EDISON

Carmat

Commercial update

CE Mark achieved, launching in Q2

Pharma & biotech

Carmat announced that it has received a CE Mark for its physiologic heart replacement therapy (PHRT) and that the product will be launched in Q221 under the brand name Aeson. The approved indication is a bridge to transplantation therapy (BTT), although over time we expect approval for Aeson as a destination therapy (DT), which will enable commercialisation to a larger number of patients. The initial commercial focus will be on France and Germany, which Carmat estimates to account for 55% of the EU mechanical circulatory support market.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS* (€)	P/E (x)	Yield (%)
12/18	0.72	(43.7)	(4.54)	0.0	N/A	N/A
12/19	0.70	(44.2)	(3.88)	0.0	N/A	N/A
12/20e	0.54	(44.4)	(3.52)	0.0	N/A	N/A
12/21e	14.26	(44.0)	(3.46)	0.0	N/A	N/A

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

A large total addressable market

Based on data from the French Agency of Biomedicine and Eurotransplant, there are a total of 1,600 people on heart transplant waiting lists in France and Germany alone. However, this is a fraction of the number of the total potential addressable market in Europe, as we estimate more than 80,000 people in Europe would likely benefit from a transplant due to late-stage heart failure.

EFICAS study to begin in France in Q2

The French Ministry of Health and Solidarity has granted €13m in funding to Carmat to conduct the EFICAS clinical study, representing approximately two-thirds of the total study cost. The EFICAS study is expected to include 52 patients, with enrolment starting in Q221. The primary endpoint will be the 180-day survival rate without a disabling stroke or until a successful cardiac transplantation. As well as providing data to drive adoption of Aeson, it will help support pricing and reimbursement for the product.

US feasibility study to begin in Q121

The company should start implanting patients in the early feasibility study (EFS) in Q121. The study will include 10 patients at seven US centres and, importantly, will be reimbursed by CMS. Enrolment is expected to complete by the end of 2021.

Valuation: €747m or €58.83 per share

We have increased our valuation to €747m or €58.83 per share from €679m or €53.88 per share. This is mostly due to our increase in the probability of commercial success for Aeson in the EU to 35% from 30% following receipt of the CE Mark. This was partially offset by more conservative near-term estimates as the launch will occur later in 2021 than expected and is also more focused. We assume a financing requirement of €40m for 2021 to fund US clinical development and the commercial launch.

11 January 2021

Price	**€33.0**
Market cap	**€419m**
	US$1.23/€
Net cash (€m) at 30 June 2020	17.8
Shares in issue	12.7m
Free float	41.8%
Code	ALCAR
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	35.3	63.9	68.1
Rel (local)	31.8	41.7	76.5
52-week high/low	€33.00		€11.60

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. It expects to initiate an early feasibility study in the US in Q121 and recently received a CE Mark in the EU.

Next events

Initiate EFS study in US	Q121

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Edison profile page

Aeson coming soon

Carmat has received a CE Mark for its PHRT, which has stated advantages of pulsatility, autoregulation and hemocompatibility. Unlike competitive products, Carmat's has so far seen no stroke, gastrointestinal bleeding or driveline infection (see Exhibit 1), making it a potentially attractive choice for both physicians and patients.

Exhibit 1: Comparative outcomes at six-month follow-up

	Survival rate	Stroke	Gastrointestinal bleeding	Driveline infection
Carmat	70%	0%	0%	0%
SynCardia	54–62%	23%	20%	22%
BIVAD	46–68%	7%	7%	7%
LVAD	90–92%	8%	8%	10%

Source: Carmat. American Society of Artificial Internal Organs Annual Conference June 2019

The approved indication is BTT, which refers to the intent to implant the device temporarily until an organ transplant is available, or until the patient's condition improves sufficiently to tolerate such surgery. Carmat has stated that the initial focus of the European launch will be on France and Germany, which together make up approximately 55% of the EU mechanical circulatory support market. Based on data from the French Agency of Biomedicine and Eurotransplant, there are a total of 1,600 people on heart transplant waiting lists in France and Germany alone.

The company will use the EFICAS study as the platform to launch Aeson in France. As a reminder, the French Ministry of Health and Solidarity granted €13m in funding to Carmat to conduct the EFICAS clinical study, representing approximately two-thirds of the total study cost. The EFICAS study is expected to include 52 patients with enrolment starting in Q221. The primary endpoint will be the 180-day survival rate without a disabling stroke or until a successful cardiac transplantation. As well as providing data to drive adoption of PHRT, it will help support pricing and reimbursement for the product. In Germany, 20 centres have so far indicated a willingness to implant Aeson and the company estimates that it will train these centres over the course of H121.

Over time, we expect the company to expand beyond France and Germany and also beyond heart transplant waiting lists. Carmat will seek approval for DT, which refers to the device being implanted permanently or in patients who are either not eligible for or not compatible with a heart transplant. This will allow it to target the larger addressable market of patients with late-stage heart failure. We believe these patients will come from two groups:

- Patients with Class IV (end-stage) HF, with biventricular failure; estimated EU market size of about 21,500.
- Patients suffering from acute MI whose severity or circumstances lead to an expected survival time of less than 30 days with conventional management (estimated EU market size of about 60,300).

Altogether, we estimate the EU target treatment population to be around 82,000.

The EU pivotal trial in patients with advanced heart failure continues to enrol, with 15 patients (out of 20) having been implanted with PHRT so far, although the rate of enrolment has been negatively affected by COVID-19. The pivotal trial will help generate further safety, performance and health economic data which will assist product adoption and reimbursement.

In the US, Carmat received approval from the FDA to initiate the EFS in 10 patients at seven US centres (three of which are already trained and ready to go), and has also announced reimbursement from the CMS for the device and routine care items and services related to the study. The trial is expected to begin after the FDA approves the last remaining amendment to the

configuration of the PHRT (eight amendments have been approved so far). The company expects the first implants to be performed in Q121, with enrolment completed by the end of the year.

Valuation

We have increased our valuation to €747m or €58.83 per share from €679m or €53.88 per share. This is mostly due to our increase in the probability of commercial success for Aeson in the EU to 35% from 30% following receipt of the CE Mark. This was partially offset by more conservative near-term estimates as the launch will occur later in 2021 than expected and is also more focused (initially targeting France and Germany).

Exhibit 2: Carmat valuation table

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	35%	2021	€160,000	2,221 in 2025	1,046.3
Carmat artificial heart in US market (under HUD)	Terminal heart failure and myocardial infarctions	20%	2021	$200,000	713 in 2025	168.0
G&A expenses						(103.9)
Net capex, NWC & taxes						(381.0)
Total rNPV						729.4
Net cash at 30 June 2020						17.8
Total firm value						747.2
Total shares (m)						12.7
Value per basic share (€)						58.83

Source: Edison Investment Research

Financials

Due to the focused nature of the launch as well as its Q221 timing, we have lowered our estimated FY21 revenues to €14.3m from €28.2m. However, peak sales remain the same. Carmat had €45.3m in cash and equivalents and around €27.5m in debt at 30 June 2020. In December 2018, Carmat engaged in a €30m non-dilutive loan agreement with the European Investment Bank (EIB). Carmat drew down the first of three available tranches of €10m in January 2019 and the second in May 2020. There is €10m remaining under the facility, which can be drawn down any time before 17 December 2021. In November, Carmat announced that it had obtained a €10m loan that is 90% guaranteed by the French state. The initial term is 12 months, but principal repayment can be extended for an additional five years.

We assume an additional financing requirement of €40m through 2021 (Carmat has stated it has resources to Q321) to fund US clinical development and the commercial launch. As per our usual methodology, we assign these additional financings to long-term debt. We do not expect Carmat to start generating sustainable, positive, recurring operating cash flows until 2022, once its sales and manufacturing efficiencies start to exceed all projected overhead costs.

Exhibit 3: Financial summary

€000s	2018	2019	2020e	2021e
31-December				
PROFIT & LOSS				
Revenue	722	702	544	14,262
Cost of Sales	0	0	0	(9,118)
General & Administrative	(11,897)	(13,634)	(14,940)	(15,870)
Research & Development	(30,672)	(28,299)	(28,500)	(30,000)
EBITDA	(41,847)	(41,230)	(42,417)	(40,726)
Depreciation	(920)	(1,164)	(1,036)	(2,878)
Amortization	0	0	0	0
Operating Profit (before amort. and except.)	(42,766)	(42,394)	(43,453)	(43,603)
Exceptionals	(2)	(104)	0	0
Other	0	0	0	0
Operating Profit	(42,768)	(42,498)	(43,453)	(43,603)
Net Interest	(945)	(1,787)	(906)	(381)
Profit Before Tax (norm)	(43,711)	(44,181)	(44,359)	(43,984)
Profit Before Tax (FRS 3)	(43,713)	(44,285)	(44,359)	(43,984)
Tax	1,984	1,636	0	0
Profit After Tax and minority interests (norm)	(41,727)	(42,545)	(44,359)	(43,984)
Profit After Tax and minority interests (FRS 3)	(41,729)	(42,649)	(44,359)	(43,984)
Average Number of Shares Outstanding (m)	9.2	11.0	12.6	12.7
EPS - normalised (€)	(4.54)	(3.88)	(3.52)	(3.46)
EPS - normalised fully diluted (€)	(4.54)	(3.88)	(3.52)	(3.46)
EPS - (IFRS) (€)	(4.54)	(3.89)	(3.52)	(3.46)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	6,139	5,611	12,514	19,636
Intangible Assets	90	28	30	30
Tangible Assets	6,049	5,584	12,483	19,606
Current Assets	30,691	59,064	31,931	20,825
Short-term investments	0	0	0	0
Cash	25,302	55,505	25,612	14,457
Other	5,389	3,559	6,319	6,367
Current Liabilities	(10,601)	(8,601)	(10,940)	(10,940)
Creditors	(10,601)	(8,601)	(10,940)	(10,940)
Short term borrowings	0	0	0	0
Long Term Liabilities	(4,698)	(16,415)	(37,527)	(77,527)
Long term borrowings	(4,698)	(16,415)	(37,527)	(77,527)
Other long term liabilities	0	0	0	0
Net Assets	21,530	39,660	(4,022)	(48,006)
CASH FLOW				
Operating Cash Flow	(37,229)	(38,458)	(41,050)	(40,773)
Net Interest	(945)	(1,787)	(906)	(381)
Tax	0	0	0	0
Capex	(2,293)	(649)	(7,938)	(10,000)
Acquisitions/disposals	0	0	0	0
Financing	5,059	59,634	0	0
Net Cash Flow	(35,408)	18,741	(49,893)	(51,155)
Opening net debt/(cash)	(57,009)	(20,603)	(39,091)	11,915
HP finance leases initiated	0	0	0	0
Other	(998)	(253)	(1,112)	0
Closing net debt/(cash)	(20,603)	(39,091)	11,915	63,070

Source: Company reports, Edison Investment Research

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