EDISON

Carmat

Resumption of clinical trial

Carmat obtains clearance to resume pivotal study

Healthcare equipment & services

Carmat announced on 2 May 2017 that it has obtained approval from the French regulatory agency (ANSM) to resume its pivotal trial for the Carmat heart. This follows a favourable review by ANSM of the actions and analyses taken by Carmat following the trial's suspension after the death in October 2016 of this trial's first patient six weeks after his implantation. Carmat maintained that the death was not due to a prosthesis malfunction, but due to poor handling of the batteries by the patient. Our valuation (previous rNPV of €747m in our 15 July 2016 update note) is under review.

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
12/16	0.3	(25.7)	(3.80)	0.0	N/A	N/A
12/17e	0.0	(21.8)	(3.62)	0.0	N/A	N/A

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

The ANSM is requesting that Carmat provide an intermediate analysis on the next five patients to take part in the pivotal study. Carmat is now also working to expand access in the 20-25-patient study to other European countries. It is also preparing to open a new production site, with more automated processes for manufacturing, which the firm indicates should be operational by year-end 2017 and should meet the manufacturing requirements for a future commercial launch.

To date, including the previous four-patient feasibility study (2013 through 2015) and the first recruited patient in the pivotal trial, five patients have thus far been implanted with the Carmat device, all with late-stage heart failure, with survival durations between one and nine months following their surgeries.

The company anticipated that the pivotal study, which first began in summer 2016, could potentially be completed in 2018. We believe it is unlikely that such a timeline will be met given the delay. Given the company's year-end 2016 net cash position of €28.0m (€31.2m gross cash minus €3.2m debt) and its 2016 cash burn rate (operating cash flow plus net capex) of €22.2m, we expect current cash on hand to fund operations into Q218.

5 May 2017

Price	**€29.46**
Market cap	**€177m**
Net cash (€m) at 31 December 2016	28.0
Shares in issue	6.0m
Free float	36%
Code	ALCAR
Primary exchange	Alternext
Secondary exchange	N/A

Share price performance

Business description

Carmat is developing a biocompatible, artificial heart to satisfy the lack of donor hearts available for terminal biventricular heart failure patients. It completed a feasibility study in early 2016, and first received authorisation to start a European pivotal study in July 2016.

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