



PRESS RELEASE

CARMAT reports its 2018 annual results and confirms its 2019 development prospects

- Increase in operating expenses in line with the strategic achievements of the Company in 2018
- Strengthened financial structure via the drawdown on the first €10 million tranche of the EIB loan

Paris, February 13, 2019 – 8.00 am CET

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, 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, 2018¹ and confirms its 2019 development prospects.

Stéphane Piat, Chief Executive Officer of CARMAT, says: *"In 2018, CARMAT reached major development milestones, including notably the completion of the first part of the PIVOTAL study, with positive clinical results, as well as the certification of the new manufacturing site in Bois-d'Arcy, near Paris. Furthermore, we have continued to hold constructive discussions with the American health authorities with a view to launch a clinical trial in the United States this year. With these strategic achievements, we are in an ideal position to address the next crucial steps, consisting first and foremost in completing the PIVOTAL study this year and subsequently obtaining CE marking to pave the way for the marketing of our bioprosthesis in Europe. With the support of our new Chairman of the Board of Directors, Jean-Pierre Garnier, the teams at CARMAT are more determined than ever to provide a therapeutic solution for patients suffering from end-stage biventricular heart failure."*

• **2018 annual results**

As the total artificial heart being developed by CARMAT is still in clinical development, the Company recorded no revenue in 2018.

The structure and increase in operating expenses, which totaled €43.5 million (+40% compared with 2017), reflect the achievement of strategic priorities of the Company, and notably:

- the continuation of the CE marking process undertaken with DEKRA, with the confirmation of the objective of submitting the technical dossier in 2019;
- the conduction of the PIVOTAL study, with the positive results of the first cohort of 10 patients having been presented by CARMAT on January 15, 2019;

¹ Annual accounts were approved by the Board of Directors on February 11, 2019. Audit procedures relative to these accounts have been carried out, and the auditor's report is currently being prepared.

- the ramping up of industrial capacity of the Company with the certification of the new manufacturing site in Bois-d'Arcy, near Paris, and the transfer of the majority of production to that site during the year;
- the ongoing transformation of CARMAT into an industrial and commercial company, notably with the strengthening of its sales and marketing structure and the adaptation of its IT system.

In thousands of euros (€)	31/12/2018	31/12/2017
Operating income		
Revenue	-	-
Other operating income	722	28
Total operating income	722	28
Operating expenses		
Purchases and external expenses	30,672	21,890
Salaries and benefits	10,726	7,384
Other operating expenses	2,091	1,789
Total operating expenses	43,489	31,063
Operating profit/loss	-42,766	-31,035
Financial profit/loss	-945	-472
Exceptional items	-2	-56
Research tax credit	1,984	2,335
Net profit/loss	-41,729	-29,228

Once other income statement items are taken into account, and notably reversals of operating provisions (other operating income) of €708.8 thousand, a financial loss of -€944.8 thousand and Research Tax Credit of €2.0 million, CARMAT recorded a net loss of €41.7 million in 2018, compared with a net loss of €29.2 million in 2017.

• 2018 highlights

Enrollment completed for the first part of the PIVOTAL study and launch of the second part

During 2018, CARMAT completed the enrollment of the 10 patients in the first cohort of the PIVOTAL study. As recently announced, 70% of the patients in this first cohort reached the primary endpoint of the study, corresponding to six-month survival with the bioprosthesis or a successful heart transplant within 6 months after the device implant.

The international investigation centers have also begun the screening of patients in the second cohort, with the first patient being implanted in September 2018.

Structuring of the management and governance

During 2018, CARMAT expanded its governance and management with experienced profiles, corresponding to the internationalization of its project:

- appointment, in December 2018, of Jean-Pierre Garnier as the new Chairman of the Board of Directors: a scientist and business leader with a PhD in Pharmacology from Louis Pasteur University and an MBA from Stanford University, Jean-Pierre Garnier was notably President and CEO of pharmaceutical group GlaxoSmithKline (GSK) from 2000 to 2008 and Chairman of Actelion (Biotechnology) from 2011 to 2017;
- appointment of Thierry Dupoux as Senior Director of Quality Assurance and Pascale d'Arbonne as Chief Financial Officer, both of whom have substantial experience – including international experience – in the Health sector.

- **2019 outlook**

In 2019, CARMAT intends to continue focusing its efforts and resources on its strategic priorities:

- finalization of the PIVOTAL study with the completion of the enrollment of the second cohort of patients in the short term;
- submission of the CE marking technical dossier;
- granting of authorization, by the FDA (Food and Drug Administration, the US health authority), to undertake an Early Feasibility Study (EFS) in the United States;
- continuous improvement in the automation and reliability of the manufacturing process;
- preparation for the commercial launch of the prosthesis.

- **Solid cash position and drawdown on the first tranche of the EIB loan**

Financial structure at December 31, 2018

At December 31, 2018, the Company had a cash position of €25.3 million, versus €60.7 million at the end of 2017.

Furthermore, CARMAT is notably benefiting from:

- a contingent equity line subscribed to with Kepler Cheuvreux, within the framework of which it had, at December 31, 2018, access to an additional €24.2 million (which may be exercised depending on its requirements and on market conditions, until end-September 2020); and
- non-dilutive financing from the European Investment Bank (EIB) via a €30 million loan agreement signed on December 17, 2018. At the end of the 2018 financial year, CARMAT had not yet made use of this loan.

Given these elements, the Company is confident in its ability to successfully undertake its clinical development and prepare for the commercial phase.

Drawdown on the first tranche of the EIB loan

The financing agreement signed with the EIB allows CARMAT to borrow up to €30 million via three tranches of €10 million each.

Within the context of the positive interim results of the first part of the PIVOTAL study, published by CARMAT on January 15, the Company carried out the drawdown on the first tranche of the EIB loan, i.e. €10 million, on January 31, 2019.

The drawdowns on the second and third tranches are subject to certain technical and financial milestones, including the successful execution of clinical trials and/or the raising of additional funds.

The amounts borrowed bear an average fixed interest rate of 8% for the first tranche, 8% for the second tranche and 5% for the third tranche. The reimbursement of each tranche will take place at the end of the loan period (bullet payment), i.e. five years from the date of the drawdown on this specific tranche.

The loan contract provides for certain information and operational commitments (such as limits on authorized debt, approval for external growth operations, etc.). Failure to comply with these conditions would give the EIB the right, if deemed necessary, to demand an early reimbursement of the loan.

The occurrence of certain changes in the shareholding structure or a change in management not approved beforehand by the EIB would also allow the latter, if deemed necessary following discussions with the Company, to demand an early reimbursement of the loan.

The loan is not secured. Any new Group subsidiary becoming material with respect to the financial contract would be personally liable for the Company. To date, CARMAT has no subsidiaries.

Furthermore, the Company has signed a royalty agreement with the EIB that provides for the payment to the latter of additional remuneration depending on the commercial performance of the Company. This agreement is valid for 13 years from the year during which the cumulative sales of CARMAT reach €500,000. The Company can decide to terminate the royalties contract at any time by paying a lump sum (net of any royalties already paid), which depends on the amount borrowed and the year during which the decision is taken.

Upon the occurrence of certain events (in particular should the EIB demand the early repayment of the loan or should a new shareholder reach 33% of the voting rights of CARMAT), the EIB could, if deemed necessary, demand from CARMAT an advance payment of royalties up to a certain percentage of the amount of the loan effectively used (this percentage would range from 100% of the borrowed amount if the event occurs during the first four years of the financial contract to 160% if the event occurs after the eleventh 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 Chirurgicale 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 (Lohas) 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: 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 registration document filed with the Autorité des Marchés Financiers under number D.18-0169 on March 22, 2018, 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.