EDISON

Carmat

Funded for studies

Setting the stage for pivotal heart study

Healthcare equipment & services

Carmat shareholders approved the terms of a €50m equity financing earlier this month. While the shares outstanding increased by 29.5%, we estimate funds on hand are sufficient to fund operations into H118, and likely through the completion of a pivotal study for the Carmat bioprosthetic heart. With the recent completion of the feasibility study, Carmat plans to start a CE mark enabling pivotal trial in H216, which could lead to commercialisation by H218. Our rNPV approach generates a valuation of €651m (up from €611m), or €116.92 per share after including an estimated mid-2016 net cash position of €41.3m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	0.0	(20.3)	(4.14)	0.0	N/A	N/A
12/15	0.0	(20.6)	(3.81)	0.0	N/A	N/A
12/16e	0.0	(21.9)	(3.35)	0.0	N/A	N/A
12/17e	0.0	(21.8)	(3.68)	0.0	N/A	N/A

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

75% in feasibility study survive beyond 30 days

Carmat completed the four-patient feasibility study in January 2016, after the death of the fourth patient to complications unrelated to the performance of the bioprosthetic heart itself. The other three patients (75%) met the company's targeted success of a survival duration of at least 30 days post-implantation. This rate is comparable to statistics cited by the Agence de Biomédecine, which reported in 2013 that the 30-day survival rate in human heart transplants is approximately 80% for patients above age 60.

Carmat plans to start pivotal study in H216

Carmat plans to finalise the protocol and obtain the necessary approvals in H116 from French authorities to start a pivotal study that could lead to CE mark clearance. Carmat anticipates that recruitment could begin in H216, with study completion by 2018. The firm anticipates it will recruit between 20 and 25 patients across France and several other European countries. Recruiting patients in parallel across multiple sites may be necessary to meet Carmat's study timelines, given the feasibility study took two years to recruit four patients.

Valuation: rNPV of €651m

We increased our rNPV valuation from €611m to €651m, or €116.92 per share after including the recent €50m equity financing, and assuming a €41.3m net cash position in mid-2016. We have adjusted our forecasts by raising our market size assumptions and taking a slightly more conservative stance on the product's likelihood of success. Our default assumption is for CE mark clearance and EU launch in H218 (from 2017, previously) and a US market entry under a humanitarian use device (HUD) approach in 2020. We expect current cash on hand to fund operations into H118, and that the firm will raise €40m in both 2018 and 2019 to prepare for launch activities; we expect Carmat to breakeven in 2020.

5 May 2016

Price	**€37.16**
Market cap	**€219m**
Net cash at YE15 (€m) (excludes €50m financing occurring in H116)	0.8
Shares in issue	5.9m
Free float	43%
Code	ALCAR
Primary exchange	Alternext
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	6.1	1.3	(47.8)
Rel (local)	6.3	(1.3)	(39.2)
52-week high/low		€73.18	€29.78

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. The company completed a feasibility study in early 2016.

Next events

Start pivotal study	H216
H116 results	August 2016

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Edison profile page

€50m financing to fund pivotal EU study

On 12 April 2016, Carmat shareholders approved the terms for a €50m financing secured in late February. Following the ratification, 1.35m shares were issued at €37.06 per share (increasing Carmat's total shares outstanding by 29.5%). Carmat finished 2015 with €3.0m in gross cash (€0.8m in net cash, after factoring €2.2m in debt), and the financing is expected to fund Carmat's planned pivotal EU study for gaining CE mark clearance to market its bioprosthetic heart in Europe.

Airbus and Truffle maintain approximately half of voting control

New investors included Air Liquide's venture capital arm (investing €1m) and CorNovum, an investment holding company held by the French government and its public pension fund, which invested €17m. Existing Carmat investors, Airbus Group (Matra Défense) and Truffle Capital, took positions of €11m and €7m, respectively, and the family offices of Pierre Bastid and Dr. Antonino Ligresti both invested €7m. All investors pledged not to sell their shares for at least two years (or until the Carmat bioprosthetic heart receives CE Mark clearance). Carmat also pledged not to raise any additional equity capital for at least 180 days post-settlement. We estimate that after this financing, Airbus Group and Truffle Capital will hold approximately 22.5% and 18.2% of Carmat's outstanding stock. Given a clause in firm's governance structure that doubles the voting rights of shares held and registered for at least two years, their voting rights are estimated at approximately 27% and 23%, respectively.

Feasibility study completed with 75% surviving beyond 30 days

Carmat completed the four-patient feasibility study in January 2016, after the death of the fourth patient to complications unrelated to the performance of the bioprosthetic heart itself. There was a minor delay in recruitment after the second patient's death, as despite a survival of nine months post-implantation the device malfunctioned due to a disruption in micro-steering electronics following a micro-leak. Carmat identified the cause of the malfunctioning and then worked on corrective measures, including a software tool predicting malfunctions, and received authorisation from French regulators to resume the study. Carmat's analyses confirmed that the malfunctioning was not due to an inherent flaw in product design, but rather issues stemming from the early stage of production not unusual for a complex medical device.

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

Patient	Centre	Date of implantation	Primary outcomes
1	Hôpital Européen Georges-Pompidou	18 December 2013	Patient survived until March 2014 (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 were at home. Malfunction caused by fault with steering motors led to circulatory insufficiency and hospitalisation on 1 May 2014. Patient re-implanted the next day but died later that same day due to multiple organ failure.
3	Hôpital Européen Georges-Pompidou	8 April 2015	Patient discharged in September 2015, but was hospitalised in November 2015 and died due to respiratory failure following a chronic renal failure.
4	Hôpital Universitaire de La Pitié Salpêtrière	22 December 2015	Patient died on 11 January 2016, but the severity of their underlying condition (patient had biventricular heart failure and required continuous life support) was deemed responsible for their death. Carmat heart believed to have functioned optimally during implantation.

Source: Company reports

Overall, while the sample size was low, the first three patients (75%) met the company's targeted success of a survival duration of at least 30 days post-implantation. The Agence de Biomédecine, a French organisation overseeing transplant procedures and organ donations, reported in 2013 that the 30-day survival rate in heart transplants (the 'gold standard' comparator for an artificial heart) is approximately 80% for patients above age 60. The Carmat bioprosthetic heart's primary advantages are that:

1. Patient blood only comes into contact with biocompatible materials (bovine pericardium treated to become chemically inert, and medical-grade ePTFE) to reduce risk of clotting or haemolysis
2. The device contains four pericardium valves, and two motor units provide a pulsatile heart beat and eject and admit blood, mimicking the natural flow action of the heart.
3. The flow rate is governed by an internal electronic device (auto-regulation), controlled by embedded sensors and software algorithms that adjust flow rate in accordance with the patient's physiological and metabolic requirements, varying both the rate and the strength at which the blood is pumped.

Carmat plans to start pivotal study in H216

Carmat intends to finalise the protocol and obtain the necessary approvals in H116 from French authorities (including the Agence Nationale de Sécurité du Médicament et des Produits de Santé, ANSM) to start a pivotal study that could lead to CE clearance and EU commercialisation. Carmat anticipates that recruitment could begin in H216.

The company is planning for the pivotal study to recruit between 20 and 25 patients, and take place in France and several other European countries. The implanted patients would be followed for up to 180 days. The firm also anticipates that regulators would permit more relaxed inclusion criteria than the feasibility study, which was limited to terminal stage patients (such as end-stage irreversible biventricular heart failure) and/or those in an immediate life-threatening situations. The target population in the pivotal study could potentially include patients with Stage IV chronic heart failure (CHF).

Carmat anticipates that it would be able to recruit patients into the pivotal study in parallel rather than sequentially, according to the number of clinical trial sites participating. This can significantly improve the recruitment rate, as the feasibility study took about two years to recruit four patients. A much more rapid level of recruitment is needed to satisfy the firm's belief that the pivotal study could be completed in 2017 or 2018. Our model assumes completion in late 2017, with CE Mark clearance and commercialisation in H218.

Carmat is also a participant in the EUnetHTA – SEED (Shaping European Early Dialogues for health technologies) programme, which enables the firm to engage in preliminary dialogue with regulators and public payers for potential reimbursement of the Carmat prosthetic heart, ahead of commencing pivotal studies.

Carmat also anticipates that once the CE mark is obtained, it will advance the incorporation of a second-generation hydrogen-generating power source developed by PaxiTech. This battery could allow up to 12 hours of autonomous operation and charge while weighing under 3kg, extending the implant's overall flexibility and versatility (the current heart uses 3kg five-hour lithium ion battery). A supplementary regulatory filing could be undertaken to permit the usage of this battery with the Carmat bioprosthetic heart.

Carmat expects pivotal study to have limited effect on burn rate

Operating expenses for Carmat, including staff, materials and other clinical costs for the feasibility study were €19.3m in both 2015 and in 2014. Carmat also received a €3.15m research tax credit in 2015; it expects to receive one for €3.2m in 2016. Overall, operating cash burn (after including net interest expenses) was €17.2m in 2015. As the firm plans to start a CE mark-enabling pivotal study in H216, it does not expect its cash burn rate to rise significantly; management suggests the upcoming annual burn rate could rise by €1-2m compared to recent trends. Based on this projection, we estimate it should have enough on hand to fund operations into H118, and thus potentially through the completion of the pivotal study.

Commercial assumptions

The commercial case for the Carmat bioprosthetic heart primarily lies in a general lack of available human heart transplants for patients who need them. Heart transplantation is considered the gold standard treatment for patients with advanced heart failure who are refractory to management with medical therapy and mechanical circulatory support. The US National Institutes of Health reported in 2010 that the potential pool of US patients for heart transplantation is over 50,000 a year, yet the number of heart transplants performed in the country has remained relatively fixed at 2,200 per year for at least a decade. A reason for this disparity is the strict criteria for potential donors (ie, aged under 61 years, not suffering from certain infectious diseases, and so on) as well as matching criteria for the recipient (ie, similar blood type, comparable height/weight; recipient must also free of certain health conditions and/or aged below 65). A similar supply/demand mismatch exists in Europe (across France, Germany and the UK there are only c 800 transplants per year)

We estimate the EU target potential market opportunity of the Carmat bioprosthetic heart can be broadly based as falling within two conditions. In both groups, the bioprosthetic heart would only be implantable in patients under age 70, and for anatomical/size compatibility, in about 86% of otherwise-eligible men and 14% of such women.

The two conditions we assume the Carmat bioprosphetic heart will be targeting are:

- Patients with Class IV (end stage) CHF, with biventricular failure; estimated EU market size of about 13,500
- Patients suffering from myocardial infarcts that lead to an expected survival time of under 30 days with conventional management (estimated EU market size of about 60,300)

Altogether the EU target treatment population is around 74,000. We assume completion of the pivotal study in H217, and potential EU launch and commercialisation in H218. We continue to assume an initial average per-device market price of €160,000 (in the mid-range of company guidance of €140,000-180,000). We estimate peak market share of 15% of this target market will be realised by 2023, with EU sales of €1.9bn in that year. This is higher than our prior peak EU sales estimate of €1.2bn, with the primary difference driving our new forecast our assumption for a higher target pool (potential market) of 74,000 potential patients per year, up from 50,000 previously.

For the US market, our base case continues to assume that product introduction will be attempted using the HUD (Humanitarian Use Device) programme, instead of a Premarket Approval (PMA) process. The HUD approach is less onerous and would shorten the amount of clinical data required for commercialisation, but could limit product usage to 4,000 patients per year. Under a HUD approach, Carmat would need to provide safety evidence but unlike a PMA, there would be no necessity to provide efficacy data. We assume US HUD commercialisation in 2020, with a US market price of $200,000 per device (same as previously). We assume peak US sales of $625m by 2024 under this scenario. Our new peak US sales forecast is also higher than our prior $560m peak US sales estimate as we now assume that, under a HUD approval scenario, the product would take a larger share of the potential target HUD market. In effect, we expect US greater physician awareness of the benefits of Carmat's heart vs other competing artificial hearts due to its utilisation in the EU. We would adjust our forecasts should Carmat proceed via the PMA route, but this would entail a higher risk adjustment, a later launch date due to the longer/larger study, and additional R&D costs of over €35m (for a >100 patient clinical trial), although the addressable market would be larger.

Valuation

We continue to value Carmat using an risk-adjusted NPV approach, employing a 12.5% cost of capital. After reviewing CHD and myocardial infarction prevalence data, we estimate the potential target market as being potentially larger than previously (up to 74,000 EU patients versus 50,000 previously) but we also assume, given the complexities involved with the artificial heart programme and its manufacturing and the relatively small (n=4) sample size to date, a slightly more conservative risk adjustment (30% vs 35% previously), for the EU market. Our risk adjustment factor also considers the timeline for completing the study, as given the time needed to complete the feasibility study, there remains a risk that it can take longer than our model currently estimates to complete the pivotal study. As we estimate that CE mark clearance would be a necessary step or milestone, before the company would embark on a US regulatory strategy, we use a lower (20%) probability for commercialisation in the US.

Exhibit 2: Carmat SA rNPV assumptions

Product contributions (net of R&D and Marketing costs)	Indication	rNPV (€m)	rNPV/share (€)	Probability of success	Launch year	Peak WW sales (€m)
Carmat artifical heart in EU market	Terminal heart failure and myocardial infarctions	876.5	147.88	30.0%	2018	$1.9bn in 2023
Carmat artifical heart in US market (under HUD)	Terminal heart failure and myocardial infarctions	159.8	26.96	20.0%	2020	$0.6bn in 2024
Corporate costs & expenses						
G&A expenses		(44.0)	(7.42)			
Net capex, NWC & taxes		(340.6)	(57.46)			
Total rNPV		**651.7**	**109.95**			
Net cash (debt) (H116e)		41.3	6.98			
Total equity value		**693.0**	**116.92**			
FD shares outstanding (000) (*H116e)		5,927				

Source: Edison Investment Research. Note: * includes the addition of 1.35m shares as part of €50m financing announced in February 2016.

Given the above adjustments, we now obtain an rNPV valuation of €652m, up from €611m previously. After including the €50m financing and the resulting additional 1.35m shares, we assume mid-2016 net cash position of €41.3m. After including this net cash position, we derive an equity value of €693m, which leads to a per-share equity valuation of €116.92. This valuation does not include any additional equity offerings, as future financings may be required to prepare for commercial product launch and ramp up manufacturing.

Once Carmat bioprosthetic heart commercialisation is secured, Carmat plans to use its know-how in cardiac mechanics and biomaterials to expand into other cardiovascular indications or devices (such as a ventricular assistance device), but until definitive R&D or clarification is made into such areas, we are not including such prospects in our valuation.

Financials

We estimate that Carmat's net cash burn rate (operating cash flow including net interest costs, minus net capex) will be €18.7m in 2016 and €21.8m in 2017. We expect the burn rate to rise in 2018 and 2019 as the firm prepares for commercialisation, with the burn rates of €37.9m, and €46.8m respectively. We expect gross margin for the Carmat heart to be negative initially, but become positive by H219. Given these cash needs, we assume the firm will raise €40m in both 2018 and in 2020, to prepare for launch activities (sales and manufacturing scale-up); as per our usual methodology, we assign these financings to long-term debt.

We assume operating cash flows will start to run positive in 2020, as product sales rise and as manufacturing efficiency gains are realised. We assume EBITDA margins will exceed 50% in 2022 and thereafter.

Exhibit 3: Financial summary

€(000)	2013	2014	2015	2016e	2017e	2018e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	2,874	49	14	0	0	13,320
Cost of Sales	0	0	0	0	0	(15,984)
General & Administrative	(4,694)	(5,408)	(6,012)	(6,000)	(6,000)	(9,150)
Research & Development	(13,376)	(14,031)	(13,392)	(16,000)	(16,000)	(6,000)
EBITDA	(15,197)	(19,390)	(19,390)	(22,000)	(22,000)	(17,814)
Depreciation	(920)	(479)	(377)	(236)	(226)	(1,216)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(16,117)	(19,869)	(19,767)	(22,236)	(22,226)	(19,030)
Exceptionals	25	(127)	(89)	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(16,091)	(19,996)	(19,857)	(22,236)	(22,226)	(19,030)
Net Interest	(324)	(476)	(838)	316	401	12
Profit Before Tax (norm)	(16,440)	(20,345)	(20,605)	(21,920)	(21,826)	(19,018)
Profit Before Tax (FRS 3)	(16,415)	(20,472)	(20,694)	(21,920)	(21,826)	(19,018)
Tax	1,770	2,209	3,149	3,200	0	0
Profit After Tax and minority interests (norm)	(14,670)	(18,136)	(17,456)	(18,720)	(21,826)	(19,018)
Profit After Tax and minority interests (FRS 3)	(14,645)	(18,263)	(17,546)	(18,720)	(21,826)	(19,018)
Average Number of Shares Outstanding (m)	4.3	4.4	4.6	5.6	5.9	5.9
EPS - normalised (€)	(3.42)	(4.14)	(3.81)	(3.35)	(3.68)	(3.21)
EPS - normalised and fully diluted (€)	(3.42)	(4.14)	(3.81)	(3.35)	(3.68)	(3.21)
EPS - (IFRS) (€)	(3.42)	(4.17)	(3.83)	(3.35)	(3.68)	(3.21)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	1,633	1,377	1,215	1,163	1,139	19,922
Intangible Assets	125	254	218	218	218	218
Tangible Assets	1,508	1,123	998	945	921	19,705
Current Assets	20,351	12,665	7,435	38,767	16,965	19,164
Short-term investments	0	0	0	0	0	0
Cash	16,884	9,219	3,012	34,344	12,543	14,613
Other	3,467	3,447	4,422	4,422	4,422	4,550
Current Liabilities	(6,254)	(4,750)	(4,722)	(4,722)	(4,722)	(4,722)
Creditors	(6,254)	(4,750)	(4,722)	(4,722)	(4,722)	(4,722)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(844)	(1,349)	(2,246)	(2,246)	(2,246)	(42,246)
Long term borrowings	(822)	(1,349)	(2,224)	(2,224)	(2,224)	(42,224)
Other long term liabilities	(22)	0	(22)	(22)	(22)	(22)
Net Assets	14,886	7,944	1,681	32,961	11,136	(7,882)
CASH FLOW						
Operating Cash Flow	(9,314)	(18,270)	(16,349)	(18,800)	(22,000)	(17,942)
Net Interest	(324)	(476)	(838)	316	401	12
Tax	0	0	0	0	0	0
Capex	(266)	(331)	(292)	(184)	(202)	(20,000)
Acquisitions/disposals	0	0	0	0	0	0
Financing	11,932	6,033	11,185	50,000	0	0
Net Cash Flow	2,029	(13,044)	(6,295)	31,332	(21,801)	(37,930)
Opening net debt/(cash)	(215)	(16,062)	(7,870)	(788)	(32,121)	(10,319)
HP finance leases initiated	0	0	0	0	0	0
Other	13,818	4,852	(787)	(0)	0	0
Closing net debt/(cash)	(16,062)	(7,870)	(788)	(32,121)	(10,319)	27,610

Source: Company reports, Edison Investment Research

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