**PRESS RELEASE**

# CARMAT reports its 2022 half-year results and issues an update on its latest progress and main strategic objectives

- Aeson® implants expected to resume in October 2022
- Strong demand from hospitals
- Cash position of €47 million, providing cash runway until March 2023

**Paris, September 15, 2022 – 7:00 am CEST**

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 results for the first half of the year to June 30, 2022[1] and issues an update on its latest progress and main strategic objectives.

**Stéphane Piat, Chief Executive Officer of CARMAT, commented:** "*In the first half of 2022, we focused our efforts on our primary goal of resuming implants of Aeson® hearts in October. Thanks to the work undertaken by our teams and our suppliers, who I would like to thank, we were able to restart production at the end of March following the implementation of the necessary changes in our supply chain.*

*At the same time, we have made good progress in our discussions with the various regulatory stakeholders in Europe (DEKRA), France (ANSM) and the United States (FDA), whose approvals are required for us to resume implants commercially and as part of clinical trials. In order to meet the strong demand from physicians and prepare for the resumption in implants, our teams have also intensified the training provided to European medical centers, taking the number of hospitals ready to perform Aeson® implants in Germany, France and Italy to 17.*

*Finally, I would like to thank our longstanding and new shareholders for their vital support as we raised €40.5 million back in April.*

*Given our progress, we are in a good position to resume Aeson® implants during the final quarter of this year, as planned, and are more confident than ever in our ability to make Aeson® a benchmark treatment in end-stage heart failure over the coming years*".

[1] First-half results were approved by the Board on September 13, 2022 and have been the subject of a limited review by the statutory auditor. The 2022 half-year report was published today and is available on the Company's website.

- **2022 half-year results**

| **Simplified income statement** (€ millions) | **30/06/2022** (6 months) | **30/06/2021** (6 months) |
|---|---|---|
| **Sales** | **0.0** | **0.0** |
| **Net operating income (expense)** | **-25.1** | **-25.5** |
| Net financial income (expense) | -1.9 | -1.5 |
| Net non-recurring income (expense) | 0.0 | 0.0 |
| Research and innovation tax credit | +0.9 | +0.7 |
| **Net profit (loss)** | **-26.0** | **-26.4** |

CARMAT did not record any sales during the first half of 2022, as a result of its decision to suspend implants voluntarily and temporarily on December 2, 2021.

The Company is building up inventories of implantable prostheses with the objective to resume implants in October 2022, provided that regulatory approvals are granted by relevant authorities.

During the first half of this year, CARMAT's efforts and resources were predominantly focused on:

- defining and implementing preventive and corrective actions to address quality issues that occurred in late 2021;
- resuming production following the implementation of these actions both at its Bois-d'Arcy plant and with its suppliers;
- working with regulatory bodies and preparing the regulatory filings necessary to resume implants;
- working with suppliers to increase production volumes;
- and supporting hospitals and physicians with training, education and reimbursement support so they are ready to resume implants.

The Company kept operating expenses under control even as extensive resources were deployed to make the prosthesis more reliable and secure the supply chain, leading to an operating loss of €25.1 million for the first half of 2022 (compared to a loss of €25.5 million for the first half of 2021).

Taking into account the net financial loss (-€1.9 million) and the Tax Credit (+€0.9 million), the net loss amounted to €26.0 million in the first half of 2022 (compared to a loss of €26.4 million for the first half of 2021).

- **Cash position and financial structure**

The Company had a cash position of €47.4 million as of June 30, 2022, compared to €39.2 million as of December 31, 2021.

The €8.2 million increase in cash in the first half of 2022 was a result of the following cash flows:

| (€ millions) | **30/06/2022** (6 months) | **30/06/2021** (6 months) |
|---|---|---|
| Cash flow from operating activities | -30.5 | -29.4 |
| Cash flow from investment activities | -1.1 | -1.0 |
| Cash flow from financing activities | +39.8 | +52.3 |
| **Change in cash position** | **+8.2** | **+21.9** |

In terms of financing, in the first half of 2022 the Company:

- raised €40.5 million, of which €36.5 million via a private placement for strategic and specialized investors and €4.1 million from individuals via the PrimaryBid platform;
- obtained €0.7 million by drawing on the equity financing line put in place with Kepler-Cheuvreux, which expired on March 27, 2022.

CARMAT's financial resources[2] should allow the Company to finance its operations, according to its current business plan, until March 2023.

The Company is confident that it is well positioned to raise additional funding needed for future development and commercialization.

- **H1 2022 highlights and recent events**

**Preparations for the resumption of Aeson® implants planned in October 2022**

On December 2, 2021, following the occurrence of quality issues affecting certain components of its prosthesis, CARMAT decided to voluntarily and temporarily suspend all implants of its Aeson® artificial heart, both commercially and in clinical trials.

Based on ongoing interactions with regulatory bodies, the Company expects to resume implants in October 2022 following approvals by regulators. The Company is actively manufacturing new prostheses that incorporate improvements to avoid past quality issues from recurring.

Implementation of corrective and preventive actions and resumption in production

From December 2021, the Company focused on characterizing identified quality issues. Corrective and preventive actions were defined and implemented at Bois-d'Arcy plant and by relevant suppliers and subcontractors with oversight from CARMAT.

Production with implementation of all corrective and preventive actions resumed by the end of the first quarter of 2022. Each of these actions is the subject of an assessment that is continuing.

Progress with regard to regulatory processes

CARMAT submitted in early August 2022 a 'notification of change' to its notified body (DEKRA). Based on usual review timeframes and current interactions, the Company is reasonably confident that regulatory approval will enable the Company to resume commercial implants of Aeson® in October in the European Union and countries that recognize CE marking.

Regarding the EFICAS clinical study in France, CARMAT submitted in early September 2022 a request to the ANSM (French National Agency for Medicine and Health Product Safety) to resume this clinical trial. Given usual review timeframes, the Company expects to receive the ANSM's approval by October, which would pave the way for the first Aeson® implants in this study of 52 patients, the aim of which is to collect medico-economic data to support Aeson®'s value proposition and reimbursement in France.

Lastly, CARMAT is working with the FDA to resume implants in the US Early Feasibility Study. CARMAT submitted two regulatory submissions to the FDA in July 2022, and plans to submit the last one in September. After their review, the Company expects to file an Investigational Device Exemption (IDE) Supplement request to the FDA, that would enable enrollment of the second cohort (7 patients) of this study involving 10 patients.

Training, education and reimbursement support for hospitals

In response to the substantial hospital interest in Aeson®, and in order to allow for strong momentum in implants in the months following their resumption, the Company has continued and accelerated training provided to medical centers since the beginning of the year, in particular in Germany, Italy and France.

[2] Primarily including the cash position at June 30, 2022 (€47.4 million), the Research Tax Credit relative to 2021 that will be received by the end of 2022 (€1.9 million) and the €13 million in financing obtained from the French State to partially fund the EFICAS study (this sum will be gradually received as patients are enrolled in this trial, which is due to begin in the final quarter of 2022).

At the end of June 2022, 17 centers had been trained (10 in Germany, 1 in Italy and 6 in France in preparation for the EFICAS study), and more will be trained during the second half of this year.

At the same time, CARMAT also continued to support the various medical centers in their attempts to secure reimbursement for therapy from the various paying agents.

**Changes in governance**

Board of Directors & management

The Annual General Meeting of May 11, 2022 approved the reduction of the term of office of the Company's directors from 6 to 3 years. The Board of Directors chaired by Jean-Pierre Garnier currently has 11 members, including 7 independents directors. Their terms of office will expire in 2025 at the end of the Annual General Meeting called to approve the Company's accounts for the year ending December 31, 2024.

On July 1, 2022, Mr. Francesco Arecchi, previously Director of Global Market Development, expanded his responsibilities to include all of the Company's marketing, sales and training activities. This development follows the scheduled departure of Eric Richez, Sales Director, at the end of the first half of this year.

Severance payments and non-competition commitment

During its session of September 13, 2022, the Board of Directors, on the recommendation of the Appointments and Compensation Committee, decided that Mr. Stéphane Piat, Board member and Chief Executive Officer of CARMAT, would benefit from a severance payment representing up to 18 months of pay (fixed and variable)[3] should he be forced to stand down from his duties[4]. An agreement has been signed to this effect by the Company and Mr. Stéphane Piat. This contract also imposes various exclusivity, non-competition, non-solicitation, confidentiality, and intellectual property commitments on Mr. Piat. Mr Piat could be paid a monthly compensation representing 40% of his fixed monthly remuneration with respect to the non-competition commitment for a period of 12 months following his departure from the Company[5]. The Company believes that the amount and terms of these payments are appropriate given the highly sensitive and risky nature of its activities.

## • Strategy and outlook

The Company's primary objective for the second half of 2022 is the effective resumption in implants from October 2022, in line with its action plan that aims to:

- ramp up production following the resumption process initiated in the first half of 2022;
- obtain the regulatory approvals required to resume implants;
- train hospitals and support them to seek reimbursement, which will generate demand and allow strong momentum in implants once resumed.

Given the improvement in the COVID-19 situation, CARMAT is not anticipating any major adverse impact in the second half of 2022, but it is closely monitoring the situation both in France and in other countries where the Company, its suppliers and customers operate. CARMAT could have to adjust its outlook should the situation deteriorate.

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[3] The maximum compensation that could be paid corresponds to 75% of the remuneration (fixed and variable) due to or received by Mr. Stéphane Piat for the two financial years preceding the termination of his duties. Of this maximum amount, two thirds are unconditional. The remaining third could be fully or partly paid to Mr. Stéphane Piat, at the sole discretion of the Board of Directors, on the basis of its appraisal of the Company's performance over the previous two years, as well as of Mr. Piat's personal contribution to this performance. It is specified that the maximum termination compensation includes any legal and statutory allowances that may be due, and the amount of this severance pay plus any non-competition compensation due with respect to Mr. Stéphane Piat's non-competition commitment, will be capped at two years of remuneration (fixed and variable).

[4] Except if Mr. Stéphane Piat is dismissed as a result of serious misconduct or gross negligence.

[5] The Board of Directors could, when the time comes, decide to waive this non-competition commitment, in which case no non-competition compensation would be due. No compensation will be due if Mr. Stéphane Piat retires, nor once he reaches 65.

## About CARMAT

CARMAT is a French MedTech that designs, manufactures and markets the Aeson® artificial heart. The Company's ambition is to make Aeson® the first alternative to a heart transplant, and thus provide a therapeutic solution to people suffering from end-stage biventricular heart failure, who are facing a well-known shortfall in available human grafts. The world's first physiological artificial heart that is highly hemocompatible, pulsatile and self-regulated, Aeson® could save, every year, the lives of thousands of patients waiting for a heart transplant. The device offers patients quality of life and mobility thanks to its ergonomic and portable external power supply system that is continuously connected to the implanted prosthesis. Aeson® is commercially available as a bridge to transplant in the European Union and other countries that recognize CE marking. Aeson® is also currently being assessed within the framework of an Early Feasibility Study (EFS) in the United States. Founded in 2008, CARMAT is based in the Paris region, with its head offices located in Vélizy-Villacoublay and its production site in Bois-d'Arcy. The Company can rely on the talent and expertise of a multidisciplinary team of more than 200 highly specialized people. CARMAT is listed on the Euronext Growth market in Paris (Ticker: ALCAR / ISIN code: FR0010907956).

For more information, please go to www.carmatsa.com and follow us on LinkedIn.

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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

**Alize RP**
Press Relations

**Caroline Carmagnol**
Tel.: +33 6 64 18 99 59
carmat@alizerp.com

**NewCap**
Financial Communication
& Investor Relations

**Dusan Oresansky**
**Quentin Massé**
Tel.: +33 1 44 71 94 92
carmat@newcap.eu


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ELIGIBLE PEA PME

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

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The significant and specific risks pertaining to the Company are those described in the Universal Registration Document ("Document d'Enregistrement Universel") filed with the Autorité des Marchés Financiers (AMF, the French stock market authorities) under number D.22-0332. Readers and investors' attention is, however, drawn to the fact that other risks, unknown or not deemed to be significant or specific, may or could exist.

Aeson® is an active implantable medical device commercially available in the European Union and other countries that recognize CE marking. The Aeson® total artificial heart is intended to replace the ventricles of the native heart and is indicated as a bridge to transplant in patients suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who are not amenable to maximal medical therapy or a left ventricular assist device (LVAD) and are likely to undergo a heart transplant within 180 days of the device being implanted. The decision to implant and the surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician manual, patient manual and alarm booklet) should be read carefully to understand the characteristics of Aeson® and information necessary for patient selection and the proper use of Aeson® (contraindications, precautions, side effects). In the United States, Aeson® is currently exclusively available within the framework of an Early Feasibility Study authorized by the Food & Drug Administration (FDA).