

# **PRESS RELEASE**

# **2017 Annual Results**

- Solid cash position of €60.7 million at December 31, 2017, following the successful capital increase in December
- Operating expenses in line with the acceleration in activities associated with the CE marking process and the Company's industrial development

## Paris, February 13, 2018 – 8 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 ending December 31, 2017<sup>1</sup>.

**Stéphane Piat, Chief Executive Officer of CARMAT, says:** "2017 saw the completion of a number of strategic objectives we had set when I was appointed CEO of CARMAT. On a clinical level, we successfully deployed the PIVOTAL study abroad, by performing the first implantations of our bioprosthesis in Kazakhstan and the Czech Republic, in medical centers renowned for their expertise in undertaking clinical trials with cardiac devices for the European market. We also continued to train medical teams in four additional countries, which should allow us to complete the study on time. Our discussions with the FDA are progressing in accordance with our goal of initiating a first clinical evaluation in the United States during 2018. From an industrial standpoint, our technical teams have intensified their efforts, and we should soon have a modern and efficient production tool. The arrivals of Wenzel Hurtak as Director of Manufacturing and Francesco Arrechi as Marketing Manager has accelerated CARMAT's transformation into an industrial and commercial company. On the back of these breakthroughs, we successfully completed a €52.9 million capital increase enabling us to finance our industrial and clinical development through to CE marking, which we expect in 2019."

<sup>&</sup>lt;sup>1</sup> Annual accounts were approved by the Board of Directors on February 12, 2018. Audit procedures relative to these accounts have been carried out. The auditor's report is currently being prepared.

### • Strengthened financial structure

At December 31, 2017, cash and marketable cash instruments of €60.7 million, a substantial increase compared to December 31, 2016 (€31.2 million) due to:

- the completion of a €52.9 million capital increase in December 2017;
- drawdowns on the second tranche of the contingent equity line subscribed to with Kepler Cheuvreux for a gross total of €8.0 million. Within the framework of this financing, CARMAT has access to an additional €29.9 million of financing that may be exercised depending on its requirements and on market conditions.

These financial resources will allow the Company to continue its industrial and clinical development until it receives CE marking, which is expected in 2019.

#### • 2017 annual results

CARMAT recorded no revenue in 2017, as its total artificial heart is still in clinical development. The CE marking process, which is a prerequisite to marketing the product in Europe, is progressing in line with the Company's expectations.

Operating expenses totaled €31.1 million in 2017, a 25% increase on 2016 due to:

- the continuation of the CE marking process undertaken with DEKRA materialized by the completion of the majority of the technical dossier;
- the ramping up of the Company's industrial development with a view to opening a new manufacturing site in the first quarter of 2018;
- the analyses and actions undertaken by the Company enabling it to be granted approval to resume the PIVOTAL study during the first half of the year;
- the internationalization of the PIVOTAL study, notably with the training of the teams from the investigation centers involved in the study and the performing of the first implantations in Kazakhstan and the Czech Republic.

In euros (€)	31/12/2017	31/12/2016
Operating income		
Operating subsidies	28,000	173,167
Other operating income (reversal of provision)		89,827
Total operating income	28,000	262,994
Operating expenses		
Purchases and external expenses	21,889,776	17,912,185
Salaries and benefits	7,383,695	6,174,384
Other operating expenses	1,789,126	755,633
Total operating expenses	31,062,597	24,842,202
Operating profit/loss	-31,034,596	-24,579,208
Financial profit/loss	-472,363	-1,142,716
Exceptional items	-55,642	-75,370
Research tax credit	2,334,690	2,817,116
Net profit/loss	-29,227,910	-22,980,178

Once a financial loss (- $\in$ 472.3 thousand), exceptional items (- $\in$ 55.6 thousand) and Research Tax Credit ( $\in$ 2.3 million) are taken into account, the net loss at December 31, 2017 was of  $\in$ 29.21 million, versus a loss of  $\in$ 23.0 million at December 31, 2016.

## • 2017 highlights

In 2017, CARMAT achieved major breakthroughs on all of its project's fundamental routes:

#### Clinical development

- On May 2, 2017, the ANSM (French national agency for the safety of medicines and health products) granted CARMAT the approval to resume the PIVOTAL study in France.
- During the second half of 2017, CARMAT internationalized the PIVOTAL study by performing the first human implantations of its bioprosthesis in Kazakhstan and the Czech Republic, in compliance with the protocol approved by the ANSM and the authorizations received from those countries' respective health authorities.
- In accordance with its clinical strategy, the Company is pursuing its efforts aimed at expanding the PIVOTAL study to four other European countries and initiating a clinical study in the United States in 2018.

#### Industrial development

- During the second half of 2017, work on the new automated assembly plant entered its final phase, and the site should become fully operational during the first quarter of 2018. It will allow manufacturing on a larger scale with a higher yield to meet the requirements of the PIVOTAL phase and the commercial launch.
- In November 2017, CARMAT signed a partnership agreement with AddUp, the Michelin and Fives Joint Venture, regarding a unique collaboration in the medical sector that will eventually lead to the 3D printing of certain components and the production acceleration in the commercial phase.

#### Governance and management

- Cooptation of 2 cardiology experts as independent Board members:
  - Mr. Jean-Luc Lemercier, Corporate Vice-President EMEA, Canada & Latin America at Edwards Lifesciences;
  - Dr. Michael Mack, a US cardiac surgeon and Director of Cardiovascular Research at the Baylor Scott & White Health group in Dallas (Texas).
- Appointment of 2 managers with substantial industrial and marketing experience:
  - Mr. Wenzel Hurtak, previously Business Director New Products at Contract Medical International GmbH, as Director of Manufacturing;
  - Mr. Francesco Arecchi, previously Product Manager EMEA Structural Heart at Abbott, as Marketing Manager.

Thanks to these strategic appointments, CARMAT has an enhanced expertise to obtain CE marking, complete the ongoing industrial transformation and successfully develop and deploy its European and American market access strategy.

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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<sup>®</sup> 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  $\in$  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 (Babalia) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.), Groupe Therabel as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: <u>www.carmatsa.com</u>

CARMAT Stéphane Piat Chief Executive Officer

Benoît de la Motte Chief Financial Officer Tel.: +33 1 39 45 64 50 contact@carmatsas.com •••

Alize RP Press Relations

#### **Caroline Carmagnol**

Tel.: +33 1 44 54 36 66 <u>carmat@alizerp.com</u>



Name: CARMAT ISIN code: FR0010907956 Ticker: ALCAR

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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.16-0200 on March 22, 2017, and in an update to the Registration Document of the Company filed with the AMF on December 4, 2017 under number D.17-0200-A01, as well as 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.

# NewCap

Investor Relations & Strategic Communication

Dusan Oresansky Emmanuel Huynh

Tel.: +33 1 44 71 94 94 carmat@newcap.fr