



PRESS RELEASE

2014 half-year results

- Operating expenses in line with clinical development
- Cash position of €7.7m at June 30, 2014
- An additional €5.4m due to be received upon completion of another milestone¹ of the Bpifrance agreement

Paris, October 21, 2014

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, aiming to provide a therapeutic alternative for people suffering from end-stage heart failure, today announces its results for the first half to June 30, 2014.

• 2014 half-year results*

In euros (€)	30/06/2014	30/06/2013
Operating income		
of which: Operating subsidies	10,000	2,873,627
of which: Other operating income (reversal of a provision)	39,342	0
Total operating income	49,342	2,873,627
Operating expenses		
of which: Other purchases and external expenses	7,955,409	5,627,234
of which: Other operating expenses	2,787,583	3,012,305
Total operating expenses	10,742,993	8,639,539
Operating profit/loss	-10,693,651	-5,765,912
Financial profit/loss	-238,046	-119,645
Exceptional items	-89,036	17,262
Research tax credit	1,096,276	933,311
Net profit/loss	-9,924,457	-4,934,984

* Half-year results to June 30, 2014 were approved by the Board on October 17, 2014.

During the 1st half of 2014, CARMAT recorded operating income of €49k, consisting of €39k from a reversal of a provision and an operating subsidy paid within the framework of a revitalization contract signed with Oracle France with the aim of supporting a structural action to accompany industrial SMEs in Vélizy-Villacoublay.

¹ Subject to the completion of milestone EC5 of the Bpifrance agreement, which notably corresponds to the follow-up of the feasibility trial, for a total of €5,410,204 (€5,251,038 in repayable advances and €159,166 in subsidies).

No revenue was recorded by the Company over the 1st half of 2014, with CARMAT's total artificial heart project still in its clinical development phase and yet to obtain CE marking, a prerequisite to marketing the product in Europe.

Operating expenses came to €10.7m over the half. The 24% increase compared with the 1st half of 2013 is a result of the development efforts undertaken on the portable patient system that should allow patients who have received an implant to be discharged from hospital. This level of external expenses has enabled its development to be finalized in line with the growth in clinical and industrialization activities.

The Medical Division has been strengthened to ensure the monitoring of patients and the processing of clinical data. The clinical teams have continued to undertake intensive efforts to train the investigation centers' teams.

The tasks associated with the analysis of data from the 1st implant and the implementation of supplementary measures, notably in terms of qualification and validation, were led by the Technical Division over the 1st half. Substantial synergy between the R&D and production teams allowed these measures to be rapidly incorporated into the production cycle to enable the rapid resumption of the enrollment process for the CARMAT heart's first-in-man trial.

Once a financial loss (-€238k), exceptional items (-€89k) and research tax credit (€1,096k) are taken into account, the 1st half of 2014 saw a net loss of -€9.9m.

- **Financial structure**

The Company had a cash position of €7.7m at June 30, 2014. This included the €1.8m in research tax credit recognized at December 31, 2013 and fully reimbursed by the tax authorities on June 6, 2014.

At the end of September 2014, CARMAT had a cash position of €6.3m, which includes the approximately €3.8m net income associated with the drawdowns on the contingent equity line (equity warrants) in August and September. These operations gave rise to the creation of 48,500 ordinary shares with a unit nominal value of €0.04 and to the payment of a net issuance premium of €3,783,045. The number of remaining shares that could be issued within the framework of this contingent equity line is 34,700.

It is important to remember that, subject to the completion of the project's milestones n°5 to 7, CARMAT should receive a further €7.2m from Bpifrance, including €5.4m for completing milestone n°5².

- **H1 2014 highlights**

- **Clinical development**

The 1st patient to receive the CARMAT bioprosthesis survived two and a half months (74 days) after the implant he received within the framework of the first-in-man trial where one of the criteria for success was the patient's 30-day survival. During this period, CARMAT's clinical teams monitored the patient, provided him with permanent support and collected clinical data in accordance with the protocol approved by the ANSM French health authority. The data thus collected was processed and analyzed, and this analysis allowed the enrollment process to resume in July 2014.

Simultaneously, theoretical training and training on animals continued in the 3 centers chosen for the first-in-man trial, with 8 animals receiving implants over the 1st half of the year.

² Please refer to the Company's 2013 registration document that was registered with the AMF on March 17, 2014 under reference n° D.14-0145, chapter 5.7 Important Contracts, page 117.

▪ **Industrial development**

CARMAT has continued to implement actions to improve quality, notably with subcontractor controls, the analysis and processing of data from the first implant and the analysis of the causes of possible deficiencies. Additional measures aimed at ensuring the sturdiness and reliability of production processes, and in particular the qualification and validation processes, were accepted by the authorities.

A special effort by the production teams has ensured that the necessary prostheses can be made available to trial teams and clinical teams within very short timeframes. The development of the portable patient system has been accelerated and the first prototypes have been delivered to the Company's software teams for functional tests.

▪ **Functional reorganization**

The Company has undergone a reorganization in order to adapt to the growing challenges of the industrialization and production of larger numbers of prostheses. Operations have thus been restructured into three divisions:

- a Technical division responsible for technical expertise and for grouping the various business segments' specialists together,
- a Production division in charge of the entire manufacturing cycle, including subcontractors' production,
- an Industrial Development division to carry out research into improving the product and manufacturing processes, and to prepare future industrial means.

▪ **Conferences and awards**

In April 2014, CARMAT participated in the 34th ISHLT ([International Society for Heart & Lung Transplantation](#)) annual meeting in San Diego, California. Its project was presented to the scientific community during a special session of the MCS Masters Academy that preceded the annual meeting itself.

In June 2014, at the [European Mechatronics Meeting](#) (EMM) in Annecy, France, CARMAT received the Mechatronics Award of the decade, which rewards products, processes, research or services that are particularly innovative in terms of mechatronics, a field combining mechanics, electronics and IT.

• **Events since the end of the 1st half**

▪ **Completion of half of the first-in-man trial**

Following a favorable opinion from the *comité de protection des personnes* (ethics committee), the data and safety monitoring board and the regulatory authorities, in mid-July, the Company resumed the enrollment of patients for its bioprosthetic heart's first-in-man trial. On September 8, 2014, CARMAT confirmed that it had completed half of the feasibility study on its bioprosthetic heart and announced an ongoing enrollment process for the two remaining patients.

▪ **Appointment of a Director of Business Development**

The Company recently announced the appointment of Mr Eric Richez as Director of Business Development. His immediate objective is to draw up the CARMAT system's market access strategy.

▪ **CARMAT receives the "Microns d'Or" Honorary Award**

On September 23, 2014, at the Micronora international microtechnology trade fair in Besançon, Eastern France, CARMAT received the "Prix d'honneur" honorary award from the *Microns d'Or* jury, for its development and creation of a self-regulated bioprosthetic artificial heart, with a proprietary micropump.

▪ **Presentation of the portable patient system at the EACTS Annual Meeting in Milan**

From October 11 to 15, 2014, CARMAT participated in the 28th EACTS (European Association for Cardio-Thoracic Surgery) Annual Meeting in Milan, Italy, where for the first time it exhibited its portable patient system, which will allow patients to be discharged from hospital and return home, following which prestigious and high-volume European centers confirmed their substantial interest and reiterated their desire to participate in the next phase of the clinical trial.

• **Outlook**

The next scientific stage will see the results of the first-in-man feasibility trial, combined with the project's good technical development. The submission of a report on this trial will represent the completion of milestone n°5, triggering a €5.4m payment from Bpifrance.³

If the results of this first-in-man trial are deemed satisfactory, CARMAT will be able to provide the supervisory authorities, in France and in other countries, with the protocol for a new study extended to around twenty patients monitored over a longer timeframe, such as 180 days for example. It should be noted that the protocol for this second study has yet to be finalized, as it will in large part be based on the outcomes of the current first-in-man trial.

The data from this second trial and from additional in-vitro tests⁴ will enable a file to be put together to request CE marking, a prerequisite to marketing the product in Europe.

Given the time that is required between each of the first-in-man trial's patients, the project's forecast schedule⁵, as presented in the 2013 registration document, will probably be pushed back by around 6 months.

Marcello Conviti, Chief Executive Officer of CARMAT, concludes: *"The first 6 months of 2014 saw a number of major events associated with our bioprosthetic heart's first-in-man trial. Most of our teams' work was devoted to analyzing the data from the first implant so that the following implants could resume as quickly as possible. These additional efforts required a lot of time and resources, but notably led to the completion of half of the first-in-man feasibility trial in early September. Furthermore, it also enabled us to make our control and production processes even safer, and we are therefore calm and confident regarding the next stages of our project."*



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.

³ Please refer to the Company's 2013 registration document that was registered with the AMF on March 17, 2014 under reference n° D.14-0145, chapter 5.7 Important Contracts, page 117.

⁴ Please refer to the Company's 2013 registration document that was registered with the AMF on March 17, 2014 under reference n° D.14-0145, chapter 2.2.3.2 Development.

⁵ Please refer to the Company's 2013 registration document that was registered with the AMF on March 17, 2014 under reference n° D.14-0145, chapter 1.3 General overview of activity

Strongly committed, prestigious founders and shareholders: [Airbus Group](#), Professor [Alain Carpentier](#), the [Centre Chirurgical Marie Lannelongue](#), [Truffle Capital](#), a leading European venture capital firm, and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com

●●●

Disclaimer

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* filed with the *Autorité des Marchés Financiers* under number D.14-0145 on March 17, 2014 and the *Note d'Opération* that was approved with visa no. 11-308 on July 11, 2011, 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. They are not available outside these trials or for sale.

●●●

CARMAT
Marcello Conviti
CEO

Patrick Coulombier
COO

Valérie Leroy
Director of Marketing
& Investor Relations

Tel.: +33 (0)1 39 45 64 50
contact@carmatsas.com

Alize RP
Press Relations

Caroline Carmagnol

Tel.: +33 (0)1 70 22 53 90
caroline@alizerp.com

ALCAR
LISTED
ALTERNEXT

NewCap
Financial Communication
and Investor Relations

Dusan Oresansky
Emmanuel Huynh

Tel.: +33 (0)1 44 71 94 94
carmat@newcap.fr

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