EDISON

Carmat

Commercialisation update

Implantation momentum

Pharma & biotech

Carmat recently announced that it has implanted nine of its physiologic heart replacement therapies (PHRT) since July, six of which were commercial implants (under the brand name Aeson in the EU) while three were part of the early feasibility study (EFS) in the United States. These nine implants are associated with approximately €2m in product revenue, which will be booked in H221. Importantly, due to the PHRT's profile, which features autoregulation, pulsatility and hemocompatibility, additional centres are expected to become commercially active in the coming months, which we believe should help drive revenue growth.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	0	(44.3)	(3.89)	0.0	N/A	N/A
12/20	0	(38.7)	(2.85)	0.0	N/A	N/A
12/21e	4.7	(52.3)	(3.66)	0.0	N/A	N/A
12/22e	26.9	(65.9)	(5.02)	0.0	N/A	N/A

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

Six implants in Europe

Since the first commercial Aeson implant in July in Italy, five additional Aesons have been implanted, four of which occurred in German hospitals and an additional one in Italy. The company is expecting to have around a dozen European centres performing implants by the end of the year, mainly in Germany.

First EFS cohort completed

The EFS study has a two-step protocol, which includes a report to the FDA on progress of the first cohort of three patients after 60 days on therapy. This report to the FDA is required before proceeding to the next group of seven patients. That initial cohort is now fully enrolled (and implanted) and the company expects to start implanting the next cohort by the end of the year.

EFICAS study starting in Q4

As a reminder, the French Ministry of Health and Solidarity previously 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 Q421. 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.

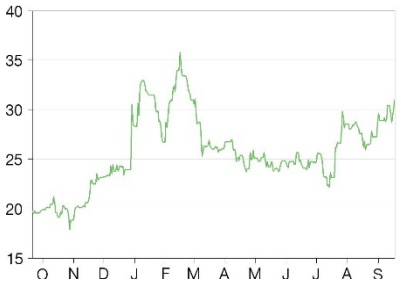
Valuation: €749m or €48.68 per share

We have adjusted our valuation from €747m or €58.83 per share to €749m or €48.68 per share. The total valuation increased slightly due to rolling forward our NPV, while the per share value fell following an offering in March, which had €55.7m in gross proceeds (approximately €52.2m net). Our model projects that the company will raise €70m through the end of 2022 (to cover the burn rate and working capital needs), after which we anticipate the company to reach profitability.

20 September 2021

Price	**€31.0**
Market cap	**€477m**
	US$1.18/€
Net cash (€m) at 30 June 2021	17.6
Shares in issue	15.4m
Free float	51.8%
Code	ALCAR
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	18.3	27.6	27.6
Rel (local)	22.2	29.1	23.1

52-week high/low €35.80 €17.88

Business description

Carmat is a France-based medical device company commercialising a biocompatible, artificial heart to satisfy the lack of donor hearts available for terminal biventricular heart failure patients. It received a CE mark in the EU and the company is conducting an early feasibility study in the United States.

Next events

Initiate EFICAS study	Q421

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Edison profile page

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H121 update

Carmat recently announced results for the first half of 2021 and provided an update on the commercialisation of the Aeson implant in Europe and the enrolment of the EFS in the United States. So far, a total of nine devices have been implanted, six in Europe (four in Germany and two in Italy) and three in the United States, all since July. Importantly, following strong positive feedback from the initial centres, the company is expecting to have around a dozen European centres performing implants by the end of the year, mainly in Germany. Also, in Q421 the company expects to begin enrolment in the EFICAS study in France, which may support pricing and reimbursement of the Aeson implant. We had previously expected the EFICAS study to start in Q221 but it was temporarily delayed as the company had to submit a dossier in H121 to be able to use the most recent version of the device in the study. The EU pivotal trial in patients with advanced heart failure also 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 and by the company's focus on commercial Aeson implants (which took time to get going as centres needed to be trained). The company expects to complete enrolment by the end of H122. Like the EFICAS study, the pivotal trial will help generate further safety, performance and health economic data, which will assist product adoption and reimbursement.

In the United States, the first cohort of three patients has been enrolled and implanted. As a reminder, the EFS study has a two-step protocol, which includes a report to the FDA on progress of the first cohort of three patients after 60 days on therapy. This report to the FDA is required before proceeding to the next group of seven patients. The company expects to start implanting the next cohort by the end of the year. Note there was a bit of a delay in implanting the first patients due to US government restrictions on travellers from France. Feedback so far has been very positive, including from Duke University, one of the top heart transplant centres in the United States. Duke held a media briefing on its implantation in July.

The company is currently also ramping up production. Eight to 10 devices are produced per month currently (which equates to the capacity to support around €2m per month in revenue) with a target of 20 devices per month by the end of the year.

Valuation

We have adjusted our valuation from €747m or €58.83 per share to €749m or €48.68 per share. The total valuation increased slightly due to rolling forward our net present value (NPV). This was mitigated in part due to more conservative near-term revenue estimates, though long-term forecasts remain the same. The per share value fell due to increased shares outstanding following an offering in March.

Exhibit 1: Carmat valuation table

Product contributions (net of R&D and marketing costs)	Indication	Probability of success	Launch year	Peak sales (€m)	rNPV (€m)
Carmat artificial heart in EU market	Terminal heart failure and myocardial infarctions	35%	2021	2,221 in 2025	1,210.2
Carmat artificial heart in US market	Terminal heart failure and myocardial infarctions	20%	2021*	713 in 2025	147.6
G&A expenses					(262.2)
Net capex, NWC & taxes					(364.3)
Total rNPV					731.3
Net cash at 30 June 2021					17.6
Total firm value					748.9
Total shares (m)					15.4
Value per basic share (€)					48.68

Source: Edison Investment Research. Note: *US launch year corresponds with the start of the EFS study.

Financials

Carmat's net loss for H121 was €26.4m, up from €20.8m in the first half of 2020 as the company made preparations for a commercial launch as well as for the EFS study. No sales were reported for H121 as implantations began in July though the company has stated the value of the nine implants so far was around €2m. Due to delays in initiating the implants we have lowered our 2021 revenue estimate to €4.7m from €14.3m previously. We have also introduced our 2022 estimate of €26.9m in sales, which we view as achievable as the company is already at a €1m per month run rate two months after the first implant and we would expect the implantations to increase going forward as new centres come onboard. Our operating expense estimate was increased by €29.5m for 2021 due to increased spending. For 2022, our operating expense estimate is €78.8m, a 4% increase over our 2021 estimate.

Carmat had €57.9m in cash and equivalents, and around €40.3m in debt at 30 June 2021 (which includes a €10m loan obtained in Q420 that is 90% guaranteed by the French state and whose maturity was recently extended by five years). The company had raised €55.7m in gross proceeds (approximately €52.2m net) in March 2021 in a share offering. 2.3m new shares were issued at a price of €24 per share.

With regards to its liquidity position, 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 the company expects to draw down in Q421. The company believes this funding and its existing cash on hand should fund its operations until the middle of 2022. We project the company will raise €70m through the end of 2022 to cover both the burn rate and provide sufficient working capital. We currently project profitability in 2023 though that will depend on a continued acceleration of uptake. If profitability is attained at a later date, additional raises may be needed.

Exhibit 2: Financial summary

€000s	2019	2020	2021e	2022e
Year end 31 December				
PROFIT & LOSS				
Revenue	0	0	4,650	26,916
Cost of Sales	0	0	(2,676)	(11,467)
Operating Expenses	(27,268)	(46,650)	(75,363)	(78,750)
EBITDA	(41,933)	(47,724)	(75,515)	(63,926)
Depreciation	(1,164)	(932)	(1,303)	(1,555)
Amortization	0	0	0	0
Operating Profit (before amort. and except.)	(43,096)	(48,656)	(76,818)	(65,481)
Exceptionals	0	0	0	0
Other Income	599	12,445	25,815	0
Operating Profit	(42,498)	(36,211)	(51,003)	(65,481)
Net Interest	(1,787)	(2,463)	(1,341)	(463)
Profit Before Tax (norm)	(44,285)	(38,674)	(52,344)	(65,945)
Profit Before Tax (FRS 3)	(44,285)	(38,674)	(52,344)	(65,945)
Tax	1,636	1,711	671	0
Profit After Tax and minority interests (norm)	(42,649)	(36,963)	(51,673)	(65,945)
Profit After Tax and minority interests (FRS 3)	(42,649)	(36,963)	(51,673)	(65,945)
Average Number of Shares Outstanding (m)	11.0	13.0	14.1	15.4
EPS - normalised (€)	(3.89)	(2.85)	(3.66)	(5.02)
EPS - normalised fully diluted (€)	(3.89)	(2.85)	(3.66)	(5.02)
EPS - (IFRS) (€)	(3.89)	(2.85)	(3.66)	(5.02)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	5,611	6,976	7,658	8,103
Intangible Assets	28	17	9	9
Tangible Assets	5,584	6,959	7,649	8,094
Current Assets	59,064	52,859	64,013	57,623
Short-term investments	0	0	0	0
Cash	55,505	35,984	37,277	30,888
Other	3,559	16,875	26,736	26,736
Current Liabilities	(8,601)	(12,499)	(11,839)	(11,839)
Creditors	(8,601)	(12,499)	(11,839)	(11,839)
Short term borrowings	0	0	0	0
Long Term Liabilities	(16,415)	(38,861)	(50,261)	(110,261)
Long term borrowings	(16,415)	(38,861)	(50,261)	(110,261)
Other long term liabilities	0	0	0	0
Net Assets	39,660	8,476	9,570	(56,374)
CASH FLOW				
Operating Cash Flow	(38,458)	(40,569)	(57,633)	(63,926)
Net Interest	(1,787)	(2,463)	(1,341)	(463)
Tax	0	0	0	0
Capex	(649)	(2,225)	(1,991)	(2,000)
Acquisitions/disposals	0	0	0	0
Financing	59,634	5,808	52,251	0
Net Cash Flow	18,741	(39,449)	(8,714)	(66,390)
Opening net debt/(cash)	(20,603)	(39,091)	2,877	12,984
HP finance leases initiated	0	0	0	0
Other	(253)	(2,519)	(1,393)	0
Closing net debt/(cash)	(39,091)	2,877	12,984	79,373

Source: Company reports, Edison Investment Research

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