Carmat’s heart sinks with another delay

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Despite encouraging interim pivotal data, Carmat’s artificial heart seems as far from market as ever.

The interim results from the pivotal European trial of Carmat’s artificial heart compare favourably, the French group says, with clinical data on the only comparable marketed device, the Total Artificial Heart made by Syncardia Systems.

But Carmat has also confessed that it will not be able to submit its European approval application until next year. After several delays investors appear to be losing patience: the group’s stock was down 7% today, and Carmat’s dwindling cash pile means it will almost certainly have to get further into debt.

2018 becomes 2020

Analysts at Edison had previously expected Carmat’s device to gain a CE mark in 2019, but even this represented a delay over previous estimates – in 2016, with its pivotal European trial about to begin, the company told Vantage that the device should become available in Europe in early 2018 (Interview – Carmat’s heart approaches market as rival hits the buffers, August 2, 2016).

Since then, progress has been slow. Carmat enrolled the tenth and final patient in the first cohort of the trial in July – but it still has another 10 to find for the second cohort of the same study. Data from all 20 patients will be needed to support CE marking.

Last year, the company said these additional patients should be enrolled by the end of 2018. But it appears to have run into problems here: in today’s announcement, Carmat said it is “currently validating additional clinical centres” in two more countries in order to get cohort two fully enrolled.

Perhaps the apparent difficulty in finding suitable patients, as well as contributing to Carmat’s tardiness, is making investors question whether the device has a market at all.

70% survival

News of the delay was buried deep in Carmat’s press release plugging results from the first cohort of the European study. The trial includes patients waiting for heart transplants and/or suffering from terminal heart failure, and its primary endpoint is survival at either six months after receiving the implant or survival until heart transplant.

Seven of 10 patients achieved this, with Carmat adding that the survival rate was better than both the 50%
seen in its feasibility study, and the 54-62% recorded in a trial of Syncardia’s Total Artificial Heart.

Syncardia’s device has been approved in the US since 2004 as a bridge to transplant; its European CE mark came a year later. The device is also in being trialled as a destination therapy, with that study due to complete later this year.

Despite having the only approved total artificial heart on the market Syncardia too has not had an easy ride: in 2016 it filed for bankruptcy protection, and later that year was acquired by the private equity firm Versa Capital Management.

The artificial heart also competes against left ventricular assist devices from the likes of Medtronic and Abbott, which are approved both as a bridge to transplant and as destination therapies. These formidable competitors could help explain why Syncardia has struggled to make a mark – and if its device ever gets approved, Carmat might have the same problem.

Getting to market is still an open question for Carmat, however. The group had just €25.2m ($29m) in cash at the end of last year, but with a €30m loan from the European Investment Bank and the option to draw down another €24m in debt, it should have enough to get through clinical development, it believes – if it sticks to its current timelines.

Given the company’s history that is starting to look like a big ask.