



## PRESS RELEASE

### 2016 Annual Results

- Operating expenses in line with the Company's development
- Solid cash position of €31.2m at December 31, 2016

Paris, February 14, 2017 – 7:30 am CET

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 announces its annual results for the year to December 31, 2016<sup>1</sup>.

#### • 2016 annual results

In euros (€)	31/12/2016	31/12/2015
Operating income		
Operating subsidies	173,167	14,350
Other operating income (reversal of provision)	89,827	
<b>Total operating income</b>	<b>262,994</b>	<b>14,350</b>
Operating expenses		
Purchases and external expenses	17,912,185	13,392,496
Salaries and benefits	6,174,384	5,681,630
Other operating expenses	755,633	707,582
<b>Total operating expenses</b>	<b>24,842,202</b>	<b>19,781,708</b>
Operating profit/loss	-24,579,208	-19,767,358
Financial profit/loss	-1,142,716	-837,644
Exceptional items	-75,370	-89,293
Research tax credit	2,817,116	3,148,534
<b>Net profit/loss</b>	<b>-22,980,178</b>	<b>-17,545,761</b>

The Company recorded no revenue in 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.

<sup>1</sup> Annual accounts were approved by the Board on February 10, 2017. Audit procedures relative to these accounts have been carried out. The auditor's report is currently being prepared.

Operating expenses totaled €24.8m over the year to December 31, 2016, and were in line with the Company's development over the past year.

The 26% increase was notably due to:

- preparatory work for, and the launch of, the PIVOTAL clinical study, a substantial portion of which was devoted to train the investigation centers' teams,
- activities associated with the CE marking process initiated with DEKRA,
- the continuation of the Company's industrial development activities.

With the financial loss (-€1.1m), exceptional items (-€75k) and Research Tax Credit (€2.8m) accounted for, the net loss at December 31, 2016 was €23m, compared with a loss of €17.5m at December 31, 2015.

#### • **Strengthened financial structure**

At December 31, 2016, cash and marketable cash instruments totaled €31.2m, an increase of €28.1m compared with December 31, 2015, given the €50m reserved capital increase carried out during the first half of the year.

CARMAT is due to receive €1.9m<sup>2</sup> in subsidies and repayable advances within the framework of the contract with Bpifrance and €2.8m in Research Tax Credit recognized at December 31, 2016.

Lastly, the Company subscribed to a contingent equity line with Kepler Cheuvreux in January 2015: the balance on the first Tranche is €8.1m, giving – with the other two Tranches being for €15m each – an available total of €38.1m. Since this contingent equity line was put in place in January 2015, 210,100 new shares have been issued for a gross total of approximately €12.1m, i.e. an average exercise price of €57.44.

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

#### • **2016 highlights**

##### ▪ **CE certification process initiated with DEKRA**

The Company has signed with DEKRA, a Notified Body and global leader in certification services, a contract to assess its design dossier and quality management system with a view to obtaining the CE marking that will validate the CARMAT system's compliance with European regulatory requirements.

##### ▪ **Clinical development**

The feasibility study, completed in early 2016, allowed the Company to accumulate 21 months of clinical experience of the CARMAT system, with over a third of this using the portable patient system allowing some patients to be discharged from hospital, and provided the Company with the necessary information to prepare the PIVOTAL clinical study.

The PIVOTAL study was launched during the summer of 2016, following 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.

The PIVOTAL study was suspended by CARMAT following the death of the first study patient, who was implanted at the end of August 2016. The analyses undertaken have shown that the prosthesis functioned correctly, and the death was due to incorrect battery handling by the patient. The ANSM has requested additional elements, which are currently being prepared by CARMAT. With these elements, the Company later expects to file a request to resume the study.

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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.

- **Stéphane Piat appointed CEO of CARMAT**

Effective September 1, 2016, Stéphane Piat is the Company's new Chief Executive Officer. His acknowledged expertise in the medical device sector, acquired with major North American cardiology groups, represents a key asset in executing CARMAT's clinical and market-access strategy.

- **Scientific conferences**

In 2016, CARMAT showcased its bioprosthetic heart to the heart failure opinion leaders' community at three benchmark events:

- the 36<sup>th</sup> ISHLT (International Society for Heart & Lung Transplantation) annual meeting in Washington DC, United-States (April 27 to 30, 2016).
- the 30<sup>th</sup> EACTS (European Association for Cardio-Thoracic Surgery) annual meeting in Barcelona, Spain (October 1 to 5, 2016),
- the 11<sup>th</sup> EUMS (European Mechanical Circulatory Support Summit) in Berlin, Germany (November 3 to 5, 2016).

- **Recent events and 2017 outlook**

- **Changes in governance**

In January, CARMAT announced the co-optation of two cardiology experts as independent Board members:

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

Subject to the approval of these appointments by the next Shareholders' Meeting, CARMAT's 8-member Board of Directors will thus have four independent directors.

- **2017 outlook**

In accordance with its clinical strategy, CARMAT confirms that it is working on expanding the PIVOTAL study to other European countries, in addition to France. The aim is to accelerate enrolment in the study and, more importantly, to optimize the selection of patient profiles in order to maximize the study's chances of success.

Furthermore, CARMAT is already studying development opportunities on the US market and has been in contact with the FDA (Food and Drug Administration), the American market having the greatest potential for mechanical circulatory support systems.

The fundraising operation carried out last year also enabled targeted investments to be launched in the development of manufacturing processes. The latter will provide results with regard to quality and productivity from the start of the first half of this year.

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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](http://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.16-0221 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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