EDISON

Carmat

Progress in clinical trials

Green light to conclude feasibility study

Healthcare equipment & services

Carmat has obtained regulatory authorisation to conclude the feasibility study of its artificial heart and to adopt a new clinical protocol enabling patients with less severe heart failure to participate. This should pave the way for a CE mark study in 2016 and could lead to a launch in CE mark regions in H217. Our valuation is raised from €591m to €611m (€129/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/13	2.9	(16.2)	(336.5)	0.0	N/A	N/A
12/14	0.0	(19.8)	(403.4)	0.0	N/A	N/A
12/15e	0.2	(19.8)	(368.3)	0.0	N/A	N/A
12/16e	1.7	(19.0)	(332.1)	0.0	N/A	N/A

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

Regulators approve final step in feasibility study

The French health regulator (ANSM) and person protection committee (CPP) have given Carmat the go-ahead to finalise the four-person feasibility study of its novel artificial heart. This follows a review of Carmat's proposed solutions to address the malfunctioning of the device in an earlier patient, caused by a minute leak of blood into the activating liquid of the prosthesis. Carmat aims to start a pivotal study in early 2016, which may pave the way for a CE mark grant and launch in 2017.

Encouraging interim data published in The Lancet

In July, The Lancet published an update on the outcome of the first two patients. The device was seen to restore blood flow and there were no adverse events caused by hemocompatibility or biocompatibility. As of the third patient, the device is powered by a new portable fuel source, making it more suitable as a destination therapy. We expect this to make physicians more likely to refer patients to take part.

Funding in place for CE mark studies

In H115 operating expenses fell to €9.2m vs €10.7m in H114. We have reduced our FY15 estimated operating expenses from €24.5m to €19.3m in line with the run rate. The end-June net cash position stood at €8.2m. In H115 Carmat drew down €8.2m on its equity line, issuing a total of 133,100 new shares at €61.6, and has the option to draw down €11m net in H215. A further €30m is available over FY16/17, which we forecast is sufficient to cover CE mark studies of the heart.

Valuation: DCF valuation of €611m

We have increased our DCF valuation from €591m to €611m, or €129 per share, adjusting our forecasts for reduced operating costs and shifting the timeline for CE mark launch from H117 into H217. Our default assumption is that Carmat will launch the heart in the US as a humanitarian use device (HUD) in 2019, subject to an indicative €35m additional funding needed to launch in CE mark regions and to achieve HUD designation. If Carmat opts to develop the heart via the PMA approval route in the US, this could lead to our valuation increasing to €1,010m.

30 November 2015

Price	**€53.00**
Market cap	**€239m**
Net cash (€m) at end June 2015	8.2
Shares in issue	4.5m
Free float	34%
Code	ALCAR
Primary exchange	Alternext
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(3.6)	(9.5)	(24.8)
Rel (local)	(5.6)	(14.3)	(33.5)
52-week high/low		€78.99	€48.01

Business description

Carmat is developing a biocompatible, artificial heart to satisfy the lack of donor hearts available for terminal heart failure patients. The development process combines the expertise of a wide range of technical and medical experts. Carmat initiated its first clinical study in man in 2013.

Estimated next events

Completion of feasibility study	Q116
Transition into the pivotal stage	H116

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Edison profile page

Clinical progress for Carmat's bioprosthetic heart

Carmat's bioprosthetic heart is being developed as a permanent replacement, initially for up to 50,000 late-stage heart failure patients on donor heart waiting lists outside the US, representing a potential market of €1.2bn, on our estimates. A US market entry longer term would offer a €560m market potential on a restrictive humanitarian use basis (4,000 patients per year). Should Carmat pursue and be successful with a more costly and time-consuming US regulatory pathway through a pre-market approval, the device may address a US patient population of around 50,000 per year.

Final stage of the feasibility study approved

The clinical feasibility study is nearing its conclusion, with three out of four patients required in the study implanted with the device. The success outcome, survival at 30 days, has been reached in all three patients. The recruitment of the final fourth patient was put on hold in May 2015 following the malfunctioning of the device implanted in the second patient on 5 August 2014. Having been satisfied with the corrective action proposed by Carmat, the French regulators have now authorised the continuation of the study and the enrolment of the final fourth patient.

Carmat identified the source of the malfunctioning in May and presented its solution to the French national agency for the safety of medicines and health products (ANSM) and the person protection committee (CPP). Carmat established that the malfunctioning was caused by a disruption in the motor-steering electronics due to a micro leak (tens of microns). This allowed crystalline deposits from the blood compartment into the activating liquid of the prosthesis. Carmat's evaluation showed a dispersal of tolerance on manufactured components. Corrective measures, including a software tool predicting malfunctions and thus ensuring better patient monitoring and care, have been tested, validated and implemented. The company's analyses have confirmed that this was not a design flaw, but rather issues stemming from the early stage of production not uncommon for a complex medical device.

Exhibit 1: Summary of feasibility study outcomes for the Carmat bioprosthetic heart

Patient	Centre	Date of implantation	Key outcome
1	Hôpital Européen Georges-Pompidou	18 December 2013	Patient survived 75 days. An electrical component fault caused the bioprosthesis to malfunction. Approval to resume study from the French National Agency for Medicines and Health Products Safety (ANSM).
2	Nantes University Hospital	5 August 2014	Patient survived nine months, of which four months was at home. Malfunction caused by fault with steering motors. Patient re-implanted but died following multiple organ failure.
3	Hôpital Européen Georges-Pompidou	8 April 2015	Patient discharged and recuperating at home supported by the portable system.

Source: Edison Investment Research, Carmat

Based on the interim results of the first implants, the regulators have also approved a more relaxed clinical trial protocol including patients with less severe conditions. Until now, the protocol only permitted patients suffering from end-stage irreversible biventricular heart failure and those in an immediate life-threatening situation to be included in the study. The criteria associated with the stage of heart failure have now been eased to allow a greater number of patients to benefit from the device. In addition, under certain conditions, patients who are eligible for a heart transplant can now also be included in the study.

The go-ahead with the enrolment of the final fourth patient and associated monitoring for 30 days may allow Carmat to conclude the feasibility study by early 2016, in our view. Subject to final planning and specifications, Carmat envisages that the subsequent pivotal study could be initiated in 2016, necessary to secure the grant of a CE mark, which may enable a European launch of the

prosthesis in late 2017, as reflected in our forecasts and valuation. In effect, this would imply an estimated delay of six months from the company's original timeline.

Over the course of the past year, Carmat's medical team has continued to provide training to heart surgery centres in France and abroad through eight surgical training sessions (acute animal trials) for various teams and 96 on-site sessions in implantation centres.

Pivotal trial preparation underway

While finalising the report on the feasibility study, Carmat intends to prepare the protocol of the pivotal study aiming to secure CE marking. This will be submitted to the ANSM, which will review and give its opinion regarding the launch of the pivotal study. The protocol of the pivotal study will also incorporate the requisite economic elements for the submission of the reimbursement dossier within the framework of the SEED (Shaping European Early Dialogues for health technologies) project.

Carmat envisages that the pivotal study will recruit around 20 patients who would be monitored for up to 180 days. Following the recent relaxation of the enrolment inclusion criteria, patients in the pivotal trial will likely have a better prognosis than those in the feasibility study. The structure of the study would depend on the results of the full analysis of the feasibility study data. Carmat envisages that it might recruit patients into the pivotal study in parallel rather than sequentially, according to the number of centres participating. For example, it is likely that the trial will be extended to centres outside France. However, these details remain to be concluded. The portable energy source developed during 2014 is now fully approved for use in the ongoing clinical study, fulfilling a key requirement of a potential destination therapy, or permanent replacement, as opposed to a temporary bridge to transplant. If the heart is approved as a destination therapy, this could lead to it attaining a greater market share than if it is approved as a bridge to transplant. The availability of a portable fuel source could help to accelerate recruitment into the pivotal study as physicians are more likely to recommend patients for the study.

Lancet article suggests good performance of Carmat's heart

In July, Carmat provided an interim report from the feasibility study, derived from clinical data. So far, the success outcome, survival at 30 days, has been satisfied. The data taken from the first two prostheses implanted show that the principles of biocompatibility of the device with a milder regimen for anticoagulation have been substantiated by the existing evidence. Anticoagulant use is associated with severe side effects including haemorrhage and is indicated after for example, implantation with the SynCardia Total Artificial Heart. Furthermore, the interim data published in an article entitled *First clinical use of a bio-prosthetic total artificial heart: report of two cases*, in The Lancet, show freedom from haemolysis and thromboembolic events, which are also major complications associated with implanting mechanical circulatory support devices. In the first patient a thromboresistant layer developed on the surface of the bioprosthesis, which could help reduce the risk of blood clotting on those surfaces of the bioprosthesis in contact with blood.

Valuation

Our DCF valuation is €611m (previously €591m) equivalent to €129 per share, using a WACC of 12.5% and a long-term growth rate of 2%. Our base case assumption is on an undiluted basis, before any potential equity funding needed to launch the product, and assumes that the device would be launched in late 2017 in CE mark regions and that Carmat will launch the device in the US via the HUD route in 2019. This means the device would be restricted to an orphan population of just 4,000 of the most critically ill patients. Alternatively, Carmat may opt to develop the bioprosthesis through the longer and more costly PMA route, in which case we would increase our

valuation to €1,010m. If Carmat opts for the PMA route, there would be additional R&D costs of c €35m, a higher risk adjustment of 15% and a later launch date of 2021 due to the longer trial. The addressable market would be larger, although we assume lower penetration of 20% than for HUD approval.

Changes to our valuation published in our note of 4 February 2015 include the adjustments to estimated operating costs in FY15 and rolling forwards our model in time. We have reduced our estimated rate of penetration in CE mark regions in launch year 2017 owing to the six-month delay in the study. Our base case valuation assumptions are illustrated in Exhibit 2. We have not broken down the valuation per region at this stage as our forecasts use a blended margin, although peak sales value in the EU is around twice the value of the US.

Exhibit 2: DCF assumptions, €m

Market	Launch date	Penetration (%)	Peak sales	Probability (%)	Valuation (€)
CE mark territories	2017	15	1,200	35	-
US via HUD	2019	70	560	25	-
Pro forma net cash end (FY15)					10.7
Total valuation					611
Value per share					129

Source: Edison Investment Research

Potential near-term catalysts include recruiting the fourth patient into the feasibility study, transition into the pivotal stage, in which case we would increase the probability of success from 35% to 60%, (in line with our standard risk adjustment metrics for developing medical devices,) and clarifying the US strategy.

Financials

In H115 Carmat earned operating income of €0.3m and reported a fall in operating expenses from €10.7m in H114 to €9.2m, notably due to lower expenditure compared to the previous year on R&D to develop the portable fuel source. We have reduced our FY15 estimated operating costs from €24.5m to €19.3m in line with the half-year run rate. We forecast FY16 operating costs of €20.6m including an R&D cost of €10.6m to cover the pivotal study.

Carmat received an H115 R&D tax credit of €1.4m and the end-June 2015 cash position stood at €10.1m following an €8.3m net equity raise, issuing 133,100 new shares at €63.9, associated with the company's contingent equity line with Kepler Cheuvreux. We estimate that Carmat has sufficient funds to take it up to CE mark approval, based on the remaining €41.6m gross that can be drawn down from the contingent equity line, including a further €11m net available until end-January 2016. Two further tranches of €15m are available in FY16 and in FY17, respectively. We forecast that Carmat will draw down the €11m balance of the €20m contingent equity tranche in H215. We assume that Carmat issues these shares at the latest close price less 6%, in line with the terms of the contingent funding agreement. Our forecasts indicate that Carmat is currently funded until late 2017 and that it would need to raise an additional €35m to launch the device in CE mark regions and to develop the heart via the HUD route.

Exhibit 3: Financial summary

€'000s	2013	2014	2015e	2016e
Year end 31 December	French GAAP	French GAAP	French GAAP	French GAAP
PROFIT & LOSS				
Revenue	2,874	49	162	1,741
Cost of Sales	0	0	0	0
Gross Profit	2,874	49	162	1,741
EBITDA	(15,156)	(18,796)	(18,718)	(18,554)
Operating Profit (before GW and except.)	(15,885)	(19,275)	(19,053)	(18,793)
Intangible Amortisation	(191)	(554)	(440)	(389)
Exceptionals	0	0	0	0
Other	(40)	(40)	(15)	0
Operating Profit	(16,116)	(19,869)	(19,508)	(19,183)
Net Interest	(324)	(476)	(704)	(226)
Profit Before Tax (norm)	(16,209)	(19,752)	(19,757)	(19,020)
Profit Before Tax (FRS 3)	(16,440)	(20,345)	(20,212)	(19,409)
Tax	1,770	2,209	3,000	2,855
Profit After Tax (norm)	(14,413)	(17,670)	(16,768)	(16,164)
Profit After Tax (FRS 3)	(14,670)	(18,136)	(17,212)	(16,554)
Average Number of Shares Outstanding (m)	4.3	4.4	4.6	4.9
EPS - normalised (c)	(336.5)	(403.4)	(368.3)	(332.1)
EPS - FRS 3 (c)	(342.5)	(414.0)	(378.1)	(340.1)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0
EBITDA Margin (%)	(527)	(38,093)	(11,553)	(1,066)
Operating Margin (before GW and except.) (%)	(553)	(39,065)	(11,759)	(1,079)
BALANCE SHEET				
Fixed Assets	1,633	1,377	964	374
Intangible Assets	125	254	31	(320)
Tangible Assets	945	668	478	239
Investments	563	455	455	455
Current Assets	20,351	12,665	16,168	15,530
Stocks	48	0	31	31
Debtors	2,952	3,102	3,102	572
Cash	16,884	9,219	12,836	14,771
Other	467	345	200	156
Current Liabilities	(7,098)	(6,099)	(6,926)	(7,252)
Creditors	(6,254)	(4,750)	(4,750)	(4,750)
Short term borrowings	(822)	(1,349)	(2,173)	(2,499)
Other	(22)	0	(3)	(3)
Long Term Liabilities	(7,654)	(12,945)	(12,945)	(12,945)
Long term borrowings	0	0	0	0
Other long term liabilities	(7,654)	(12,945)	(12,945)	(12,945)
Net Assets	7,232	(5,002)	(2,740)	(4,294)
CASH FLOW				
Operating Cash Flow	(9,792)	(18,875)	(17,005)	(15,925)
Net Interest	0	(476)	(704)	(226)
Tax	153	129	1,458	2,899
Capex	(266)	(331)	(186)	(38)
Acquisitions/disposals	0	0	0	0
Financing	11,881	6,160	19,350	15,000
Dividends	0	0	0	0
Net Cash Flow	1,977	(13,393)	2,913	1,709
Opening net debt/(cash)	(10,675)	(16,062)	(7,870)	(10,663)
HP finance leases initiated	0	0	0	0
Other	3,410	5,201	(121)	(100)
Closing net debt/(cash)	(16,062)	(7,870)	(10,663)	(12,271)

Source: Edison Investment Research, company accounts. Note: *Contingent equity funding, we assume shares will be issued at a 6% discount to the closing share price of €55.1.

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