



PRESS RELEASE

2015 half-year results in line with the Company's stage of development

- Operating expenses down 15%
- Cash position of €10.1m at June 30, 2015 (+9.8% compared with December 31, 2014)

Solid clinical progress during the start of the 2nd semester

- Hemocompatibility of the bioprosthesis confirmed by interim results of the feasibility study
- The 3rd patient implanted with a CARMAT heart returns home

Paris, September 10, 2015

CARMAT (FR0010907956, ALCAR, PEA-PME eligible), 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 heart failure, today announces its results for the first half to June 30, 2015¹.

• 2015 half-year results

In euros (€)	30/06/2015	30/06/2014
Operating income		
of which: Operating subsidies		10,000
of which: Other operating income (reversal of provision)	2,854	39,342
Total operating income	2,854	49,342
Operating expenses		
of which: Other purchases and external expenses	6,120,297	7,955,409
of which: Other operating expenses	3,050,714	2,787,583
Total operating expenses	9,171,010	10,742,993
Operating profit/loss	-9,168,156	-10,693,651
Financial profit/loss	-460,292	-238,046
Exceptional items	-11,320	-89,036
Research tax credit	1,440,331	1,096,276
Net profit/loss	-8,199,438	-9,924,457

¹ Half-year results were approved by the Board on September 9, 2015 and have been the subject of a limited review by the Company's statutory auditors.

No revenue was recorded by the Company over the period, as CARMAT's total artificial heart project is still in its clinical development phase and has yet to obtain CE marking, a prerequisite to marketing the product in Europe.

Operating expenses totaled €9.2m in the first half of 2015. Their 15% decrease compared with the first half of 2014 is in line with the reduction in R&D expense after the completion of the portable patient system.

Preparing industrialization of the prosthesis manufacturing consumed a substantial portion of the Company's resources, notably with improvements in the prosthesis' manufacturing and quality processes.

The clinical teams continued to focus their efforts on the ongoing feasibility study and on the training of the investigation centers' teams.

Once a financial loss (-€460k), exceptional items (-€11k) and Research Tax Credit (€1,440k), are taken into account, the net loss was -€8.2m in the first half of 2015.

• **Financial structure**

The Company had a cash position of €10.1m at June 30, 2015 versus €9.2m at December 31, 2014. This includes €2.2m in research tax credit recognized at December 31, 2014 and fully reimbursed by the tax authorities on June 29, 2015, as well as net income associated with drawdowns on the contingent equity line (equity warrants) put in place with Kepler Cheuvreux at the start of the year. These drawdowns resulted in the creation of 133,100 ordinary shares with a unit nominal value of €0.04 and in the payment of a net issuance premium of €8.3m. The remaining drawdowns that may be undertaken via this contingent equity line within the framework of the first tranche that expires at the end of January 2016 total €11.6m. As a reminder, the Company has access to two additional optional tranches of €15m valid for 12 months each.

CARMAT is still due to receive a further €1.9m² in subsidies and repayable advances within the framework of the contract with Bpifrance.

These financial resources will allow CARMAT to pursue its clinical development and ensure the progress of its activities through 2016.

• **H1 2015 highlights**

▪ **Clinical development**

The regulatory authorities having approved the use of the portable power and alert system in the ongoing feasibility study, allowing the patient implanted with the CARMAT bioprosthetic heart at Nantes University Hospital on August, 2014 to be discharged in early January 2015. The portable system is now available to all patients taking part in the clinical study.

After this second patient returned home, CARMAT's clinical teams continued to monitor the implanted heart and provide the patient with all the necessary support until his passing early May. They participated in the analysis and resolution of the malfunction, in constant liaison with the technical teams, and kept the ANSM (French health authority) continually updated on the progress made. They provided the necessary support for the implantation of a CARMAT heart in a third patient in April 2015 and his monitoring from that date. By the end of the first half of 2015, clinical data had been collected over a total time period of over 14 months.

▪ **Industrialization and production**

The Company has continued to implement actions aimed at improving quality, notably in terms of subcontractor controls, analysis and risk management. The R&D teams have identified the reason for the malfunction of the prosthesis in May. They have identified the industrial solution and overseen its implementation. They have developed a software tool predicting malfunctions and thus ensuring better patient monitoring and care.

² Balance still due within the framework of the master contract with Bpifrance for reaching the two final milestones, n° 6 and n° 7, consisting of €159,166 in subsidies and €1,741,218 in repayable advances.

- **Participation in the EUnetHTA SEED program**

At the end of January 2015, CARMAT was chosen to participate in the EUnetHTA SEED project. This program allows the Company to initiate preliminary dialogue with European Health Technology Assessment agencies regarding new health products that are currently in the development stage prior to receiving CE marking.

- **Changes in the Company's Board of Directors and Management team**

In March 2015, CARMAT's Board of Directors decided to co-opt Mrs. Anne-Pascale Guédon, representative of Matra Défense, a 100% subsidiary of Airbus Group, as a Director of CARMAT, replacing Mr. Michel Finance, who stepped down. Mrs. Guédon co-option was approved by the Shareholders' Meeting of June 24, and will allow the Company to benefit from her financial and industrial expertise when defining its strategic orientations.

In May 2015, CARMAT continued to develop its organizational structure in line with the growth of the project by appointing Mr Benoît de la Motte as its Chief Financial Officer.

- **Events since the end of H1 2015**

- **Publications and scientific congresses**

In late July 2015, the prestigious European medical journal The Lancet published the article by Professor Alain Carpentier called [*First clinical use of a bioprosthetic total artificial heart: report of two cases*](#), which presented the data resulting from an analysis of the first two implants. Professor Carpentier commented on the interim results of the feasibility study at the ESC Congress in London on August 31, results that notably confirm the hemocompatibility of the CARMAT prosthesis.

- **The 3rd patient has returned home**

Following a rehabilitation period at Strasbourg University Hospitals, the patient operated on by the Georges Pompidou European Hospital - *Assistance Publique-Hôpitaux de Paris* (AP-HP) surgical team in April has returned home. The patient received training in the use of the portable system and will continue to be monitored by CARMAT's clinical teams.

- **Outlook**

The next scientific stage is the completion of the feasibility study, marked by an analysis of at least 30-day data from all 4 patients.

If the final results of this feasibility study are deemed to be satisfactory, the Company could then provide the supervisory authorities in France and other countries with the protocol for a new study covering around twenty patients monitored over a longer period, 180 days for example. It should be noted that the protocol for this future study has yet to be finalized, as it will in large part depend on the lessons learned from the current feasibility study.

The data from this future study and from supplementary in-vitro tests³ will enable CARMAT to file for CE Marking, which is a prerequisite for the bioprosthesis' commercialization in Europe.

The Company is assessing the effects of the progress made by the feasibility study and its interim results on the one hand, and the various ongoing actions in the clinical and industrial fields on the other, on the project's anticipated schedule.

Marcello Conviti, Chief Executive Officer of CARMAT, says: *"Over the first half of 2015, we made significant progress in every aspect of our project. From a medical and clinical perspective, our patients' return home thanks to our portable system is a major success, as it allows us to monitor the prosthesis' response to everyday situations. The scientific input from the second patient and, more recently, the third patient are thus invaluable to us regarding the future of this project. From an industrial perspective, our technical teams have been able to find and implement appropriate solutions to ensure that the prosthesis functions optimally following the implant."*



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

³ Please refer to the Company's 2014 registration document that was registered with the AMF on March 16, 2015 under reference n° D.15-0138, chapter 2.2.3.2 Development.

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](#), Professor [Alain Carpentier](#), the [Centre Chirurgical Marie Lannelongue](#), [Truffle Capital](#), a leading European venture capital firm, and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com



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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.15-0138 on March 16, 2015, 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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