



## PRESS RELEASE

### **CARMAT reports its 2019 annual results and confirms its 2020 objectives**

- Operating expenses under control in a context of intensifying the European market access strategy
- Strong cash position of €55.5 million at December 31, 2019, providing financial visibility until mid-2021
- Full FDA approval for a clinical feasibility study in the United States, with enrollment expected to begin in the fourth quarter of 2020

**Paris, February 12, 2020 – 7.00 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 reports its annual results for the year ending December 31, 2019<sup>1</sup>, and presents its 2020 development prospects.

**Stéphane Piat, Chief Executive Officer of CARMAT, said:** *“2019 was a crucial year for CARMAT, as we were able to successfully strengthen all strategic pillars of our project: the manufacturing system, the quality of the bioprosthesis that is continuing to fulfill its role within the PIVOTAL study in line with expectations, and the Company’s financial structure. Firstly, we completed the transfer of all our manufacturing activities to the Bois-d’Arcy site, where the production of prostheses resumed in May following the implementation of the final technical adjustments. This had a direct effect on the PIVOTAL study that was then able to gradually resume thanks to the approvals received from the health authorities in Denmark, the Czech Republic and Kazakhstan. The 12<sup>th</sup> patient of the study was thus able to benefit from the new prosthesis in December, enabling us to reach over 7 years of cumulative support to date within the framework of the study. At the same time, we continued our very constructive discussions with the FDA that led, in September, to the conditional approval being granted to undertake a feasibility study in the United States. Since then, we have responded to all remaining questions and recently obtained the full approval of the FDA that will enable us to accelerate discussions with the 7 chosen American medical centers, but also with the Centers for Medicare & Medicaid Services (CMS) to obtain coverage of the costs of the study, for which enrollment could begin during the fourth quarter of 2020. Lastly, we significantly strengthened our financial structure through a €60 million private placement with investors who share our long-term vision. These funds have provided us with a financial visibility through to mid-2021 and the necessary resources to continue achieving various milestones of our project, notably including our key objective of obtaining CE marking in 2020.”*

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<sup>1</sup> Annual accounts were approved by the Board of Directors on February 10, 2020. Audit procedures relative to these accounts have been carried out, and the auditor’s report is currently being prepared.

## 2019 annual results

As the total artificial heart is still in its clinical development phase, CARMAT generated no revenue in 2019.

The annual operating loss was €42.4 million, a slight improvement compared with 2018 (which saw an annual operating loss of €42.8 million).

In 2019, CARMAT's operating expenses totaled €43.1 million, a slight decrease of €0.4 million on 2018 thanks to the cost rationalization efforts undertaken by the Company, notably in the second half of 2019.

Operating expenses were thus primarily allocated to:

- studies and tests undertaken within the framework of the process for obtaining CE marking on one hand, and approval to initiate an EFS (early feasibility study) in the United States on the other;
- ensuring the reliability of the production process and preparing for the ramping up of production at the Bois-d'Arcy plant;
- continuing the transformation of CARMAT into an industrial and commercial company.

<b>Simplified income statement (€ millions)</b>	<b>2019</b>	<b>2018</b>
<b>Operating income</b>	<b>0.7</b>	<b>0.7</b>
<b>Operating expenses</b>	<b>-43.1</b>	<b>-43.5</b>
<b>Operating profit/loss</b>	<b>-42.4</b>	<b>-42.8</b>
Financial profit/loss	-1.8	-0.9
Exceptional items	-0.1	-0.0
Research tax credit	+1.6	+2.0
<b>Net profit/loss</b>	<b>-42.6</b>	<b>-41.7</b>

The doubling of the financial loss from -€0.9 million in 2018 to -€1.8 million in 2019 was a result of the increase in the interest on loans, the Company having carried out, at end-January 2019, the drawdown on the €10 million first tranche of the €30 million conditional loan granted in December 2018 by the EIB (European Investment Bank).

Once exceptional items (-€0.1 million) and Research Tax Credit (+€1.6 million) are taken into account, the 2019 annual net loss was €42.6 million in 2019, versus a loss of €41.7 million in 2018.

### • 2019 highlights

#### Major progress towards European market access

In terms of European market access, CARMAT submitted, in July 2019, its technical dossier to the DEKRA certification body.

Moreover, implants within the framework of the PIVOTAL clinical study resumed in December, following the granting of the approvals required for this study in all its investigation centers in Denmark, the Czech Republic and Kazakhstan. As of December 31, 2019, 12 patients had been implanted within the framework of the study, including 10 patients from the first cohort and 2 patients from the second cohort of 10 patients whose enrollment is continuing.

The positive results obtained from the study's first cohort, presented in January 2019, were confirmed and strengthened with the presentation, in November 2019, of the results recorded with the first 11 patients having been implanted: 73% of these patients achieved the primary endpoint of the study,

corresponding to 6-month survival with the bioprosthesis or a successful heart transplant within 6 months of the device being implanted. The data gathered from the patients again confirm the prosthesis' fundamentals, and notably its biocompatibility and excellent safety profile, never achieved before by other technologies, principally as a result of the absence of any cerebrovascular accidents, gastrointestinal bleeding or infections due to the percutaneous cable. To date, the prosthesis has achieved, within the framework of the PIVOTAL study, over 7 years of cumulative continuous support taking into account all the patients who have benefited from the prosthesis.

### **Conditional approval granted to conduct a feasibility study in the United States**

Regarding the Company's development in the United States, in September 2019, CARMAT obtained the conditional approval from the FDA (Food and Drug Administration, the US health authority) to initiate an Early Feasibility Study (EFS) at 7 renowned US health centers selected by CARMAT.

### **A strengthened manufacturing system that meets future commercial requirements**

During the first half of 2019, CARMAT completed the transfer of all its production activities to its new industrial site at Bois-d'Arcy, where production effectively resumed in May. The new manufacturing processes incorporated the lessons learnt from the experience accumulated during the first part of the PIVOTAL study and the test benches, enabling the Company to further enhance the prosthesis' reliability.

All prostheses are henceforth manufactured at the Bois-d'Arcy plant where the production processes comply with the very stringent standards governing the production of medical devices. The Company is continuing to focus on the continuous improvement of its processes, the securing of its supplies and the ramping up of its production in preparation for its commercial phase. Within this context, Mr. Alexandre Eléonore, new Director of Manufacturing with substantial experience and in-depth knowledge of this sector, joined the management team of CARMAT in November 2019.

### **Enhanced financial visibility**

At December 31, 2019, the Company had a cash position of €55.5 million, versus €25.3 million at December 31, 2018. This change in the cash position was notably due to:

- the €60 million raised through a private placement in September 2019;
- the drawdown on the €10 million first tranche of the EIB loan at the end of January 2019;
- the operating cash burn of €41 million over the year.

This level of cash should cover CARMAT's financing requirements until mid-2021.

The fundraising carried out in September 2019, supported by the Company's longstanding shareholders, enabled the entry of prestigious new entrepreneur and family shareholders into CARMAT's capital structure including the Gaspard family, which owns the Lyreco group (Corely Belgium SPRL and Bratya SPRL), and Mr. Pierre-Edouard Stérin, founder of Smartbox (BAD 21 SPRL), who are eager to be by CARMAT's side over the long term.

Furthermore, the Company also has access to:

- two additional €10 million tranches of the EIB loan, use of which is subject to certain technical milestones being achieved;
- a balance of €22 million on the contingent equity line subscribed to with Kepler-Cheuvreux in September 2018, which may be exercised until end-September 2020.

### **• Recent events and 2020 outlook**

CARMAT recently announced that it had obtained full approval from the FDA to launch an Early Feasibility Study (EFS) of its total artificial heart in the United States. The amended EFS protocol has been extended to 10 transplant-eligible subjects, and the primary endpoint is identical to that of the European PIVOTAL study, i.e. patient survival at 180 days after the implant or a successful heart transplant within 180 days of the implant. A progress report on the first 3 patients after 60 days will be assessed by the FDA prior to the enrollment of the following 7 patients. CARMAT has also obtained the conditional approval of two hospitals' Institutional Review Boards (IRB), and is in ongoing discussions with the other IRBs and research contract offices. The Company is also working closely with the Centers for Medicare & Medicaid

Services (CMS) to obtain coverage of the costs of the study, with the aim of starting patient enrollment in the fourth quarter of 2020.

In 2020, CARMAT intends to focus its resources on its strategic priorities:

- rapidly complete the enrollment in the PIVOTAL study, and obtain CE marking;
- begin implants within the framework of the EFS in the United States;
- continue enhancing the reliability of its processes and the ramping up of its production;
- prepare for the commercial launch of the prosthesis.

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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, composed of the implantable bioprosthesis and its portable external power supply system to which it is connected, 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.

**The first physiological artificial heart:** given its size, the use of highly biocompatible materials, its unique self-regulation system and its pulsatile nature, the CARMAT total artificial heart could, assuming the clinical trials are successful, potentially save the lives of thousands of patients each 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:** Matra Défense SAS (subsidiary of the Airbus Group), 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 (Lohas), of Dr. Antonino Ligresti (Santé Holdings S.R.L.), of the Gaspard family (Corely Belgium SPRL and Bratya SPRL) and of M. Pierre-Edouard Stérin (BAD 21 SPRL), 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](http://www.carmatsa.com)

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**CARMAT**  
**Stéphane Piat**  
Chief Executive Officer

**Pascale d'Arbonneau**  
Chief Financial Officer  
Tel.: +33 1 39 45 64 50  
[contact@carmatsas.com](mailto:contact@carmatsas.com)

**Alize RP**  
Press Relations

**Caroline Carmagnol**

Tel.: +33 6 64 18 99 59  
[carmat@alizerp.com](mailto:carmat@alizerp.com)



**NewCap**  
Investor Relations &  
Strategic Communication

**Dusan Oresansky**  
**Alexia Faure**

Tel.: +33 1 44 71 94 94  
[carmat@newcap.eu](mailto:carmat@newcap.eu)

Name: **CARMAT**  
ISIN code: **FR0010907956**  
Ticker: **ALCAR**

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*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.19-0135 on March 12, 2019, 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.*