PRESS RELEASE

CARMAT reports its 2018 half-year results and provides an update on its developments

- With a cash position of €44.0 million at June 30, 2018, financial resources will allow the continuation of clinical and industrial developments through to the granting of CE marking, expected in 2019
- Operating expenses are in line with the transformation of CARMAT into an industrial and commercial company
- The 1st part of the PIVOTAL study has confirmed the bioprosthesis' fundamentals and its adaptability to a broader patient population than initially expected
- More than 50% of patients in the PIVOTAL study have now been implanted

Paris, September 28, 2018 – 7.00 am CEST

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, today announced its results for the first half of the year at June 30, 2018[1] and provides an update on its developments.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: *"The first half of 2018 was marked by a significant acceleration of our project, as we have so far completed the enrollment of half of the patients in the PIVOTAL study and reached a decisive industrialization milestone with the opening of our new manufacturing site. The PIVOTAL study has now moved into its second phase. Indeed, the first phase of this study showed the ability of our prosthesis to provide effective support to patients suffering from end-stage heart failure. Furthermore, the successful heart transplant of the first Kazakh patient, after 8 months of support provided by the CARMAT heart, demonstrates that the latter can also be used in patients suffering from comorbidities that prevent an immediate transplant.*

Beyond this success, one of the main lessons lies in the fact that the size of our bioprosthesis allows us to target a broader patient population than initially expected, as it has been correctly implanted in patients with a smaller thorax size.

Today, we are at a turning point in our project, and are delighted to be able to count on the expertise of the medical teams who are accompanying us in France and abroad. Our objective is to move forward towards the completion of the PIVOTAL study at a dynamic and controlled pace, and we continue our

[1] First-half accounts were approved by the Board on September 27, 2018, and have been the subject of a limited review by the statutory auditors.

efforts to expand the study to other leading European centers, as well as our discussions with the FDA to obtain the approval to initiate a feasibility study in the United States by the end of the year."

- **2018 half-year results**

CARMAT recorded no revenue over the first half of 2018, as its total artificial heart project is still in clinical development. The CE marking process, which is a prerequisite to marketing the product in Europe, is progressing in line with the Company's expectations.

In the first half of 2018, operating expenses increased by 37% to €20.1 million, driven by a number of developments undertaken during the half year, and in particular:

- progress in the CE marking process, with the finalization of all technical modules;
- preparatory work for the opening of the new manufacturing site in Bois-d'Arcy, now operational;
- the ramping up of the PIVOTAL study, with the training of the teams from the international investigation centers involved in the study and the acceleration in patient enrollment.

In €	**30/06/2018**	**30/06/2017**
Operating income		
Operating subsidies		7,000
Other operating income (reversal of provision)	708,481	
Total operating income	**708,481**	**7,000**
Operating expenses		
Purchases and external expenses	13,652,764	10,686,047
Salaries and benefits	5,343,558	3,496,632
Other operating expenses	1,106,148	538,583
Total operating expenses	**20,102,470**	**14,721,262**
Operating profit/loss	-19,393,989	-14,714,262
Financial profit/loss	-455,421	-679,814
Exceptional items	-2,692	-18,752
Research tax credit	986,532	1,318,578
Net profit/loss	**-18,865,570**	**-14,094,250**

Once the financial loss (-€455.4 thousand), exceptional items (-€2.7 thousand) and Research Tax Credit (€1.0 million) are taken into account, the net loss at June 30, 2018 was €18.9 million, versus a loss of €14.1 million over the six months to June 30, 2017.

- **Strong financial structure**

Cash and marketable cash instruments totaled €44.0 million at June 30, 2018, versus €60.7 million at December 31, 2017, due to:

- cash burn of €20.7 million over the first half of 2018;
- drawdowns on the second tranche of the contingent equity line subscribed to with Kepler Cheuvreux, for a gross total of €4.0 million. Given the expiry of the initial contract and in order to continue to benefit from an equity financing reserve, CARMAT[2] has signed a new contract, under identical conditions[3] and for a sum equal to the unused balance, i.e. €25 million, with Kepler Cheuvreux, again acting as financial intermediary. This additional financing ability, to which Kepler Cheuvreux has committed to subscribe to on its own initiative providing the contractual conditions are respected, may be adjusted by the Company in accordance with its requirements

[2] In accordance with the 8th resolution approved by the Shareholders' Meeting of April 5, 2018
[3] Shares will be issued on the basis of the volume-weighted average share price over the two trading days preceding each issue, minus a maximum discount of 6.0%

and market conditions over the coming 36 months[4]. This operation did not require a prospectus to be submitted to the AMF for a visa.

These financial resources will allow the Company to continue its industrial and clinical development until it receives CE marking expected in 2019.

- **PIVOTAL study continuing in line with the aim of completing patient enrollment by end-2018**

  - **Enrollment in the 1st part of the study has been completed**

In July 2018, CARMAT announced that patient enrollment in the first part of the PIVOTAL study had been completed, corresponding to the inclusion of the 10th patient, out of 20 planned for the entire study.

During this first phase, the Company was able to gather important information for its remaining clinical development:

- the bioprosthesis fulfilled its role in accordance with the requirements of the clinical protocol;
- the surgical procedures, 100% successful, showed that the size of the bioprosthesis – equivalent to that of a sick heart – could adapt even to a smaller patient thorax. Initial assumptions, indicating anatomic compatibility for 86% of men and 14% of women, are now considered very conservative;
- the *National Research Center for Cardiac Surgery* (Astana, Kazakhstan) surgical teams successfully carried out the first heart transplant on a patient who benefited from the CARMAT heart for 8 months. This procedure, a world first, highlighted the possibility of using the CARMAT bioprosthesis not only as a definitive therapy, but also as a treatment option while awaiting a transplant (a bridge to transplantation), significantly expanding the targeted patient population. The feasibility of the bridge to transplantation was confirmed by a second heart transplant performed by the Astana teams in a patient who had benefited from the CARMAT bioprosthesis for 5 months.

  - **Start of the 2nd part of the study in the 3 approved countries**

Following the analysis of the clinical data available to date on the first 10 patients, the health authorities of the countries participating in the trials have approved the continuation of the PIVOTAL study without any changes in the protocol.

Patient enrollment in the second part of the study has therefore begun in the investigation centers, under the control of Principal Investigator, Professor Ivan Netuka (Director of the Cardiovascular Surgery Department at the IKEM institute, Prague, Czech Republic), and Co-Principal Investigator, Professor Finn Gustafsson (Rigshospitalet, Copenhagen, Denmark).

Furthermore, CARMAT is still working intensely to expand the PIVOTAL study to other European countries and complete the implantations at the end of 2018.

  - **Enrichment of the PIVOTAL study learning curve**

To date, 11 patients have been treated, i.e. over 50% of the planned number of patients in the study. The efforts of the clinical team are focused on enrolling patients that best meet the inclusion criteria in order to complete the study in line with the schedule and maximize the chances of success.

The CARMAT heart cumulative support time has reached 3 years 5 months. This accumulated experience shows the ability of the CARMAT technology to offer numerous benefits to patients, as well as the stability of its performances observed so far:

- the 1-month survival rate is 91%, versus 75% in the feasibility study, which can be explained by the generally less compromised clinical profile of patients than previously;

[4] Should the entire equity line be utilized, a shareholder with a 1.00% stake in CARMAT beforehand would see this stake reduced to 0.91% on a non-diluted basis

- surgery time has been reduced to 5 hours (versus almost 7 hours for the first three implants) with just 2 hours 40 minutes of extracorporeal circulation (versus close to 3 hours 30 minutes for the first three implants);
- the time before leaving intensive therapy has been cut to 6 days;
- the hospitalization time before patients can return home has been reduced to 35 days.

• Transformation of CARMAT into an industrial and commercial company

▪ Certification of the Bois-d'Arcy manufacturing plant

Following the recent certification of its new automated manufacturing site in Bois-d'Arcy, near Paris, CARMAT now has an industrial site that meets the highest technological standards enabling it to produce up to 800 prostheses a year at full capacity. The assembly of the hybrid membranes with the help of industrial robots is already performed on site.

▪ Development of remote patient monitoring

In order to ensure a better therapeutic follow-up, CARMAT has initiated the development of a remote monitoring solution to record the cardiac parameters of patients as well as the CARMAT heart function data remotely. This solution was developed in collaboration with WISNAM (Acireale - Italy), an expert in the field of connected objects.

• Ongoing restructuring of the teams

CARMAT recently announced the appointment of Thierry Dupoux, previously Worldwide Vice President of Quality Assurance at LivaNova, as Senior Director of Quality Assurance. Following the appointments of a Marketing Manager and a Director of Manufacturing last year, the Company is thus continuing to expand its managerial team in key positions with experts who will support its transformation into an industrial and commercial company.

•••

About CARMAT: the world's most advanced total artificial heart project

A credible response to end-stage heart failure: CARMAT aims to eventually provide a response to a major public health issue associated with heart disease, the world's leading cause of death: chronic and acute heart failure. By pursuing the development of its total artificial heart, CARMAT intends to overcome the well-known shortfall in heart transplants for the tens of thousands of people suffering from irreversible end-stage heart failure, the most seriously affected of the 20 million patients with this progressive disease in Europe and the United States.

The result of combining two types of unique expertise: the medical expertise of Professor Carpentier, known throughout the world for inventing Carpentier-Edwards® heart valves, which are the most used in the world, and the technological expertise of Airbus Group, world aerospace leader.

Imitating the natural heart: given its size, the choice of structural materials and its innovative physiological functions, CARMAT's total artificial heart could, assuming the necessary clinical trials are successful, potentially benefit the lives of thousands of patients a year with no risk of rejection and with a good quality of life.

A project leader acknowledged at a European level: with the backing of the European Commission, CARMAT has been granted the largest subsidy ever given to an SME by Bpifrance; a total of €33 million.

Strongly committed, prestigious founders and shareholders: Airbus Group (Matra Défense), Professor Alain Carpentier, the Centre Chirurgical Marie Lannelongue,Truffle Capital, a leading European venture capital firm, ALIAD (Air Liquide's venture capital investor), CorNovum (an investment holding company held 50-50 by Bpifrance and the French State), the family offices of Pierre Bastid (Lohas) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.), Groupe Therabel as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: *www.carmatsa.com*

•••

CARMAT
Stéphane Piat
Chief Executive Officer

Benoît de la Motte
Chief Financial Officer
Tel.: +33 1 39 45 64 50
contact@carmatsas.com

Alize RP
Press Relations

Caroline Carmagnol

Tel.: +33 1 44 54 36 66
carmat@alizerp.com

NewCap
Investor Relations &
Strategic Communication

Dusan Oresansky
Alexia Faure

Tel.: +33 1 44 71 94 94
carmat@newcap.eu

Name: **CARMAT**
ISIN code: **FR0010907956**
Ticker: **ALCAR**

•••

DISCLAIMER

This press release and the information contained herein do not constitute an offer to sell or subscribe to, or a solicitation of an offer to buy or subscribe to, shares in CARMAT ("the Company") in any country. This press release contains forward-looking statements that relate to the Company's objectives. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties. Potential risks and uncertainties include, without limitation, whether the Company will be successful in implementing its strategies, whether there will be continued growth in the relevant market and demand for the Company's products, new products or technological developments introduced by competitors, and risks associated with managing growth. The Company's objectives as mentioned in this press release may not be achieved for any of these reasons or due to other risks and uncertainties.

No guarantee can be given as to any of the events anticipated by the forward-looking statements, which are subject to inherent risks, including those described in the Document de Référence *registration document filed with the* Autorité des Marchés Financiers *under number D.18-0169 on March 22, 2018, as well as changes in economic conditions, the financial markets or the markets in which CARMAT operates. In particular, no guarantee can be given concerning the Company's ability to finalize the development, validation and industrialization of the prosthesis and the equipment required for its use, to manufacture the prostheses, satisfy the requirements of the ANSM, enroll patients, obtain satisfactory clinical results, perform the clinical trials and tests required for CE marking and to obtain the CE mark. CARMAT products are currently exclusively used within the framework of clinical trials.*