EDISON

Carmat

Clinical and funding update

A new lease of life and a cash injection

Healthcare equipment & services

The discharge of the second patient implanted with the Carmat heart last August satisfies the 30-day success criteria of the feasibility study. The patient returned home supported by a 3kg portable energy source newly approved for trials, which enhances the clinical and commercial utility of the bio-prosthesis. Carmat has secured a contingent equity line up to €50m, which could fund CE mark approval. We have raised our DCF valuation to €591m from €533m due to running the model forward a year and updating for estimated post-equity raise net cash of €24.8m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/12	0.0	(21.9)	(403.8)	0.0	N/A	N/A
12/13	2.9	(16.2)	(336.5)	0.0	N/A	N/A
12/14e	5.4	(16.3)	(325.4)	0.0	N/A	N/A
12/15e	0.3	(24.5)	(445.3)	0.0	N/A	N/A

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

Patient from CE mark feasibility study discharged

The discharge of the patient implanted on 5 August with the Carmat heart, supported by a portable energy source, demonstrates that a patient with very limited life expectancy has been rehabilitated by the device, and exceeds the 30-day success criteria of the four-patient feasibility study. Furthermore, the approval to develop the energy source in parallel with the prosthesis could help accelerate recruitment into the forthcoming 20-patient pivotal study.

Option to fund CE mark development via equity line

Carmat has agreed a contingent equity line up to €50m gross with Kepler Chevreux, which has committed to an initial €20m tranche of shares over the next 12 months. Shares will be issued at up to a 6% discount to the prevailing share price, implying, at current levels, up to 0.3m new shares at €65.7. It has the option to issue a further two tranches of €15m, envisaged over two successive 12-month periods. The initial €20m tranche provides an estimated cash reach into Q116. Thereafter, the equity line provides flexibility to fund CE mark approval studies.

A route to reimbursement in Europe

Carmat has been selected by the French SEED consortium for inclusion in dialogue with the European Health Technology Assessment agencies, allowing Carmat the opportunity to present its development plan and to enter into early discussions with the agencies, potentially expediting CE mark reimbursement approval.

Valuation: Raised to €591m

We have raised our DCF valuation to €591m from €533m or €122 to €127 per share. This assumes Carmat launches the heart in CE mark regions in H117 and in the US as a humanitarian use device in 2019. If Carmat opts to develop the heart via PMA approval route in the US this could lead to an increase in our valuation to €979m.

4 February 2015

Price	**€69.90**
Market cap	**€301m**

Gross cash (€m) at January 2015	7.7
Shares in issue	4.3m
Free float	34%
Code	ALCAR
Primary exchange	Alternext
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	3.0	(1.4)	(27.8)
Rel (local)	(5.2)	(11.3)	(36.4)

52-week high/low	€99.25	€63.60

Business description

Carmat is developing a biocompatible, artificial heart to satisfy the lack of donor hearts available for terminal heart failure patients. The development process combines the expertise of a wide range of technical and medical experts. Carmat initiated its first clinical study in man in 2013.

Next events

FY14 results	11 February 2015
Clinical update	2015

Analysts

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Edison profile page

Clinical and financial update

The second patient, implanted in August in the four-patient feasibility study of the Carmat bio-prosthetic heart, was discharged in January supported by the portable fuel cell, which has been newly approved for use in clinical studies. The fuel cell provides up to 12 hours of autonomy and is a marked contrast to the hospital console, which is a cumbersome device the size of a fridge. The discharge of the patient shows that the 30-day survival outcome was more than satisfied and this was facilitated by the availability of the energy source. Carmat indicated at September 2014 that the feasibility study was 50% recruited. The pivotal trial will recruit up to 20 patients.

Approval of the device for clinical trials means that physicians are likely to be much more amenable to approve the inclusion of patients in ongoing studies. In addition, the availability of a portable energy source, which is being developed in parallel to the bio-prosthesis, fulfils a key requirement needed for destination therapy approval, that is to say a device designed to be a permanent replacement for a donor heart. Other requirements include clinical data and a positive outcome from long-term durability testing.

The initiation of discussions with the European Health Technology Assessment agencies could facilitate reimbursement approval in CE mark regions, which is an important factor given the heterogeneity of health administration systems in Europe. The Carmat heart was one of four medical technologies selected for inclusion in the discussions by the European SEED consortium, (Shaping European Early Dialogues for health technologies).

Financials and valuation

Carmat has covered its immediate financing needs, and has flexibility on future requirements, by means of a contingent equity agreement up to €50m with Kepler Chevreux. The agreement includes commitment from Kepler to subscribe to an initial €20m of equity over the next 12 months. Carmat has the option to issue a further two tranches, each of €15m, which it envisages will be issued over two subsequent 12-month periods. The terms state that the shares are issued at a discount of up to 6% to the prevailing share price. We have updated our FY15 forecasts, to include €20m financing minus costs, based on the latest closing price discounted at 6% to €65.7, leading to potentially 0.3m shares being issued. Carmat has flexibility to control the timing of share issuance both for the initial and subsequent tranches, and can opt to terminate the agreement at any time. The terms relating to the contingency have not been disclosed.

Our forecasts indicate that the initial €20m tranche will cover Carmat's immediate funding need in FY15, providing a cash reach to Q116. The availability of the remaining €30m gives Carmat the option to issue further shares to supplement funding of CE mark clinical studies, although if it opts to issue the full €30m balance in FY16, our forecasts indicate this would fund the company to CE mark approval. Alternatively, the flexibility of the agreement means that Carmat may seek alternative sources of financing post-2015, needed to fund US development. Its options include securing a partnership with a medical technology company.

Our default assumptions are that Carmat develops the V1 of the heart via the humanitarian device exemption (HDE) route in the US, approving it for a so-called orphan subset of 4,000 patients in the very late stages of heart failure. If it pursues PMA approval either for V1 or for a follow on version, this would result in a longer development timeline, higher costs but a much broader potential market of up to 50,000 patients. We have updated our FY15 forecasts to include the first €20m tranche net of costs, which, in addition to end-September gross cash of €7.7m and a €5.3m subsidy received in December, takes our FY15 net cash forecast to €4m.

Our DCF valuation is €591m, with base assumptions unchanged, but updating for estimated pro forma net cash and running our model forward a year, which leads to an increase from €122 to €127 per share. Our default valuation assumes US V1 approval via HDE. If Carmat opts for a PMA, our indicative valuation would be €979m.

Exhibit 1: Financial summary

€'000s	2012	2013	2014e	2015e
Year end 31 December	French GAAP	French GAAP	French GAAP	French GAAP
PROFIT & LOSS				
Revenue	18	2,874	5,410	291
Cost of Sales	0	0	0	0
Gross Profit	18	2,874	5,410	291
EBITDA	(20,814)	(15,156)	(15,472)	(23,847)
Operating Profit (before GW and except.)	(22,017)	(15,885)	(15,945)	(24,165)
Intangible Amortisation	(271)	(191)	(74)	(66)
Exceptionals	(34)	0	0	0
Other	(98)	(40)	(20)	(20)
Operating Profit	(22,420)	(16,116)	(16,038)	(24,251)
Net Interest	110	(324)	(373)	(322)
Profit Before Tax (norm)	(21,907)	(16,209)	(16,317)	(24,487)
Profit Before Tax (FRS 3)	(22,310)	(16,440)	(16,411)	(24,573)
Tax	5,015	1,770	2,196	3,686
Profit After Tax (norm)	(16,787)	(14,413)	(14,210)	(20,801)
Profit After Tax (FRS 3)	(17,295)	(14,670)	(14,215)	(20,887)
Average Number of Shares Outstanding (m)	4.2	4.3	4.4	4.7
EPS - normalised (c)	(403.8)	(336.5)	(325.4)	(445.3)
EPS - FRS 3 (c)	(416.0)	(342.5)	(325.5)	(447.1)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0
EBITDA Margin (%)	(115,707)	(527)	(286)	(8,195)
Operating Margin (before GW and except.) (%)	(122,392)	(553)	(295)	(8,304)
BALANCE SHEET				
Fixed Assets	2,267	1,633	1,341	1,032
Intangible Assets	168	125	142	107
Tangible Assets	725	945	636	362
Investments	1,373	563	563	563
Current Assets	17,431	20,351	9,145	7,977
Stocks	0	48	57	57
Debtors	6,092	2,952	1,779	1,779
Cash	11,135	16,884	7,099	5,714
Other	204	467	210	426
Current Liabilities	(5,939)	(7,098)	(3,866)	(4,275)
Creditors	(5,327)	(6,254)	(2,594)	(2,594)
Short term borrowings	(460)	(822)	(1,269)	(1,678)
Other	(152)	(22)	(3)	(3)
Long Term Liabilities	(3,817)	(7,654)	(7,654)	(7,654)
Long term borrowings	0	0	0	0
Other long term liabilities	(3,817)	(7,654)	(7,654)	(7,654)
Net Assets	9,941	7,232	(1,034)	(2,921)
CASH FLOW				
Operating Cash Flow	(18,108)	(9,792)	(16,582)	(23,819)
Net Interest	0	0	(373)	(322)
Tax	154	153	866	3,470
Capex	(516)	(266)	(200)	(35)
Acquisitions/disposals	0	0	0	0
Financing	240	11,881	6,131	19,000*
Dividends	0	0	0	0
Net Cash Flow	(18,229)	1,977	(10,158)	(1,706)
Opening net debt/(cash)	(29,153)	(10,675)	(16,062)	(5,830)
HP finance leases initiated	0	0	0	0
Other	(248)	3,410	(74)	(88)
Closing net debt/(cash)	(10,675)	(16,062)	(5,830)	(4,036)

Source: Edison Investment Research, company accounts. Note: *Number of shares shown as issued in our forecast equity line is dependent on prevailing share price at a 6% discount; for the purposes of our model, our FY15 forecast assumes 0.3m shares are issued at a discounted price of €65.7.

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