EDISON

Carmat

Financial and clinical update

First half of CE mark-enabling trial fully enrolled

Healthcare equipment & services

In July, Carmat announced the enrolment of the 10th and final patient included in the first leg of its EU pivotal study investigating the surgical implantation of the Carmat total artificial heart (TAH) in patients suffering from end-stage biventricular heart failure (HF). Following the successful surgeries, the company expects to enrol an additional 10 patients in the second cohort by the year end. According to Carmat, data from all 20 patients should be sufficient to obtain CE marking for the bioprosthesis in 2019. Most notably, Carmat announced the first successful donor heart transplant of a TAH patient who was initially too sick to receive a donor heart.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	0.3	(25.7)	(3.80)	0.0	N/A	N/A
12/17	0.03	(31.5)	(3.24)	0.0	N/A	N/A
12/18e	0.7	(39.6)	(4.21)	0.0	N/A	N/A
12/19e	0.0	(28.7)	(3.11)	0.0	N/A	N/A

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

Completes enrolment of first leg of pivotal trial

Carmat announced the completion of enrolment of the first portion of its EU pivotal study investigating the safety and efficacy of the surgical implantation of the Carmat TAH as an alternative therapeutic among those waiting for human transplants and/or suffering from terminal HF and potentially terminal acute myocardial infarctions (MI). The primary endpoint of the trial is overall survival at six months post-implant, or overall survival to human cardiac transplantation.

Sights set on the CE mark in 2019

In light of the successful completion of the first 10 Carmat TAH implantations, the company plans to begin enrolling patients in the second cohort immediately at the three active international medical centres. According to the company, data from all 20 patients should be satisfactory to achieve CE marking for the Carmat TAH device, which is expected in 2019.

Carmat TAH patient receives donor heart transplant

In August, Carmat announced the completion of the first successful donor heart transplant of a patient previously implanted with the Carmat TAH in October 2017. For eight months, the Carmat TAH supported the patient, who was in end stage HF and previously ineligible for a heart transplant due to pulmonary hypertension. The patient successfully received a donor heart in June.

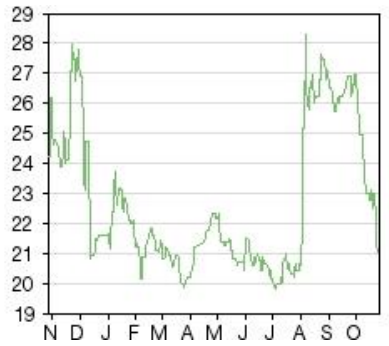
Valuation: €773m or €83.89 per share

We have raised our valuation of Carmat to €773m or €83.89/share from €697.3m or €77.34share. This increase is due mainly to a rise in the probability of success in the EU market from 25% to 30% as enrolment is progressing well. This is offset by an increase in G&A expenditure, net working capital (NWC) and CAPEX.

26 October 2018

Price	**€21.05**
Market cap	**€194m**
	US$1.18/€
Net cash (€m) at 30 June 2018	39.8
Shares in issue	9.2m
Free float	29.8%
Code	ALCAR
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(19.8)	3.2	(10.8)
Rel (local)	(12.7)	11.1	(5.2)
52-week high/low		€28.3	€19.8

Business description

Carmat is a France–based, medical device company developing a biocompatible, artificial heart to satisfy the lack of donor hearts available for terminal biventricular heart failure patients. The company completed a feasibility study in early 2016, and received authorisation to resume a European pivotal study in May 2017.

Next events

Complete pivotal trial surgical implantations	Year-end 2018
CE mark for Carmat TAH	2019

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Half-way there

In July 2018, Carmat announced the successful surgical implantation of the Carmat TAH device into the 10th and final patient, marking the completion of the first half of the CE mark-enabling pivotal trial. Following this update, the company plans to enrol an additional 10 patients to participate in the second leg of the trial at the three presently active medical centres in France, the Czech Republic, and Kazakhstan. However, the company has stated that to keep up with the current implantation rate and meet its guidance to complete enrolment by year-end, it will expand on the network of investigating centres to four new European countries. This expansion includes the Heart Center of the Rigshospitalet hospital in Copenhagen, Denmark, which was recently approved to perform the surgery earlier this year. Nonetheless, we continue to expect completion in mid-2019.

As of 29 September 2018, 11 patients have been surgically implanted with the Carmat TAH. Thus far, the Carmat TAH recipients have demonstrated a one-month survival rate of 91% compared to a one-month survival of 75% demonstrated in the previous feasibility study. Surgery time has also been reduced from seven hours to five hours. Patients spend about six days in intensive therapy and can typically return home from the hospital in 35 days. According to the company, the device has provided cumulative support time of three years and five months.

On 1 August 2018, the company announced the first successful human cardiac transplant of a Carmat TAH recipient at the National Research Center for Cardiac Surgery in Kazakhstan. This end-stage HF patient (male) was initially ineligible to receive a donor heart due to pulmonary hypertension, which is high blood pressure that affects the arteries of the lungs and right side of the heart. Carmat's device supported the patient for eight months and facilitated recovery from the condition. In June, the patient underwent explanation of the bioprosthetic and implantation of a donor heart. This is the first demonstration of the Carmat TAH effectively serving as a therapeutic bridge to transplant. Later in August, Carmat announced the certification of its new manufacturing site located in Bois-d'Archy, France. According to the company, the automated manufacturing site will enable the production of up to 800 Carmat TAH units per year at full capacity, which should support the recent enrolment ramp-up for the pivotal trial and meet the demands of industrial manufacturing.

To review, the Carmat device is the first biocompatible, biventricular mechanical heart and is designed to replicate the functionality and morphology of the human heart as closely as possible, by applying technology involving self-regulatory mechanisms and biocompatible materials. The device aims to provide a long-term (or potentially permanent) solution to patients suffering from advanced biventricular HF and potentially terminal acute MI (commonly referred to as heart attack), for whom no human transplant is available and who have exhausted all remaining treatment possibilities.

The primary endpoint of the ongoing single arm trial is overall survival on the Carmat TAH at 180-days post-implant, or survival to human cardiac transplantation (provided this occurs prior to the 180-days post-implant mark). The secondary endpoints of the trial include the New York Heart Association (NYHA) HF classification (Exhibit 1), a six-minute walk test, and quality of life measurements that will be assessed at baseline and one, three and six months post-transplant. Adverse events will also be collected throughout the course of the study (ie frequency and incidence of all adverse events as well as frequency, incidence, and type of device malfunction).

Exhibit 1: NYHA heart failure grading system

	Class I	Class II	Class III	Class IV
Symptoms	No symptoms	Tiredness, palpitations, shortness of breath after sustained effort	Symptoms or discomfort on the least effort	Symptomatic even at rest
Activity	No limitations	Modest limitations	Marked reduction	Inability to perform nearly all activities; permanently confined to bed

Source: Company reports. Notes: NYHA= New York Heart Association.

This trial follows previous encouraging data from a four-patient feasibility study completed in January 2016. 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 (Exhibit 2). 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.

As a reminder, the current trial, which was first initiated mid-2016, was suspended promptly after the death of the first patient, implanted with the device in August 2016. The study was resumed in May 2017 following analyses that elucidated the cause of death was related to poor battery handling by the patient and not due to device malfunction.

According to the company, data from all 20 patients should be sufficient to achieve a CE mark for the Carmat TAH, which is expected in 2019. The company has also stated that initial commercialisation efforts in the EU will be focused specifically in Germany and France. Moreover, conversations with the FDA and potential US participating medical centres remain ongoing.

Exhibit 2: 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. The Carmat heart was believed to have functioned optimally during implantation.

Source: Company reports

Valuation

We have increased our valuation of Carmat to €773m or €83.89 per share from €697.3m or €77.34 per share. This increase is due mainly to an increase in the probability of success in the EU market from 25% to 30% as the trial continues to progress well without additional issues (as a reminder we had previously lowered the probability of success in the EU market from 35% to 25% following the trial stoppage). This was offset by an increase in G&A expenditure, net working capital (NWC) and capex (see financial section below). As we believe the company places a higher priority on obtaining CE mark clearance for the EU market than on developing the Carmat heart for the US market, we continue to apply a lower (20%) probability for commercialisation in the US. We expect to update our valuation with interim data from the pivotal trial and with feedback from the FDA regarding potential trial initiation in the US.

Exhibit 3: Valuation of Carmat

Product contributions (net of R&D and Marketing costs)	Indication	Prob. of success	Launch year	Launch pricing	Peak sales (€m)	rNPV (€m)
Carmat artificial heart in EU market	Terminal heart failure and myocardial infarctions	30%	2020	€160,000	2,169 in 2024	1021.8
Carmat artificial heart in US market (under HUD)	Terminal heart failure and myocardial infarctions	20%	2021	$200,000	620 in 2025	160.4
Corporate costs & expenses						
G&A expenses						-73.7
Net capex, NWC & taxes						-375.0
Total rNPV						733.5
Net cash (at 30 June 2018)						39.8
Total firm value						773.3
Total shares (m)						9.2
Value per basic share (€)						83.89

Source: Edison Investment Research

Financials

Carmat's H118 post-tax loss was €18.9m, up 34% from the same period for the year prior (H117: loss of €14.1m), which is attributable to increases in both R&D expenditure and SG&A. This includes costs associated with the continuation of the CE marking process including finalisation of technical models, preliminary work for the opening of the Bois-d'Archy manufacturing site, which is now operational, and the internationalisation of the pivotal study, which includes training teams at new investigation centres.

Carmat finished H118 with €39.8m in net cash (€44.0m gross cash at 30 June 2018 minus €4.2m in long-term debt). We continue to expect that Carmat's burn rate in 2018 will be significantly higher than in 2017, due to our expectations of an increased recruitment rate for the ongoing EU pivotal trial and reflecting CAPEX investments incurred to expand production capacity.

We estimate that Carmat's funds on hand will support its operating runway into Q219. We continue to assume that Carmat will need an additional €100m to complete the regulatory, manufacturing and commercial activities needed for the Carmat device to reach Carmat sustainable profitability. We assume Carmat will raise €50m in each of 2019 and 2020, which we illustrate as long-term debt (Exhibit 4). We do not expect Carmat to start generating sustainable, positive, recurring operating cash flows until 2021, once its sales and manufacturing efficiencies start to exceed all projected overhead costs.

Exhibit 4: Financial summary

€(000)	2016	2017	2018e	2019e
31-December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	263	28	708	0
Cost of Sales	0	0	0	0
General & Administrative	(6,426)	(8,421)	(11,473)	(14,248)
Research & Development	(17,912)	(21,890)	(27,442)	(10,000)
EBITDA	(24,075)	(30,283)	(38,207)	(24,248)
Depreciation	(504)	(752)	(1,237)	(4,389)
Amortization	0	0	0	0
Operating Profit (before exceptionals)	(24,579)	(31,035)	(39,444)	(28,636)
Exceptionals	(75)	(56)	(3)	0
Other	0	0	0	0
Operating Profit	(24,655)	(31,090)	(39,447)	(28,636)
Net Interest	(1,143)	(472)	(157)	(43)
Profit Before Tax (norm)	(25,722)	(31,507)	(39,601)	(28,679)
Profit Before Tax (FRS 3)	(25,797)	(31,563)	(39,604)	(28,679)
Tax	2,817	2,335	987	0
Profit After Tax and minority interests (norm)	(22,905)	(29,172)	(38,615)	(28,679)
Profit After Tax and minority interests (FRS 3)	(22,980)	(29,228)	(38,617)	(28,679)
Average Number of Shares Outstanding (m)	6.0	9.0	9.2	9.2
EPS - normalised (€)	(3.80)	(3.24)	(4.21)	(3.11)
EPS - normalised and fully diluted (€)	(3.80)	(3.24)	(4.21)	(3.11)
EPS - (IFRS) (€)	(3.81)	(3.24)	(4.21)	(3.11)
Dividend per share (€)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	1,751	4,752	15,204	35,815
Intangible Assets	196	72	91	91
Tangible Assets	1,555	4,680	15,113	35,724
Current Assets	35,738	65,098	19,747	20,456
Short-term investments	0	0	0	0
Cash	31,163	60,723	14,809	15,519
Other	4,575	4,375	4,937	4,937
Current Liabilities	(5,195)	(7,944)	(7,609)	(7,609)
Creditors	(5,195)	(7,944)	(7,609)	(7,609)
Short term borrowings	0	0	0	0
Long Term Liabilities	(3,213)	(3,714)	(4,240)	(54,240)
Long term borrowings	(3,213)	(3,714)	(4,240)	(54,240)
Other long term liabilities	0	0	0	0
Net Assets	29,082	58,191	23,101	(5,578)
CASH FLOW				
Operating Cash Flow	(20,111)	(23,806)	(38,079)	(24,248)
Net Interest	(1,143)	(472)	(157)	(43)
Tax	0	0	0	0
Capex	(1,096)	(3,559)	(11,689)	(25,000)
Acquisitions/disposals	0	0	0	0
Financing	50,175	57,537	4,012	0
Net Cash Flow	27,825	29,700	(45,913)	(49,291)
Opening net debt/(cash)	(788)	(27,951)	(57,009)	(10,569)
HP finance leases initiated	0	0	0	0
Other	(662)	(642)	(527)	0
Closing net debt/(cash)	(27,951)	(57,009)	(10,569)	38,721

Source: Company reports, Edison Investment Research

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