

# Carmat

## Cleared to start pivotal study in France

Carmat has received approval from the health regulatory authorities in France to start a CE mark enabling a pivotal trial for the Carmat bioprosthetic heart. We expect recruitment to start in the coming weeks, which could lead to commercialisation in Europe by H218. Following this clearance, we have raised our Carmat heart probability of success estimate for the EU market to 35% (from 30% previously). This raises our rNPV valuation to €747m (up from €651m), or €133.00 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.

## Pivotal trial expected to start in H216

In addition to patients with end-stage biventricular heart failure, patients who are eligible for a heart transplant but who have a very low likelihood of receiving a donor heart will be allowed to participate in the trial. This inclusion criteria is more relaxed than that of the prior four-patient feasibility study (completed in early 2016), which was limited to terminal-stage biventricular heart failure patients and/or those in an immediate life-threatening situations. Carmat is also working on obtaining clearances to enrol patients in other European countries.

## Carmat intends to complete study in 2018

Carmat intends to recruit between 20 and 25 patients across multiple sites, who would be followed for up to 180 days. The firm anticipates that it would be able to recruit patients into the pivotal study in parallel rather than sequentially (as was done in the feasibility trial). This could 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 CE mark clearance and EU commercialisation could occur in 2018.

## Valuation: Risked NPV rises to €747m

Regulatory clearance for Carmat to start a CE mark enabling pivotal study is a key development step, and patient recruitment should begin shortly. We have raised our probability of success estimate for the Carmat heart in the EU market to 35% (from 30% previously). This leads to an increased rNPV valuation of €747m (up from €651m and excluding cash), or €133.00 per share after including the H116 €50m financing and assuming a €41.3m net cash position in mid-2016. We assume CE mark clearance and EU launch in H218 and a US market entry under a humanitarian use device (HUD) approach in 2020. We continue to 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 break even in 2020.

Update – clinical trial

Healthcare equipment & services

15 July 2016

**Price** €33.97  
**Market cap** €201m

Net cash (€m) at end 2015 (excludes €50m equity 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 6.8 (12.0) (43.0)

Rel (local) 1.0 (9.4) (35.0)

52-week high/low €63.49 €26.00

### 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

Report H116 results August 2016

### Analysts

Pooya Hemami +1 646 653 7026

Maxim Jacobs +1 646 653 7027

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

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**Exhibit 1: Financial summary**

	€000s	2013	2014	2015	2016e	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>							
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)
Amortisation		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
<b>BALANCE SHEET</b>							
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)
<b>CASH FLOW</b>							
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: Carmat accounts, Edison Investment Research

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