



## PRESS RELEASE

### 2016 half-year results in line with the progress achieved by the Company

- Operating expenses in line with the roadmap
- Solid cash position of €43.4m at June 30, 2016
- PIVOTAL clinical study currently underway in France

#### Paris, September 8, 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 results for the first half of the year to June 30, 2016<sup>1</sup>.

#### • 2016 half-year results

In euros (€)	30/06/2016	30/06/2015
Operating income		
Operating subsidies	7,000	
Other operating income (reversal of provision)	89,827	2,854
<b>Total operating income</b>	<b>96,827</b>	<b>2,854</b>
Operating expenses		
Purchases and external expenses	8,269,450	6,120,297
Salaries and benefits	2,748,452	2,765,364
Other operating expenses	376,342	285,350
<b>Total operating expenses</b>	<b>11,394,244</b>	<b>9,171,010</b>
Operating profit/loss	-11,297,417	-9,168,156
Financial profit/loss	-590,302	-460,292
Exceptional items	-54,417	-11,320
Research Tax Credit	1,768,114	1,440,331
<b>Net profit/loss</b>	<b>-10,174,022</b>	<b>-8,199,438</b>

The Company recorded no revenue over the first half of 2016, as CARMAT's total artificial heart project is still in its clinical development phase. The CE marking process, which is a prerequisite to marketing the product in Europe, is underway.

Operating expenses for the six months to June 30, 2016 totaled €11.3m, in line with the Company's stage of development over the first half. Their 24% increase was due to preparatory work for the PIVOTAL clinical study, with a substantial portion devoted to training the chosen investigation centers' teams, actions associated with the CE marking process and the continuation of the Company's industrial development actions.

<sup>1</sup> First-half accounts were approved by the Board on September 7, 2016, and have been the subject of a limited review by the statutory auditors.

Once a financial loss (-€590.3k), exceptional items (-€54.4k) and Research Tax Credit (€1.8m) were taken into account, the net loss at June 30, 2016 was €10.2m, compared with a loss of €8.2m at June 30, 2015.

- **Strengthened financial structure**

At June 30, 2016, cash and marketable cash instruments totaled €43.4m, an increase of €40.4m compared with December 31, 2015 given the €50m reserved capital increase carried out during the first half of the year.

Moreover, CARMAT is still due to receive €1.9m<sup>2</sup> in subsidies and repayable advances within the framework of the contract with Bpifrance. €2.2m of the €3.1m of Research Tax Credit recognized at December 31, 2015 was the subject of an assignment with an accredited body. The remaining Research Tax Credit due in 2016 is therefore €0.9m.

Lastly, the Company subscribed to a contingent equity line with Kepler Cheuvreux in January 2015: the balance on the 1<sup>st</sup> Tranche is €8.1m, giving, with the other two Tranches being for €15m each, an available total of €38.1m.

These financial resources support the Company's industrial and clinical development in order to obtain CE marking.

- **H1 2016 highlights**

- **End of the feasibility study**

The Company has completed the feasibility study, which enabled it to accumulate 21 months of clinical experience in the working CARMAT system and provided it with the necessary information to prepare the PIVOTAL clinical trial.

- **Participation in the ISHLT annual meeting in Washington DC**

In April, CARMAT presented its bioprosthetic heart to European and American opinion leader cardiologists and surgeons at the 36<sup>th</sup> [ISHLT \(International Society for Heart & Lung Transplantation\)](#) annual meeting, one of the world's largest forums in this field, which took place in Washington DC.

- **CE certification process initiated with DEKRA**

The Company has signed with DEKRA, a global leader in certification services, a contract to assess its design dossier and quality management system with a view to obtaining CE marking. This assessment is a major prerequisite to marketing the CARMAT prosthesis, as it aims to validate the bioprosthesis' compliance with European regulatory requirements.

- **Recent events**

- **Start of the PIVOTAL clinical study in France**

The PIVOTAL study phase on CARMAT's bioprosthetic artificial heart has begun, in accordance with the authorizations obtained from the ANSM (French national agency for the safety of medicines and health products) and CPP (patient protection committee). The data resulting from this study and that obtained by supplementary in-vitro tests<sup>3</sup> will be added to the CE marking dossier, to seek the marketing of the bioprosthesis in Europe.

- **Stéphane Piat has been appointed CEO of CARMAT**

The Board of Directors has appointed Stéphane Piat as CARMAT's new CEO, effective September 1, 2016, thus replacing Marcello Conviti. The Company having reached a crucial stage in its development

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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.

<sup>3</sup> Please refer to the Company's 2015 registration document that was registered with the AMF on March 29, 2016 under reference n° D.16-0221.

with the effective launch of the PIVOTAL study and the pre-marketing phase, the Board of Directors felt that Stéphane's acknowledged expertise in the field of medical devices would be a key asset in the execution of CARMAT's market access strategy.



#### 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](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.16-0221 on March 29, 2016 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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