



PRESS RELEASE

2017 half-year results

- Operating expenses in line with the acceleration of the Company's industrial development
- Cash position of €19.9 million at June 30, 2017
- Confirmation of the objective of completing the PIVOTAL study at the end of 2018

Paris, September 26, 2017 – 6 pm CEST

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced artificial heart project, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, today announces its results for the first half of the year to June 30, 2017¹.

Stéphane Piat, CEO of CARMAT, says: *"The first half of 2017 was particularly intense in terms of both clinical and industrial activities. Our teams accomplished outstanding work to resume the PIVOTAL study² in a timeframe enabling us to remain on schedule with our objective of completing the study at the end of 2018. Within this context, in order to carry out additional implants as soon as possible, we have also accelerated our efforts to expand the PIVOTAL study to other European countries. Likewise, we intensified discussions with the FDA to assess our clinical development opportunities in the United States. At the same time, we have continued to invest in our manufacturing capacities in order to have, by the beginning of 2018, an industrial tool that complies with the highest quality and productivity standards."*

• 2017 half-year results

CARMAT recorded no revenue over the first half of 2017, as its total artificial heart project is still in the clinical development phase. The CE marking process, which is a prerequisite to marketing the product in Europe, is ongoing.

In the first half of 2017, operating expenses totaled €14.7 million, an increase of 30% compared with the first half of 2016 due to:

- analyses and actions undertaken by the Company enabling it to be granted approval to resume the PIVOTAL study during the half;
- training of the teams from the investigation centers involved in the study;
- continuation of the CE marking process initiated with DEKRA;
- acceleration of the Company's industrial development, notably with a view to opening a new manufacturing site in early 2018.

¹ First-half accounts were approved by the Board on September 25, 2017, and have been the subject of a limited review by the statutory auditors.

² The PIVOTAL study is the second phase of the clinical trials required to complete the CE Mark clinical file. It follows the feasibility study undertaken on 4 patients.

In €	30/06/2017	30/06/2016
Operating income		
Operating subsidies	7,000	7,000
Other operating income (reversal of provision)		89,827
Total operating income	7,000	96,827
Operating expenses		
Purchases and external expenses	10,686,047	8,269,450
Salaries and benefits	3,496,632	2,748,452
Other operating expenses	538,583	376,342
Total operating expenses	14,721,262	11,394,244
Operating profit/loss	-14,714,262	-11,297,417
Financial profit/loss	-679,814	-590,302
Exceptional items	-18,752	-54,417
Research tax credit	1,318,578	1,768,114
Net profit/loss	-14,094,250	-10,174,022

Once a financial loss (-€679.8 thousand), exceptional items (-€18.6 thousand) and Research Tax Credit (€1.3 million) are taken into account, the net loss at June 30, 2017 was €14.1 million, compared with a loss of €10.2 million over the six months to June 30, 2016.

• Financial structure

At June 30, 2017, the Company had cash and marketable cash instruments of €19.9 million, compared with €31.2 million at December 31, 2016, reflecting similar cash burn to the previous half.

During the first half of 2017, CARMAT carried out several drawdowns on the second tranche of the contingent equity line subscribed to with Kepler Cheuvreux, issuing 132,500 shares for a gross total of €3.6 million, giving an average exercise price of €27.2 and a real discount of -3.3% at June 30, 2017. Within the framework of this financing, CARMAT has access to an additional €34.4 million of financing that may be exercised depending on its requirements and on market conditions.

These financial resources will enable the Company to continue its industrial and clinical development until the beginning of the second quarter of 2018. The Company is looking into a number of different options to prepare the financing of the upcoming stages required to pursue its project. Information on the terms and schedule of any such financing will be published once decided upon, in accordance with usual practices and in compliance with applicable regulations.

• Confirmation of the timeframe of the PIVOTAL study

Throughout the first half of 2017, CARMAT continued its development and the implementation of the measures required to secure its project in accordance with the following fundamental routes:

- Clinical: ongoing screening of patients eligible for the PIVOTAL study and training of the implant centers with a particular emphasis on the quality of the postoperative follow-up, a key criterion in this type of clinical trial. The Company expects implants of its total artificial heart to resume shortly.
- Reliability: putting in place tools and procedures enhancing the safety of the patients participating in the trial, in accordance with the ANSM's demands;
- Production: work on the new automated assembly plant is ongoing, and the site should be completely operational in early 2018. It will allow manufacturing on a larger scale with a higher yield to meet prosthesis requirements during the entire PIVOTAL phase and beyond.

Given the progress made simultaneously on all these critical routes, CARMAT is today able to confirm its objective of completing the PIVOTAL study and submitting the clinical module of the CE marking file at the end of 2018.

- **H1 2017 highlights**

- **Two cardiology experts join the Board**

The Shareholders' Meeting of April 27, 2017 approved the appointment of CEO Mr. Stéphane Piat as a Board member and the cooptation of two cardiology experts as independent Board members:

- Mr. Jean-Luc Lemerrier, Vice-President Transcatheter Heart Valve EMEA with US group Edwards Lifesciences;
- Dr. Michael Mack, an internationally recognized US cardiac surgeon and current Director of Cardiovascular Research at the Baylor Scott & White Health group in Dallas (Texas).

The Board of Directors now consists of 9 members, 4 of them being independent.

- **Setting up a new Free Preferential Share Allocation plan**

Following the approval of the Shareholders' Meeting of April 27, 2017, CARMAT has adopted a Free Preferential Share Allocation plan. The purpose of this type of performance-based remuneration is to align the interests of the Company's management and employees with the interests of the shareholders and various stakeholders. It is an important factor to increase loyalty of teams and attract talented new staff who will support its development. The Free Preferential Share already allocated could be converted into up to 423,000 ordinary shares of CARMAT, subject to the completion of various milestones.

- **Resumption of the PIVOTAL study in France**

On May 2, 2017, the ANSM (French national agency for the safety of medicines and health products) gave CARMAT permission to resume its PIVOTAL study in France. This decision follows the positive outcome of the analyses and actions requested by the regulator.

- **Recent events since end-H1**

- **Strengthening of the managerial team**

In the third quarter of 2017, CARMAT bolstered its managerial team by appointing two new managers with substantial industrial and marketing experience:

- Mr. Wenzel Hurtak, previously Business Director New Products at Contract Medical International GmbH, has been appointed Director of Manufacturing. His main objective is the development and optimization of the Company's manufacturing capacities in order to be ready for the industrial scaling up of the project.
- Mr. Francesco Arecchi, previously Product Manager EMEA Structural Heart at Abbott, has joined the Company as Marketing Manager. His mission is to implement a marketing plan adapted to the specificities of the total artificial heart developed by CARMAT.

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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 (ZAKA) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.) as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com

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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* filed with *the Autorité des Marchés Financiers* under number D.16-0200 on March 22, 2017 and 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.

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CARMAT
Stéphane Piat
CEO

Benoît de la Motte
CFO

Tel.: +33 (0)1 39 45 64 50
contact@carmatsas.com

Alize RP
Press Relations

Caroline Carmagnol
Wendy Rigal

Tel.: +33 (0)1 44 54 36 66
carmat@alizerp.com

NewCap
Investor Relations &
Strategic Communication

Dusan Oresansky
Emmanuel Huynh

Tel.: +33 (0)1 44 71 94 94
carmat@newcap.eu



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