



## PRESS RELEASE

### 2015 annual results in line with CARMAT's stage of development

- Stable operating expenses
- Cash position of €3.0m at December 31, 2015

### 2016 outlook:

- €50.0m equity financing to reinforce CARMAT's cash resources
- Upcoming European launch of the PIVOTAL study

#### Paris, February 26, 2016

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 annual results for year-end 2015<sup>1</sup>.

#### • 2015 annual results

In euros (€)	31/12/2015	31/12/2014
Operating income		
Operating subsidies	14,350	10,000
Other operating income (reversal of provision)		39,342
<b>Total operating income</b>	<b>14,350</b>	<b>49,342</b>
Operating expenses		
Purchases and external expenses	13,392,496	14,030,567
Salaries and benefits	5,681,630	5,065,503
Other operating expenses	707,582	822,280
<b>Total operating expenses</b>	<b>19,781,708</b>	<b>19,918,350</b>
Operating profit/loss	-19,767,358	-19,869,008
Financial profit/loss	-837,644	-476,155
Exceptional items	-89,293	-127,078
Research tax credit	3,148,534	2,209,185
<b>Net profit/loss</b>	<b>-17,545,761</b>	<b>-18,263,056</b>

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

<sup>1</sup> Annual accounts were approved by the Board on February 24, 2016. Audit procedures relative to these accounts have been carried out. The auditor's report is currently being prepared.

Operating expenses totaled €19.8m in 2015, stable compared with December 31, 2014 and in line with the Company's stage of development. The majority of these resources were devoted to improving the prosthesis' manufacturing and quality processes, to the feasibility study completed in early 2016 and to training the investigation centers' teams.

Once a financial loss (-€838k), exceptional items (-€89k) and Research Tax Credit (€3.1m), are taken into account, the net loss was €17.5m in 2015.

## • Financial structure

At December 31, 2015, the Company had a cash position of €3.0m, versus €9.2m at December 31, 2014. This includes income associated with drawdowns on the contingent equity line (equity warrants) put in place with Kepler Cheuvreux in January 2015. These drawdowns led to the creation of 190,100 ordinary shares over the year with a unit nominal value of €0.04 and to the payment of a net issuance premium of €11.1m. This first tranche of the contingent equity line expired at the end of January 2016, with a carry-over balance of €8.5m in 2016. The Company has access to 2 additional optional tranches of €15m for 2016 and 2017.

CARMAT is still due to receive €1.9m<sup>2</sup> in subsidies and repayable advances within the framework of the contract with Bpifrance, as well as €3.1m in Research Tax Credit recognized at December 31, 2015.

## • 2015 highlights

### ▪ Clinical development

In 2015, CARMAT made substantial progress within the framework of the feasibility study:

- the portable power and alert system was made available to all the patients taking part in the clinical trial, and provided total satisfaction for the trial's 2<sup>nd</sup> and 3<sup>rd</sup> patients, with the support and remote monitoring enabling extensive information to be gathered regarding the prosthesis' behavior in real-life situations;
- at the end of 2015, all recruitments had been carried out for the feasibility study, thus allowing CARMAT to accumulate substantial experience with a view to completing this study.

### ▪ 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 confirmed the hemocompatibility of the CARMAT prosthesis.

### ▪ Industrialization and production

The Company has developed actions aimed at improving quality, notably in terms of subcontractor controls, analysis and risk management. The R&D teams identified the reason for the malfunction of the prosthesis in May. They identified the industrial solution and oversaw its industrial implementation. They developed a software set-up that predicts this malfunction, thus ensuring better patient monitoring and care.

### ▪ Reimbursement process: participation in the EUnetHTA SEED program

In January 2015, CARMAT was selected to take part in the EUnetHTA SEED program, which allows the Company to hold preliminary talks with European health technology assessment agencies from the medical device's development stage until it receives CE Marking, the aim being to obtain its reimbursement. These discussions with European agencies are continuing.

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<sup>2</sup> 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

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

In 2015, CARMAT further strengthened its governance:

- the Shareholders' Meeting of June 24, 2015 approved the co-option of Mrs. Anne-Pascale Guédon, representative of Matra Défense, a 100% subsidiary of Airbus Group, as a Director of CARMAT;
- in May 2015, Mr. Benoît de la Motte was appointed Chief Financial Officer of CARMAT.

- **Key events since the end of 2015**

- **Completion of the feasibility study**

The Company has completed the feasibility study, which has allowed the CARMAT system to accumulate 21 months of clinical experience. CARMAT now has all the elements it needs to prepare the PIVOTAL clinical trial.

- **50 Million Euro equity financing to reinforce CARMAT's cash resources**

The Company has today announced the launch of a reserved capital increase project for approximately 50 Million Euros. A pool of strategic investors, ALIAD, Air Liquide's venture capital investor, CorNovum, an investment holding company that will be held 50-50 by Bpifrance and the French State (Programme des Investissements d'Avenir - PIA), the family offices of Pierre Bastid (ZAKA) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.), and core shareholders Airbus Group (Matra Défense) and Truffle Capital (via an existing fund and a number of new funds) will fully subscribe this €50.0m equity financing. This reserved capital increase may be potentially supplemented by a private placement among qualified investors of a size yet to be determined.

The round of financing will allow CARMAT to finance further industrial and clinical development with a view to requesting the CE Mark.

- **Outlook**

CARMAT is continuing to analyze the data from the feasibility study in order to complete the file that will be submitted to the ANSM (French national agency for the safety of medicines and health products). If the definitive results of the feasibility study are deemed to be satisfactory, the Company will be able to initiate the PIVOTAL study in France and in other European countries in accordance with the protocol currently being finalized and which should involve 20 to 25 patients monitored over a 180-day period.

The data from this new study and from supplementary in-vitro tests<sup>3</sup> will enable the Company to file for CE Marking, which is a prerequisite for the bioprosthesis to be marketed in Europe.

**Marcello Conviti, Chief Executive Officer of CARMAT, says:** *"2015 provided us with a wealth of knowledge and information regarding our project. We faced complex technical situations that we were able to overcome thanks to the commitment of our teams. We also experienced a particularly emotional period. The contribution of the surgical teams and of all our patients, in particular the 4<sup>th</sup> patient, and their families has enabled us to complete the feasibility study and reach a crucial stage in our unique technological and medical journey. We would again like to pay tribute to them. It should also be noted that the analysis of the malfunction of the 2<sup>nd</sup> implanted prosthesis required substantial human and financial resources. We are now in a position to initiate the PIVOTAL study. This is why we have today decided to launch a refinancing project via a reserved capital increase, which should provide us with the necessary financial means to calmly and confidently tackle this final stage prior to obtaining CE Marking for our bioprosthesis."*



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<sup>3</sup> 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.

## 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, and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

**For more information:** [www.carmatsa.com](http://www.carmatsa.com)



### 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.15-0138 on March 16, 2015 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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