PRESS RELEASE

CARMAT reports its 2023 half-year results and provides an update on its strategic progress

- Revenue of €0.6 million in H1 2023, negatively impacted by supply disruptions
- Production back to normal since the summer: inventory of c. 20 Aeson® hearts to date
- 40 hospitals trained to date, 25 of them for commercial implants
- 8 additional countries in the process of commercial activation
- Sales forecast of €4 to 6 million for the second half of 2023
- Increase in the annual production capacity to 500 Aeson® prostheses, currently being finalized to enable strong and sustained sales growth
- Cash position of €23.8 million as of June 30, 2023
- Several financing options being actively explored to extend cash runway beyond end-October 2023

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Paris, September 25, 2023 – 5.45 pm 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, today reports its results for the first half of the year to June 30, 2023[1] and issues an update on its strategic progress and achievements.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: *"During the first half of 2023, the production ramp-up we were anticipating was significantly disrupted by supply issues. Due to the lack of a sufficient number of devices, we were late in generating the demand from hospitals, hence limited revenues in the first half of the year.*

With production returning to normal during the summer, 25 centers have been trained for commercial implants, and we continue to activate operations in eight more countries. Moreover, we have identified a substantial number of eligible candidates for Aeson® across active centers. This positions us favorably to achieve substantial sales growth in a sustainable manner, with projected revenues in the range of €4 to 6 million in the second half of 2023.

[1] First-half results were approved by the Board on September 21, 2023, and are currently the subject of a limited review by the Company's statutory auditors. The 2023 half-year report was published today and is available on the Company's website.

We are progressing well in extending our Bois-d'Arcy manufacturing site, which is set to increase our nominal production capacity to 500 hearts annually by the end of 2023. This expansion opens the door to potential annual revenues of €100 million, reflecting our determination to scale effectively.

We are diligently working to secure in the near term the necessary financial resources to sustain our activities going forward. This includes accelerating the pace of implantations to align with our strategic goals.

Since restart in November last year, Aeson® has supported patients for more than 500 days in aggregate and performed as expected. We want to emphasize our unwavering confidence in our therapy and its potential to make a profound impact on patients with advanced heart failure. We are resolute in our commitment to success, supported by our teams, loyal shareholders, and partners. Together, we aim to establish CARMAT as a leader in addressing advanced heart failure, a vast and critical market."

- **2023 half-year results**

Simplified income statement (€ millions)	**30/06/2023** (6 months)	**30/06/2022** (6 months)
Revenue	**0.6**	**0.0**
Net operating expense	**-25.9**	**-25.1**
Net financial expense	-1.7	-1.9
Net non-recurring income	0.0	0.0
Research and innovation tax credit	+1.0	+0.9
Net loss	**-26.7**	**-26.0**

The Company generated €0.6 million in revenue in the first half of 2023, corresponding to the sale of 3 Aeson® artificial hearts, 2 for commercial implants and one for an implant as part of the EFICAS clinical study in France.

Despite demands arising from hospitals, Aeson® implants were held back by the low number of prostheses available over the period, due to supply problems which delayed the ramp-up in production initially planned by the Company. The vast majority of these supply difficulties were resolved by the end of the first half of the year, enabling output to gradually ramp-up during the summer.

In the first half of 2023, CARMAT's efforts and resources were predominantly focused on:

- extending its Bois-d'Arcy manufacturing site, which will enable the Company to reach a production capacity of 500 hearts a year by the end of 2023;
- training more centers (25 centers trained to date for commercial implants) and preparing for the launch of Aeson® in 8 new countries;
- ramping up for the EFICAS clinical study in France in the second half of the year;
- continuing its discussions with the FDA with a view to ultimately gaining market access for Aeson® in the United Sates.

Within this context, operating expenses were kept under control, hence an operating loss of €25.9 million in the first half of 2023, broadly flat vs that of 2022 (€25.1 million).

After taking into account net financial expense of €1.7 million and €1.0 million in income from the research tax credit, CARMAT ended the first half of 2023 with a net loss of €26.7 million (compared with a €26.0 million net loss in the first six months of 2022).

- **Cash position and financial structure**

At June 30, 2023, the Company had €23.8 million in cash and cash equivalents, versus €51.4 million at December 31, 2022.

The change in the cash position over the first half of the year results from the following cash flows:

(€ millions)	**30/06/2023** (6 months)	**30/06/2022** (6 months)
Cash flow from operating activities	-30.7	-30.5
Cash flow from investment activities	-1.6	-1.1
Cash flow from financing activities	4.7	39.8
Change in cash position	**-27.6**	**+8.2**

In terms of financing, in the first half of 2023, the Company received the following funds:

- €0.7 million corresponding to the 2nd tranche of the €1.4 million "CAP23" grant[2] awarded to CARMAT as a winner of the French government's "Industrial Recovery Plan – Strategic Sectors" call for projects;
- the first tranche (€1.1 million) of the total €2.5 million grant awarded to the Company at the end of 2022 for its winning proposal in the European Union's "EIC Accelerator" funding program[3];
- the first €3.3 million tranche of the €13.2 million blended financing package[4] awarded to CARMAT in April 2023 under the "France 2030" plan.

Also, as planned, CARMAT began to repay its government-guaranteed loans taken out in the final quarter of 2020, making a first half-yearly repayment of €0.6 million in April.

As of June 30, 2023, the Company's net financial debt stood at €32.7 million, breaking down as follows:

(€ millions)	**30/06/2023**
+ Long-term financial liabilities	39.8
+ Short-term financial liabilities	16.8
- Cash and cash equivalents	23.8
Net financial debt	**32.7**

Short-term financial liabilities include an aggregate €2.0 million payable in the fourth quarter of 2023, mainly corresponding to repayments of government-guaranteed loans[5], and an aggregate of €14.9 million payable in the first half of 2024, primarily relating to the repayment of the first tranche (drawn down in January 2019) of the loan taken out with the EIB.

Based on its updated business plan, CARMAT's confirmed financial resources[6] should enable it to fund its activities until the end of October 2023, while honoring all of its contractual payment maturities. The

[2] The remaining balance of this grant (€0.3 million) is due in 2024.
[3] The remaining balance of this grant is due in 2024.
[4] The €13.2 million blended financing package consists of a €7.9 million grant and a €5.3 million conditional advance, to be received in 4 tranches over 2023-2026. The second tranche is due in 2024.
[5] Second half-yearly repayment of the state-guaranteed loan taken out with BNP Paribas in 2020 and first yearly repayment of the state-guaranteed loan taken out with Bpifrance in 2020.
[6] Including cash at June 30, 2023 and the €0.9 million balance of the 2022 research tax credit due to be received by end-October 2023.

Company is actively working on various financing options to secure, in the short term, the financial resources it requires to continue as a going concern beyond that date[7].

- **H1 2023 highlights and recent developments**

Implementation of the industrial plan

Ramp-up in production

As the vast majority of supply problems were resolved by the end of first half 2023, the Company's production gradually returned to normal over the summer, allowing CARMAT to hold c.20 prostheses on shelf to date. Production has continued to gain momentum since then, and CARMAT now anticipates to manufacture more than 10 hearts a month between September and December 2023. The Company therefore expects to reach a total output of 60 to 70 hearts for full-year 2023.

Strengthening of the supplier portfolio

To support the ramp-up in production, CARMAT has drawn up an ambitious multi-year roadmap to strengthen its supplier portfolio, which led to tangible progress in the first half of 2023 with the signing of a new partnership agreement with French company Vygon for the prosthesis' connector conduits[8] and the stepping up of its partnership with Swiss company MPS for producing the motor pump. These initiatives enable CARMAT to both strengthen its supply continuity and reduce Aeson®'s production costs.

Increase in the production capacity

Meanwhile, CARMAT also began work on expanding its production capacity with, in particular, the extension of its cleanroom and the creation of additional production facilities at the Bois-d'Arcy site. The finalization of this work is underway, and the Company can confirm that it will reach a nominal production capacity of 500 hearts a year by the end of 2023, representing potential annual revenue of €100 million. By 2027, CARMAT is planning to double its production capacity again, to 1,000 hearts a year.

Commercial development

Training of hospitals and geographical expansion

The Company continued to actively train hospitals, in line with its goal of 30 medical centers trained for commercial implants by the end of 2023. To date, 40 hospitals have been trained, including 25 for commercial implants and 15 for implants in the EFICAS study in France and the EFS in the United States.

As part of this, CARMAT also supports the hospitals in getting appropriate funding for the therapy and can confirm that it is secured in the vast majority of them.

In addition to the two countries in which the device has already been sold for commercial implants (Germany and Italy), the Company is planning to make the heart commercially available in eight more countries from the second half of 2023, both in Europe (Austria, Greece, Slovenia, Croatia, Serbia and Switzerland) and outside Europe (Israel and Saudi Arabia). Hospitals have been trained in five of these eight new countries so far.

Patient numbers and sales forecasts

In view of a solid base of trained medical centers where a substantial number of eligible patients have already been identified, and given that production has returned to normal, the Company forecasts sales revenue between €4 million and €6 million in the second half of 2023.

[7] See Section 4.2.1 of the 2023 half-year financial report for the factors underlying the going concern principle used by the Board of Directors.
[8] Conduits connecting the prosthesis and the cardiovascular system.

Continuation of the EFICAS clinical study in France

In early January 2023, CARMAT announced the first Aeson® implant as part of the EFICAS study. This implant was performed in December 2022 by Professor André Vincentelli and his team at Lille University Hospital, one of the six centers participating in the study.

This study, which is expected to get completed in 2025, will involve a total of 52 patients eligible for a heart transplant in France. It will allow CARMAT to collect additional data on the efficacy and safety of its artificial heart, as well as medico-economic data that can be used to support the value proposition and obtain the reimbursement of the device.

This study is critical for Aeson®'s future commercial launch and social security reimbursement in France, but also to support CARMAT's application for the Premarket Approval ("PMA"), i.e., the authorization to market Aeson® in the United States.

CARMAT benefits from €13 million in funding from the French National Innovation Fund[9] to partially finance this study.

Optimized US market access strategy

During the first half of this year, the Company continued its in-depth discussions with the FDA (the US Food & Drug Administration).

In order to optimize its US market access strategy, CARMAT intends to rely on the EFS[10] as well as on data collected from the ongoing EFICAS study in France, which could enable the Company to avoid having to undertake a substantial PIVOTAL study in the United States.

Given both the EFS and EFICAS study's current schedules and all other elements it is aware of, CARMAT can confirm that it is expecting – subject to both studies being successful – to apply for Premarket Approval ("PMA") by the end of 2026.

Publication of a scientific article in the first US implantation of the Aeson® artificial heart

In March 2023, an article entitled The First Autoregulated Total Artificial Heart Implant in the United States was published in the official journal of the American Society of Thoracic Surgeons. This article describes the implantation of Aeson® performed at Duke University Hospital in the summer of 2021 as part of the Early Feasibility Study (EFS).

It shows that the Aeson® heart delivers notable improvements compared with other circulatory support devices. These include enhanced hemocompatibility and autoregulation enabling increased cardiac output in response to higher filling pressures, while avoiding complications such as strokes and hemorrhages. After 5 months of support on the Aeson® device, the patient was successfully bridged to transplant when a human heart became available and has made a full recovery.

€13.2 million non-dilutive blended financing package obtained under the "France 2030" plan

In April 2023, CARMAT obtained a €13.2 million blended financing package (comprising a €7.9 million grant and a €5.3 million repayable advance) under the "France 2030" plan. This financing will be used to help drive the increase in the annual production capacity of Aeson® artificial hearts to 1,000 per year within 5 years and to reduce the production cost of the device.

This package is split into 4 tranches, each of which will become available over the period from 2023 to 2026 as the project progresses. The first tranche of €3.3 million was received in June and the second is anticipated in 2024.

[9] This financing will gradually be received as and when the implants are performed during the study.
[10] The EFS is a feasibility study on 10 patients eligible for a heart transplant. The EFS design provides for two successive cohorts of 3 and 7 patients. The first cohort was completed during the second half of 2021. The initiation of the second cohort is subject to FDA approval being granted. Given the low number of points still being discussed with the FDA, the Company is expecting the second cohort to be initiated during the second half of 2024.

- **Strategy and outlook**

Substantial acceleration in sales expected from the fourth quarter of 2023

With c. 20 devices available on the shelf and a production output back to normal (in excess of 10 hearts a month), CARMAT has, during the past weeks, encouraged its trained centers to very actively resume patients screening, in view of both commercial implants, and implants in the EFICAS clinical study in France.

Given the number of patients eligible to Aeson®, already identified in the active centers, CARMAT anticipates a strong and imminent ramp-up in sales, and revenues of c. €4 to 6 million in the second half of the year, which will ideally set the Company for a significant sales growth in 2024.

This ramp-up will in the coming months, also be sustained by Aeson® being progressively launched in additional countries, including 8 where the activation process has already started (Austria, Greece, Slovenia, Croatia, Serbia, Switzerland, Israel and Saudi Arabia).

Confirmation of key objectives

In light of its first-half achievements and recent developments, the Company reiterates its confidence in reaching the key objectives from its strategic roadmap:

- successful sales development in Europe;
- annual production capacity of 500 hearts by the end of 2023;
- 30 centers trained for commercial implants by the end of 2023;
- ramp-up of implants in the EFICAS study in France;
- apply for US "PMA" by the end of 2026.

In the short term, CARMAT also intends to secure financings that will enable it to extend its cash runway beyond the end of October 2023.

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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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*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. 23-0323. 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).