

Carmat

Regulatory agency suspends Carmat implants

On 30 November, Carmat announced that the first patient implanted with its bioprosthetic heart as part of its European pivotal trial has died. The implantation occurred in late August and press sources report that the death was in October. The company's analyses do not suggest the prosthesis was responsible for the death, although the French regulatory agency (ANSM) is suspending future Carmat implantations. Our valuation (previous rNPV of €747m) 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
12/16e	0.1	(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, share-based payments

The [pivotal study](#) began in July and intends to assess the Carmat heart in 20-25 patients, with six-month survival one of the key endpoints. Three of the four patients from the prior feasibility study, completed in early 2016, met the objective of survival beyond 30 days. We believe survival duration for the pivotal trial was planned to be longer, given that patients could be recruited at less severe disease stages.

The ANSM's decision to suspend future implantations after an unexpected death is not surprising given that recruitment delays (of between three and five months each) followed each of the first two deaths in the feasibility trial. One of these was attributed to a device malfunction (disruption in micro-steering electronics), which Carmat had remedied via corrective measures. We believe the ANSM is requiring further analyses to rule out device involvement in this most recent patient death. It is unclear what steps will be needed or what timelines are required for recruitment to resume. Our valuation is under review pending the attainment of updated information. The company previously anticipated that the pivotal study could potentially be completed in 2018; we believe it is unlikely that such a timeline will be met. We expect current cash on hand to fund operations into H118, potentially longer, depending on the timing for resuming implantations.

Update on clinical trial

Healthcare equipment & services

1 December 2016

Price €33.75
Market cap €200m

Net cash (€m) at 30 June 2016	40.3
Shares in issue	5.9m
Free float	48%
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 received authorisation to start a pivotal study in July 2016.

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