

PRESS RELEASE

CARMAT accelerates its sales momentum and reiterates its confidence in its development outlook

- 20 implants of the Aeson® artificial heart performed in the first half of 2024
- Pace of 4 implants per month in the second guarter
- Half-year sales at €3.2 million, higher than the 2023 full-year sales
- Unique safety and performance profile of Aeson® confirmed, based on more than 70 implants made since inception

Videoconference in French this evening at 6:00 pm CEST. To participate, <u>please register by clicking on this link</u>.

Paris, July 9, 2024 - 7:00 am CEST

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from advanced biventricular heart failure (the "**Company**" or "**CARMAT**"), provides an update on its achievements over the first half of 2024 and reiterates its confidence in its development outlook.

Stéphane Piat, Chief Executive Officer of CARMAT, comments: "Overall, our first-half achievements are very positive. With sales of €3.2 million (i.e., 20 implants) in the first 6 months of the year, we have already exceeded our 2023 annual sales; and the trajectory is extremely encouraging, with twice as many implants in the second quarter as in the first.

With 14 implants since January 1st and a total of 25 since its initiation, the momentum of our EFICAS study in France is excellent. We expect to pass the halfway mark of the targeted 52 inclusions in the study very soon, which means we can anticipate completing these inclusions in the first half of 2025. This progress demonstrates that, once introduced to Aeson®, healthcare professionals rapidly adopt the therapy, which is a positive signal for our ongoing commercial development.

Building on these achievements, on a European network of 42 hospitals trained for commercial implants, on 3 commercially active countries (Germany, Italy, and Poland) and 6 others now ready, as well as on our growing and convincing clinical experience (70 implants carried out since the inception of CARMAT), I am confident that our sales will continue to grow gradually, quarter after quarter; and this, all the more as awareness around Aeson® is growing, notably driven by spontaneous communication from many centers that have implanted Aeson®.

I would like to thank our teams for their commitment and determination, and all our shareholders, whose support make these advances possible. More than ever, we remain resolutely committed to making CARMAT a leader in the field of advanced heart failure."

Marked acceleration in sales

20 Aeson® implants were performed in the first half of 2024, versus 3 in the first half of 2023. The pace of Aeson® implants reached 4 per month in the second quarter of this year, doubling from 2 hearts per month in the first quarter.

In the first 6 months of 2024, CARMAT generated sales of €3.2 million, already exceeding the annual sales for 2023 (€2.8 million).

Sales were achieved for the first time in Poland, bringing the number of commercially active countries to 3 (Germany, Italy, and Poland). A total of 9 hospitals implanted Aeson® for the first time in 2024, including 4 in Germany, 3 in France and 2 in Poland.

This very positive trend reflects an encouraging spread of the therapy across Europe.

Excellent momentum in EFICAS study

Since the beginning of 2024, 14 Aeson® implants¹ were made as part of the EFICAS study in France, at a pace of more than 2 implants per month.

This brings the total number of Aeson® implants performed to date in this study to 25, which paves the way for the imminent completion of half of the targeted recruitments, i.e. 52 patients in total.

All French centers taking part in the study (10 in total²) have already referred patients, and 9 of them have performed at least one implant. The hospitals of Lille, Rennes, and the Hôpital Européen Georges Pompidou (HEGP) in Paris have each already carried out 5 implantations, which reflects the marked satisfaction of healthcare professionals with the therapy, as they become familiar with Aeson® and identifying eligible patients.

CARMAT anticipates publishing the results of the EFICAS study in the last quarter of 2025. The Company believes that this will lead to a strong and sustained acceleration in the adoption of Aeson® in Europe.

EFICAS is also a key study both for securing reimbursement for Aeson® in France and obtaining the "PMA" (marketing authorization in the United States issued by the FDA - Food & Drug Administration), which the Company anticipates in 2027.

• Business development continues

In the first half of 2024, CARMAT trained 9 new hospitals for Aeson® commercial implants, expanding its network to 42 centers in 14 different countries³. The Company is thus well on track to meet its target of 50 trained hospitals by the end of 2024.

Of these 42 centers, three-quarters are active, having already submitted patient scanners to CARMAT to assess patients' eligibility for implantation.

In addition, 6 countries (Switzerland, Austria, Slovenia, Croatia, Greece, and Israel) have now been activated and are therefore ready to carry out implants. The Company plans to activate more countries in Europe in the second half of the year.

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¹ Data as of July 1, 2024 (included).

² AP-HP GHU Pitié Salpêtrière, Hôpital Européen Georges Pompidou, CHU de Rennes, CHU de Strasbourg, Hospices Civils de Lyon, CHRU de Lille, Hôpital Marie-Lannelongue, CHU de Montpellier, CHU de Nantes and CHU de Dijon

³ Germany, Italy, Poland, Switzerland, Israel, Slovenia, Saudi Arabia, Serbia, Croatia, Austria, Denmark, Netherlands, Czech Republic and Greece.

Outlook

With over 70 patients implanted since inception, corresponding to 27 patient-years, CARMAT benefits from substantial and convincing clinical experience with Aeson®, which continues to confirm the technology's unique performance and safety profile, even though the Company tends to treat patients at an increasingly severe stage of the disease.

Based on this promising set of clinical data, Aeson® benefits from a growing reputation within the medical community, particularly supported by a ripple effect between centers, spontaneous positive communication from physicians and institutions performing implants, and CARMAT's regular presence at medical and scientific conferences and forums.

Building on this experience and visibility, as well as on the on-going development of a very solid network of trained hospitals across Europe (three-quarters of which are already active), the Company is confident in the gradual spread of its technology in Europe. This should be further strengthened, from the end of 2025, by a key catalyst i.e. the publication of the results of the EFICAS study, the largest ever conducted by CARMAT

For the second half of 2024, CARMAT anticipates that the quarterly sales growth observed in the first part of the year will continue to reach annual sales of around €14 million.

CARMAT's cash runway currently extends to the end of September 2024, and the Company continues to work very actively on securing the financial resources it needs to pursue its development beyond this timeframe.

Next financial press release

2024 Half-Year Results: September 30, 2024 (before stock market opening)

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 circa 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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This press release and the information contained herein do not constitute an offer to sell or subscribe, nor a solicitation of an order to buy or subscribe to CARMAT shares in any country.

This press release may contain forward-looking statements by the Company regarding its objectives and prospects. These forward-looking statements are based on the current estimates and anticipations of the Company's management and are subject to risk factors and uncertainties, including those described in its universal registration document filed with the Autorité des Marchés Financiers (AMF) under number D.24-0374 and available on Carmat's website.

Readers' attention is particularly drawn to the fact that the Company's current cash runway is limited to the end of September 2024, the Company being subject to other risks and uncertainties, such as the Company's ability to implement its strategy, the pace of development of CARMAT's production and sales, the pace and results of ongoing or planned clinical trials, technological evolution and competitive environment, regulatory changes, industrial risks, and all risks associated with the company's growth management. The Company's forward-looking statements mentioned in this press release may not be achieved due to these elements or other risk factors and uncertainties, unknown or not considered material and important by the Company to date.

Aeson® is an active implantable medical device commercially available in the European Union and other countries recognizing 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 for patients suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who cannot benefit from maximal medical therapy or a left ventricular assist device (LVAD) and who are likely to undergo a heart transplant within 180 days of implantation. 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 carefully read to understand the features of Aeson® and the information necessary for patient selection and proper use (contraindications, precautions, side effects). In the United States, Aeson® is currently exclusively available as part of an Early Feasibility Study approved by the Food & Drug Administration (FDA).