questions should be answered after full publication of the Phase II data and during the Phase III trials, which will be placebo controlled and double blind.

A potential breakthrough in an orphan disease

Cell Therapy is applying for Orphan Drug Designation based on the use of Heartcel in patients undergoing CABG deemed to be at risk of ICR. Scientific Advice from the European regulator has confirmed that Cell Therapy should consider all heart failure patients undergoing CABG and at risk of ICR as its target indication and not only those who are NYHA IV. The company is now looking to test Heartcel in this population in phase III trials in both the US and Europe. To qualify for orphan drug designation, the FDA requires that the target disorder must affect <200,000 people in the US.

Successful applicants receive various development incentives and, importantly, seven years of commercial exclusivity following approval. As stated previously, c 37% of patients undergoing CABG have ICR. Given that there are less than 300,000 CABG procedures in the US each year, then the total addressable market for Heartcel is less than 110,000. A successful application in the EU also results in development incentives and assistance, as well as 10 years of commercial exclusivity.

In addition to this, Cell Therapy will apply for Breakthrough designation for Heartcel in the US. A breakthrough therapy is a drug that treats a serious condition, with preliminary clinical evidence indicating that the drug demonstrates substantial improvement over existing therapies on one or more clinically significant endpoints. For a drug designated as breakthrough therapy, the FDA expedites the development and review processes. Cell Therapy believes that Heartcel meets these criteria on the basis of the Phase II data.

Routes to market have been defined

In Europe, Cell Therapy has been given formal scientific advice by the EMA SAWP on the requirements for a marketing authorisation application, which includes a small placebo controlled study (~36 patients) in NYHA II-IV patients undergoing CABG at risk of ICR. The EMA agreed that the phase III study could be an adaptive trial, with interim readouts at 3 months, 6 and 9 months. Clear signs of efficacy at interim stage analysis would allow for launch of Heartcel as early as H217.

For FDA approval Cell Therapy will need to perform a trial in the US. Cell Therapy will submit an IND application to the FDA in the near future with a Phase III study due to commence shortly after receipt of this. Working on the basis of standard regulatory timelines, this could allow launch in 2019. The trial will be a double-blind Phase III trial with 12-month MACE-free survival as the primary outcome. At present, Cell Therapy anticipates that the trial will take place at two sites, large US centres performing c 50 CABG procedures per week. Should the Breakthrough and/or Orphan status applications be successful, it would allow for results to be submitted on a rolling basis during the trial, thus accelerating the timeline and allowing for possible approval in H217 and launch in H118.

Myocardion targets a broader heart failure population

Myocardion is also developed from the PML cell line; although Cell Therapy reports that the cells have some differences from iMPs, including a 20% difference in receptor expression. There is currently limited public information on the cells; although Cell Therapy states that the cells used in Myocardion have a greater overlap with embryonic stem cells, with a phenotype that favours regenerative potential over inflammation modulation. They are also said to be hypoxia-resistant, which is appropriate for delivery by catheter. Cell Therapy has performed extensive preclinical studies. Myocardion will be used in NYHA II-III patients undergoing PCI and who are identified as being at risk of ICR.

Myocardion is designed for delivery via catheter during PCI, using a trans-septal approach via the left atrium and into the LV. Cell Therapy is in discussions with a medical device company, for a device and cell combination; once finalised, an IND will be filed (aiming H216). Cell Therapy hopes to receive Breakthrough designation based on preclinical data by H216.

Cell Therapy intends to advance Myocardion straight to an adaptive Phase II/III trial on the basis of the Heartcel safety and clinical trial data, as they are both derivatives of PMLs. The trial is a multi-centre (two in the US, one in EU), placebo controlled trial (n=200). The first stage (n=50) will provide safety and efficacy data, before continuing to the second stage with a further 150 patients. Cell Therapy is confident that the trial will begin recruiting as early as H216, pending the necessary agency approvals, and believes full recruitment could be achieved in three months. The primary

endpoint will be MACE-free survival at 12 months, with Phase II results available in H118. Full Phase III stage completion would then likely be in 2018-19 with an approval in 2019-20.

Given the lack of Phase I or II studies and dose-escalation data in humans, we have adopted a more cautious approach. We assume that the differences between the products are sufficient to require that a Phase I/II safety and dose-ranging study be performed before a large multi-centre Phase III trial (as has been performed by peers such as Celyad/Cardio3). This would mean launch in 2023. This leaves room for significant upside should approval be achieved sooner.

Commercialisation strategy reflects different audiences

As the number of PCIs performed per year exceeds the number of CABGs by more than three times, and as the two procedures are performed by different specialists, the routes to market for Myocardion and Heartcel may differ. In Europe, Cell Therapy intends to commercialise Heartcel on its own, believing itself capable of addressing the comparatively smaller target market of cardiac surgeons, helped by its already established relationships with key opinion leaders. However, for the US commercialisation of Heartcel, Cell Therapy will seek a partner for co-commercialisation. For Myocardion, Cell Therapy recognises the need to partner for co-commercialisation in both Europe and the US, in order to penetrate the much larger market of interventional cardiologists.

The agreement with Daiichi Sankyo (DS)

The licensing agreement with DS provides for the development and commercialisation of Heartcel in Japan. In addition to an upfront payment of £12.5, DS will be responsible for all development costs and pay a royalty and potentially pay further milestones. Cell Therapy will also supply the active ingredient in finished form. The regulatory environment for regenerative medicines is currently favourable in Japan and a well-defined route exists for early provisional approval with conditions. DS is the second largest pharmaceutical company in Japan, with a well-established portfolio of cardiovascular medicines. The current aim is to secure provisional approval and, if successful in doing so, launch as early as H217. Pricing may well be comparable to Terumo's HeartSheet (which was also filed under the conditional approval system), or JCR's Temcell, which the company and its partner believe would equate to a fully reimbursed price of around $100,000 per treatment.

Novel cells for tissue regeneration

Cell Therapy's cardiac products have been developed using a proprietary cellular discovery process that allows for highly targetable cells to be isolated. This combines computational algorithms, novel discovery agents and high-throughput FACS[8] to discover novel progenitor cells which are then characterised in vitro to capture rare but potent progenitor cells. Progenitor cells are early descendants of stem cells that can differentiate to form one or more kinds of cells, but cannot divide and reproduce indefinitely. A proprietary novel expansion platform, EnhanceI, enables the efficient development of these targeted cells while retaining cell quality. Both technologies were developed in-house and are covered by multi-jurisdictional patents.

Cell Therapy discovered and isolated PMLs, which have a specific marker expression pattern. These novel and distinct progenitor cells can be cultured from mononuclear cells (MCs) and are capable of efficiently migrating to and repairing damaged tissues where they exert an anti-inflammatory effect. The therapies have been developed to be allogeneic; however in principle these cells could also be harvested from a patient for autologous administration. Cell Therapy is able to culture the PMLs to preferentially express, and under express, different receptors, thus conferring different phenotypes suitable for different disease conditions. This potentially enables a

[8] FACS – Fluorescence-activated cell sorting.

diverse array of therapies, including Heartcel and Myocardion, to be developed from the platform. For Heartcel, Cell Therapy cultured iMPs from PMLs using epigenetic modification; these have been found to act as a potent cardio-specific cellular therapy. Although being MSC-like and plastic adherent, iMPs do not meet the criteria for MSCs as defined by the ISSCR.[9] Cell Therapy asserts that iMPs possess a distinct phenotype that is optimised for cardiac regeneration.

Cell Therapy believes that the PMLs act via a paracrine mechanism to exert an anti-inflammatory effect, which promotes the survival, repair and regeneration of neighbouring cells. In the case of Heartcel, Cell Therapy postulates that iMPs exert their anti-inflammatory via an effect on matrix metalloproteinases (MMP), and their inhibitor family, 'tissue inhibitor of metalloproteinases' (TIMPs). MMPs are a family of enzymes that acutely participate in inflammatory processes and chronically mediate tissue remodelling, including LV remodelling. More specifically, Cell Therapy hypothesises that iMPs modulate certain components of these families, MMP9, MMP-2 and TIMP-1/2.

The competitive landscape in heart disease

The potential of cell-based therapies to transform the treatment of heart failure has led to a number of players entering the field. As current standards of care are particularly expensive over the duration of the illness (in terms of the cost of drugs, hospitalisations, primary care visits, nursing home care, physiotherapy, etc) significant appeal lies in the prospect of rapid clinical uptake coupled with an attractive reimbursement from healthcare payers.

Exhibit 3 summarises the pipeline of cell-based therapies that we know are in development for heart disease, divided into those delivered alongside CABG (Heartcel competitors) and PCI (Myocardion competitors). The PCI market is more crowded, with a number of clinical products in late stage development that may challenge Myocardion's market position. Should Heartcel be granted orphan drug designation, this would guarantee market exclusivity for seven and 10 years in the US and Europe respectively. However it is unclear if this would be limited to allogeneic stem cell therapies only. It is worth noting that a Heartcel dose is c 2-4m cells, which is much smaller than that of other products in development. Cell Therapy believes that, due to the tissue-specific nature of its iMP cells, and their propensity to migrate to damaged tissue, the dose required is significantly smaller. Finally, although the majority of these trials involve much larger patient numbers, unlike Heartcel they are not confined to CABG only, let alone those at risk of ICR, which is a comparatively smaller sub-population.

[9] International Society for Stem Cell Research.

Exhibit 3: Cell-based therapy competitive landscape

Company (product)	Product – cell source – type	Dose	Delivery	Lead indication	Status
Coronary artery bypass grafting (CABG)					
Allogeneic					
Assistance Publique - Hôpitaux de Paris	Human embryonic stem cell-derived CD15+ Isl-1+ progenitors	Not specified	Epicardial delivery by biocompatible fibrin gel	LV dysfunction (LVEF≤35%)	6-pt Phase I
Autologous					
St. Petersburg State Pavlov Medical University	Bone-marrow – mononuclear cells	Not specified	Intramyocardial +/- intracoronary	NYHA III-IV	100-pt Phase III
Centre hospitalier de l'Université de Montréal/ Miltenyi Biotec, Inc.	Bone marrow – CD133+ stem cells	Not specified	Intramyocardial injection	Ischaemic heart disease (LVEF≤45%)	20-pt Phase II
National Heart, Blood and Lung Institute	Bone marrow – stromal stem cells	Not specified	Intramyocardial injection	Coronary heart disease (LVEF≤50%)	60-pt Phase I
Percutaneous Coronary Intervention (PCI)					
Allogeneic					
Mesoblast/Teva (Revascor)	Bone marrow – mesenchymal precursor cells (MPC)	150m cells	Transendocardial injection	Chronic heart failure (NYHA II-III)	1,730-pt Phase III
The University of Miami Miller School of Medicine	Bone marrow – mesenchymal stem cells	20-100m cells	Transendocardial injection	Chronic LV dysfunction after MI (LVEF≤50%)	30-pt Phase II
Capricor (CAP-1002)	Heart tissue – Cardiosphere-Derived Cells	25m cells	Intracoronary infusion	Acute MI (LVEF≤45%)	274-pt Phase I/II
Coretherapix (CTX-101)	Heart tissue – Cardiac stem cells	10-35m cells	Intracoronary infusion	Acute MI(LVEF≤45%)	55-pt Phase I
Autologous					
Baxter	Bone marrow – CD34+ endothelial progenitor stem cells	1m cells/kg (~75m)	Endocardial catheter (Noga)	Chronic myocardial ischemia	444-pt Phase III
Celyad* (C-Cure)	Bone marrow – cardiac progenitor cells	600m cells	C-Cath catheter	Advanced chronic heart failure (LVEF≤35%)	240-pt Phase III
Bioheart (Myocell)	Skeletal muscle tissue – myoblasts (muscle stem cells)	400-800m cells	Intramyocardial injection catheter	Congestive heart failure (NYHA II-IV, LVEF≤35%)	170-pt Phase III
Queen Mary University of London	Bone-marrow – mononuclear cells	Not specified	Intracoronary infusion	Acute MI (LVEF≤45%)	3000-pt Phase III
Vericel* (Ixmyelocel-T)	Bone marrow – CD90+ mesenchymal cells, CD14+ monocytes	100-150m cells	Endocardial catheter (Noga)	Dilated cardiomyopathy (NYHA III-IV, LVEF≤35%)	108-pt Phase II
Cytori Therapeutics (ADRC)	Adipose tissue – stromal vascular fraction cells	400,000 cells/kg (~30m)	Intramyocardial injection catheter	Chronic myocardial ischemia (NYHA II-III, LVEF≤45%)	45-pt Phase II
NeoStem (AMR-001)	Bone marrow – CD34+/CXCR4+ cells	10m cells	Intracoronary infusion	Acute MI (NYHA I-III, LVEF≤48%)	160-pt Phase II
Cedars-Sinai Medical Center	Bone-marrow – mesenchymal stem cells	Not specified	Intracoronary infusion	Acute MI (LVEF≤50%)	30-pt Phase I

Source: Edison Investment Research, clinicaltrials.gov. Note: MI: myocardial infarction. *Formerly Cardio3. **Formerly Aastrom.

Production is complex but established and scalable

The great promise of regenerative therapy is to reverse the effects of disease and effectively cure the patient, however the costs of manufacturing cell-based therapies is currently such that any treatment is likely to be expensive relative to existing small molecule drugs and even biological agents which may limit adoption. Cell Therapy is well placed in this context as its cell therapies can be easily scaled to commercial quantities (at reasonable costs); they are administered “off the shelf” and do not have onerous supply chain requirements; and currently immunosuppressive co-treatments are not required. Even so, management has directed the development focus on therapeutic areas where the cost burden is high and current treatments are inadequate, hence providing a strong cost-benefit rationale for reimbursement. Cell Therapy will have 50,000 patient doses of Heartcel stockpiled in preparation for launch.

Cell Therapy has three established manufacturing facilities in Wales, Greece and Canada, all of which operate under good laboratory practice (GLP) conditions in ISO/CASCO accredited laboratories. The manufacturing system involves a complex, multi-step process that uses novel reagents and methods invented by Cell Therapy to optimise efficiency and reproducibility. As a result, Cell Therapy forecasts COGs around 10% while maintaining a high quality and quantity of

product output. Although the actual manufacturing process is complex, distribution to, and use by, the surgeon is simple, quick and routine.

Tendoncel: A novel platelet lysate therapy

Lateral epicondylitis (tennis elbow) is a painful, debilitating tendinopathy that has an incidence of between 1-3% of the general population.[10] Tendinopathies are thought to be due to cumulative microtrauma that exceeds capacity for repair, leading to tendon degeneration. A number of non-surgical treatments exist for lateral epicondylitis, including corticosteroid injections, acupuncture, extracorporeal shock wave therapy, orthotic devices and ultrasound. However numerous systematic reviews have found insufficient evidence to support any one treatment over another.[11] Interventions that have been shown to have short-term benefit (3 months), such as corticosteroid injections, ultrasound and acupuncture, have failed to maintain this in the long term.[13,14] Nevertheless, in the majority of cases lateral epicondylitis settles with conservative management. In 5-10% of cases (c 800,000 patients in the US and Europe) the condition persists beyond 6 months despite conservative measures, at which point surgical intervention is considered.[13]

Platelets play an essential role in enhancing tissue recovery and wound healing through the production of growth factors; these include transforming growth factor-β, platelet-derived growth factor, insulin-like growth factor, fibroblast growth factor, vascular endothelial growth factor and endothelial cell growth factor. Platelet-rich therapies (PRTs) have increasingly been investigated for their regenerative potential in conditions such as tendinopathy, whereby delivery to the injury site could 'empower' the biocellular environment to promote and accelerate the healing process.[3]

A novel platelet therapy

Tendoncel is a proprietary allogeneic topical platelet-lysate gel incorporating a unique combination of platelet growth factors. Platelet-lysate is a derivative of platelet-rich plasma (PRP), in which platelets are lysed to release the growth factors into the serum. Its therapeutic use has somewhat been restricted by notorious batch-to-batch variation.[12] Cell Therapy believes that its novel formulation overcomes this limitation, asserting that the cellulose-derived gel enables the controlled release of the growth factors, thus optimising bioavailability and dose. As a topical therapy, Tendoncel is easy to use, does not require specialist application and is significantly less invasive than other platelet-rich therapies (PRTs) currently in use (many of which require injection).

A recent Cochrane review found that there is currently insufficient evidence to support the use of PRTs for the treatment of musculoskeletal soft tissue injuries, including tendinopathies.[3] Another systematic review looking at PRP in lateral epicondylitis specifically, found that there is limited but evolving evidence for its use, with one trial showing significant benefit versus corticosteroids with regard to pain and functional scores at 1- and 2-year time points.[13] However, the PRTs included in the reviews were autologous and were also administered by injection or as an adjuvant to surgical intervention, and thus are not directly comparable to Tendoncel.

[10] Taylor SA, *et al.* Evaluation and management of elbow tendinopathy. *Sports Health.* **4**(5):384-393 (2012).

[11] Bisset *et al*. A systematic review and meta-analysis of clinical trials on physical interventions for lateral epicondylagia. *Br J Sports Med* **39**:411-422 (2005).

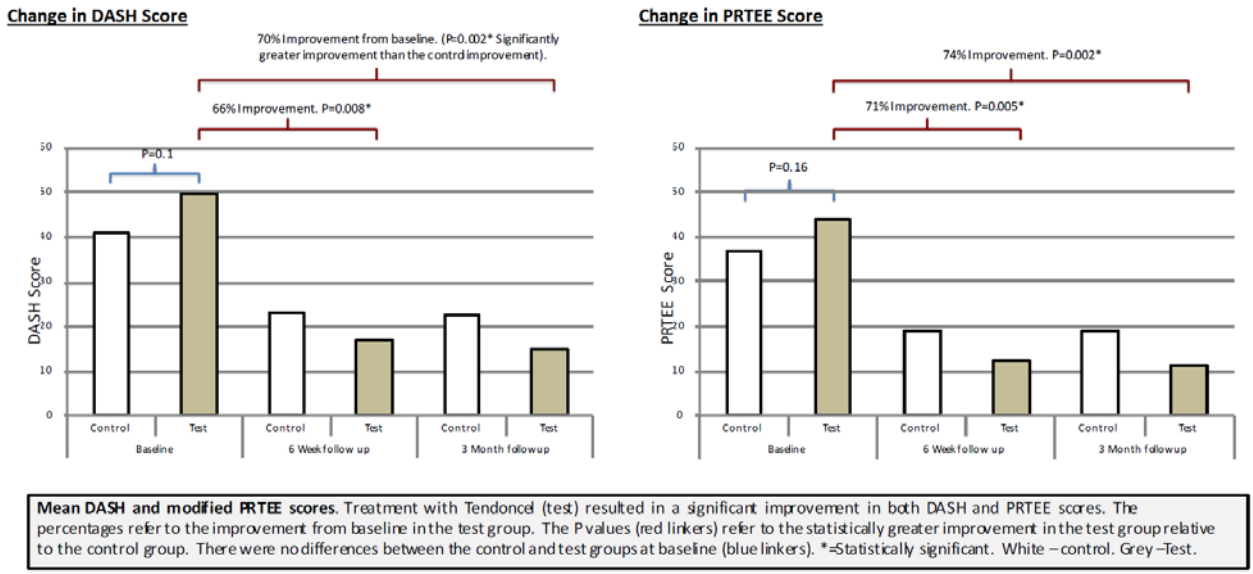
[12] Radtke S *et al*. Platelet lysates and their role in cell therapy. *ISBT Science Series*. **9**(1):193-197 (2014).

[13] Ahmed Z, *et al.* The effect of platelet-rich plasma on clinical outcomes in lateral epicondylitis. Arthroscopy. **29**(11):185-1862 (2013).

Phase II study completed

Tendoncel has completed a double-blind, placebo controlled Phase II trial in the treatment of severe lateral epicondylitis. In the trial, 34 'elbows' (31 patients) were randomised to receive once daily topical applications (under an adhesive dressing) of either Tendoncel (n=18) or placebo gel (n=16) for 21 days. Efficacy was assessed using two functional questionnaires, DASH and PRTEE.[14] These were measured at baseline and repeated by telephone at 4-, 6- and 12-weeks, at which time the patient also reported any adverse effects such as cutaneous reactions. Blood samples were taken on day 1 and day 21 to measure IgE levels (a measure of systemic immune response). Treatment with Tendoncel led to significant improvements in DASH and PTREE scores compared to controls and compared to baseline (Exhibit 4). Tendoncel was found to be safe, with no changes in IgE levels.

Exhibit 4: Tendoncel Phase II results



Mean DASH and modified PRTEE scores. Treatment with Tendoncel (test) resulted in a significant improvement in both DASH and PRTEE scores. The percentages refer to the improvement from baseline in the test group. The P values (red linkers) refer to the statistically greater improvement in the test group relative to the control group. There were no differences between the control and test groups at baseline (blue linkers). *=Statistically significant. White – control. Grey –Test.

Source: Cell Therapy, Edison Investment Research. Note: *Statistically significant.

Seeking a partner

Cell Therapy now intends to find a partner for the further development of Tendoncel. The partner would then be responsible for conducting, and funding, further trials, including the required US studies for FDA approval. We anticipate that initial development will focus on the use of Tendoncel in the severe lateral epicondylitis population, as a means to delay or allay the requirement for surgery. However it seems likely, given its ease of use and promising data to date, that its use could be expanded beyond this patient population, to include a much larger share of the lateral epicondylitis market. The partner may decide to investigate this either through additional Phase III studies, or through a Phase IV study. In addition, studies are under way in other chronic tendinopathies that are amenable to topical treatment, specifically in Achilles and shoulder.

We assume that Cell Therapy will successfully partner Tendoncel, with Phase III trials in Europe and the US commencing in 2016. We anticipate launch in Europe in 2018, and in the US in 2019.

[14] DASH: Disabilities of the Arm, Shoulder and Hand questionnaire. PTREE: Patient-rated Tennis Elbow Evaluation questionnaire.

Sensitivities

Cell Therapy is subject to the risks typically associated with drug development and commercialisation. These include the possibility of clinical development delays, unfavourable outcomes in clinical trials and regulatory reviews, success of competitors, commercial decisions by potential partners and slow adoption upon approval.

Specifically, it will be the upcoming regulatory decisions regarding Heartcel, namely Orphan in Europe and Breakthrough and Orphan Drug designations, which will have an impact on the development timeline and eventual market exclusivity. For development and launch in Japan, Cell Therapy will need to secure a partner for both the cardiac and tendinopathy programmes.

Furthermore, the outcomes of the Heartcel, Myocardion and Tendoncel clinical trials are particularly important to determining the next development steps and eventual commercial potential. Positive clinical data would offer the opportunity of fresh (non-dilutive) finance from the possible formation of partnerships for US commercialisation of Heartcel, European and US commercialisation of Myocardion and out-licensing of all products for the Japanese markets. Negative or inconclusive data would raise doubts about the viability in these specific indications, and could have a negative read-across to other programmes in other potential indications.

Should Heartcel and Myocardion be approved and commercial expectations met, then Cell Therapy's ability to penetrate the Heartcel market independently in Europe, and manage the subsequent growth requirements will be additional sensitivities. Our valuation assumes Cell Therapy will find a partner for co-commercialisation of Myocardion and for the co-commercialisation of Heartcel in the US. Our valuation also assumes that a partner is found for Tendoncel who will fund future trials and its commercialisation. Finally, our valuation assumes that Cell Therapy out-licenses Heartcel, Myocardion and Tendoncel for future development and commercialisation in Japan. Our partnering assumptions include fairly typical royalty estimates for the stage of development at licensing; any material difference in the eventual deal arrangements would have an impact on our valuation.

Future pricing and market dynamics are hard to predict in this emerging field, thus assessing the opportunity for Cell Therapy's products is not straightforward. We have made assumptions on market launch, cost of treatment and commercial uptake, which are likely to be subject to change on the basis of clinical trial outcomes and available finance. Although Cell Therapy appears to be well-positioned in the stem cell field, we note that this sector remains highly competitive, and some companies (eg Mesoblast/Teva) currently have significantly greater financial resources to advance their technologies, which may be to the detriment of Cell Therapy, in particular for Myocardion.

Valuation

Cell Therapy is a classic drug discovery and development play that is best valued using a discounted cash flow method, with the rNPV of the individual clinical programmes (adjusted for the likely success probabilities) summed and netted against the costs of running the operation. Cell Therapy is operating in a frontier area of medical science with high clinical and commercial potential but also considerable risk. As a result, we have erred on the side of caution in our assumptions.

The success probabilities of each project are based on standard industry criteria for each stage of the clinical development process, but are flexed to reflect the inherent risks of the individual programme, the indication targeted and the trial design. We use a 12.5% discount rate, which is our standard rate for such early-stage companies.

Our valuation model and key assumptions are summarised in Exhibit 5. Our valuation does not include the other programmes or the inherent value of the technology platforms, leaving upside potential for when these programmes progress and the securing of partners/funding.

Maintaining this approach, we have assumed that approval is granted for Heartcel in Europe in H217, although we forecast limited uptake until 2020; in the US we forecast Heartcel market launch in 2019. In Japan we assume provisional approval is granted, but allow more time for the partnership deal to be finalised, and for the Phase II bridging study to be finalised and completed; hence we forecast launch in 2018, with full approval in 2020. We forecast launch of Myocardion in 2023 and a European and Japanese launch of Tendoncel in 2019; in the US, 2020. While we acknowledge that the timelines could be accelerated, we view such progress as upside.

Exhibit 5: rNPV valuation of the clinical pipeline

Product	Setting	Status	Launch	Peak sales ($m)	NPV (£m)	Probability of success	rNPV (£m)	Key assumptions
Heartcel	NYHA II-IV CABG at risk of ICR	Ph II	2017 (EU) 2019 (US) 2018 (Japan)	1,239	910	33%	313	Price/treatment $75k in US, $100k in Japan and $45k in Europe. Market alone in Europe (effective contribution 65%); co-commercialise in US (effective contribution 40%). Partner in Japan, with 20% royalty on sales. Upfront payment of £12.5m received from Daiichi not discounted or risk adjusted.
Myocardion	NYHA II-III PCI at risk of ICR	Pre-IND	2023 (EU, US and Japan)	1,899	393	8%	32	Price/treatment $20k in US and Japan, $15k in Europe. Co-commercialise in Europe and the US (effective contribution 40%). Partner in Japan, with 15% royalty on sales.
Tendoncel	Severe lateral epicondylitis	Ph II	2018 (EU+ Japan) 2019 (US)	258	53	30%	21	Price/treatment $3k in US and Japan, $2.5k in Europe. Partner in H215, with 20% royalty on sales.
Portfolio total (excluding £20m NPV of centrally allocated R&D and marketing costs)							366	

Source: Edison Investment Research

Given the relatively early stage of development of Cell Therapy's technology, and the higher-than-average risk involved in the lead indications, we have been similarly cautious in the success probabilities used (30% for Heartcel and Tendoncel, 8% for Myocardion). This is also seen in our rate of clinical adoption and peak sales estimates.

Peaks sales of c $1,239m in 2026 for Heartcel are based on a pricing per treatment estimate of $75,000 in the US, $100,000 Japan, and $45,000 in Europe. This is in line with current estimates for other cell therapies in development. It is driven by the assumption that a one-off treatment with Heartcel could potentially provide a significant decrease in mortality and improvement in the quality of life of patients who are disabled or compromised with heart failure, one of the key criteria behind reimbursement decisions, as well as the potential savings to healthcare services from reduced rate of hospitalisations. However, based on continuing patient survival at 20-29 months in the Heartcel study, Cell Therapy believes that a cost per treatment of $140,000 in the US and Japan and $80,000 in Europe could be achievable. We have not included this in our estimates ahead of the data read out from pivotal Phase III trials. We forecast penetration of 66% in the US and Japan, 50% in Europe.

For Myocardion we have forecast peak sales of c $1,899m in 2030, with pricing per treatment of $20,000 in the US and Japan, and $15,000 in Europe, as we believe Cell Therapy will price competitively with other cell therapy players close to the market. If the clinical trial data suggest superiority, Cell Therapy could justify a higher price. We assume low penetration, given the more advanced stage of competitors: 8% in the US and Japan, 5% in Europe.

For Tendoncel our valuation includes sales for its use in those patients with severe lateral epicondylitis who have not responded to conservative measures and require surgery. We have forecast peak sales of c $258m in 2025, based on the company's expected per treatment

prescription price of $3000 in the US and Japan, and $2500 in Europe. We have assumed conservative penetration of 10%, given the under-performance of surgery-sparing treatments in the past (for example, Jetrea (ThromboGenics) for vitreomacular adhesion). Cell Therapy believes that penetration could reach 30%, and on that basis the peak sales would be $774m, representing significant upside. A potential expansion of the addressable market to include moderate lateral epicondylitis would also increase sales potential; however, we would anticipate that the price per treatment would have to reduce accordingly to compete with existing treatments. We have not included potential sales in other tendinopathies, which we also view as upside.

Our valuation assumes that Cell Therapy will market Heartcel directly in Europe, and co-commercialise in the US. We also assume co-commercialisation of Myocardion to address the larger interventional cardiologist audience. Assuming the manufacturing costs remain as projected (c 10%), this drives an effective product contribution of 65% for Heartcel in Europe and 40% for Heartcel in the US and for Myocardion. For the cardiac programmes in Japan, we assume that a partner is found in H116 that will cover all development and marketing costs. For Heartcel we include a 20% royalty on sales, and for Myocardion 15%. We do not include deal metrics such as upfront payments and potential milestones until they have been announced, all of which represent upside to our valuation.

Our valuation assumes that Cell Therapy partners Tendoncel in 2016, and that the partner will cover all development and marketing costs. We include a 20% royalty on global sales, commensurate with an asset out-licensed once proof-of-concept data are available. As with the cardiac programmes in Japan, we do not include potential upfront payment, development and sales-related milestones, providing a base-case valuation, with room for upside.

Plugging these factors into our model suggests a valuation of £346m, despite adopting relatively conservative assumptions and ignoring potential deal metrics, the value of other programmes, the technology platform and production facilities. Clearly, as progress is achieved and visibility improves, we would expect to revisit the model and anticipate the valuation would reflect this. The main value inflection points should be clarity on EU and US clinical and regulatory pathways, as well as further clinical data on Heartcel, Myocardion, Tendoncel and other programmes.

Financials

As Cell Therapy is a private company, we do not make financial forecasts. Cell Therapy reports current cash of £17.0m (vs £1.2m at end FY15) including the £12.5m upfront payment from DS and a successful fund-raising from existing shareholders and high net worth individuals. We estimate a substantial R&D requirement to complete the planned clinical trials; additional funds will be required to develop a salesforce to market Heartcel (albeit small) and for the co-commercialisation of Myocardion (potentially larger).

Exhibit 6: Financial summary*

£'000s	2013**	2014	2015
Year end 31 July			
PROFIT & LOSS			
Revenue	0	0	0
Cost of Sales	0	0	0
Gross Profit	0	0	0
R&D	(163)	(463)	(483)
G&A	(308)	(317)	(1,096)
EBITDA	(469)	(776)	(1,570)
Operating Profit (before GW and except.)	(471)	(780)	(1,579)
Intangible Amortisation	0	0	0
Exceptionals	0	0	0
Other	158	1,163	0
Operating Profit	(313)	383	(1,579)
Net Interest	0	0	0
Profit Before Tax (norm)	(471)	(780)	(1,579)
Profit Before Tax (FRS 3)	(313)	383	(1,579)
Tax	(116)	0	0
Profit After Tax (norm)	(587)	(780)	(1,579)
Profit After Tax (FRS 3)	(429)	383	(1,579)
Average Number of Shares Outstanding (m)	0.0	0.0	0.0
EPS - normalised (€)	N/A	N/A	N/A
EPS - FRS 3 (€)	N/A	N/A	N/A
Dividend per share (€)	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A
BALANCE SHEET			
Fixed Assets	70	121	216
Intangible Assets	62	99	198
Tangible Assets	8	22	18
Investments	0	0	0
Current Assets	922	203	1,267
Stocks	0	0	0
Debtors	143	150	44
Cash	779	53	1,224
Other	0	0	0
Current Liabilities	(1,183)	(238)	(860)
Creditors	(1,183)	(238)	(860)
Short term borrowings	0	0	0
Other	0	0	0
Long Term Liabilities	(112)	(6)	0
Long term borrowings	0	0	0
Other long term liabilities	(112)	(6)	0
Net Assets	(302)	80	624
CASH FLOW			
Operating Cash Flow	599	(672)	(826)
Net Interest	0	0	0
Tax	0	0	0
Capex	(24)	(54)	(126)
Acquisitions/disposals	0	0	0
Financing	35	0	2,122
Dividends	0	0	0
Net Cash Flow	610	(726)	1,171
Opening net debt/(cash)	(169)	(779)	(53)
HP finance leases initiated	0	0	0
Other	0	0	0
Closing net debt/(cash)	(779)	(53)	(1,224)

Source: Company accounts, Edison Investment Research. Note: *As Cell Therapy is a private company, we do not make financial forecasts. **FY13 is unaudited.

Contact details	Revenue by geography
Cell Therapy Cardiff Gate Business Park Malthouse Avenue Pontprennau Cardiff, CF23 8RU Wales, UK www. celltherapyltd.com/index.html	N/A

Management team	
President and Chief Scientific Officer: Professor Sir Martin Evans	CEO: Ajan Reginald
Co-founded Cell Therapy in 2009. A long history in stem cell research, with numerous awards including Nobel Laureate in Medicine (2007), Copley Medal, Royal Society (2009), Knighthood for Medical service (2004), Albert Lasker Award (2001), Fellow of the Royal Society (1993). President (2009) and Chancellor (2012), University of Cardiff.	Co-founded Cell Therapy in 2009. Previously global head of emerging technologies and business development director, Roche Pharmaceuticals; director of corporate relations, University of Warwick; consultant, Boston Consulting Group; and Fulbright Scholar, University of London. Qualified as a dentist from London Hospital School of Medicine and Dentistry in 1996. MBA from Kellogg Business School, Northwestern University.
Chief Financial Officer: Mark Hughes	Chairman: Lord Digby Jones of Birmingham
Joined Cell Therapy as CFO in January 2015. Previously held role of CFO for Mediwatch (2012-14), INNOVO Networks (2011-13), David Brown Hydraulic Systems (2009-11) and Advanced Transport Systems (2007-09). In the course of his career as raised c £79m in financings. MBA from the Warwick Business School (University of Warwick) and a qualified Chartered Accountant.	Former UK Minister for Trade & Investment (2007-08) and Director General of the Confederation of British Industry (2000-06). He also serves as the Chairman of Triumph Motorcycles and acts as an Advisor to BP, JCB and Jaguar Land Rover. Read law at UCL after which he spent 20 years with Edge & Ellison, a Birmingham-based law firm.

Principal shareholders	(%)

Companies named in this report
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