CARMAT

N°6 - September 2014

shareholder newsletter

INTERNATIONAL EDITION

A word from the CEO

Dear shareholders,

I am pleased to be able to address you again in this 6th Newsletter*, the core of which is devoted to our portable patient system that will allow patients to return home once they have received the implant.

This ergonomic system, designed with the objective of providing patients with sufficient autonomy to have good mobility along with living conditions that are as least restrictive as possible with our bioprosthesis, will be presented for the first time at the EACTS (European Association for Cardio-Thoracic Surgery) annual meeting in Milan next month, and we are giving you an exclusive preview of its first pictures. To the right, you can discover the system's key features, and I invite you to learn more of its development rationale through an interview with André Maulet, the system's project manager at CARMAT.

As you know, in recent weeks we have also satisfactorily completed half of the first-in-man trial for our bioprosthesis and are pursuing the enrollment of two additional patients. We felt that this would be a good time for a quick summary, in 10 key points, of our project's key differentiators. As well as the specificities of our bioprosthetic heart project, there is a summarized look at the targeted pathology and the patient population we are aiming to address, a population that is unfortunately continuing to increase.

As usual, there is also a section dedicated to your questions. Most recently, they were about the 2nd implant and the lack of any published information on the patient's status. This lack of information results of our obligations to comply with the laws and regulations that govern clinical trials and medical confidentiality. This Q&A section on the last page of this Newsletter will hopefully help you understand better the various obligations that govern our communications.

We operate in the field of advanced medical technology where we have to make headway and seek solutions for all patients who require them, and today there are a number of reasons for us to be confident.

Our first-in-man trial is progressing, and the rapid availability of our patient system should further facilitate patient enrollment.

The appointment of Eric Richez as Director of Business Development is further proof that CARMAT is firmly focusing on the future.

Lastly, two rewards from our peers in the international microtechnology and industrial community this year have established our project's exemplary nature in terms of technological innovation.

Please allow me to thank you again for the trust and support you continue to show us on a daily basis.

Marcello Conviti
CEO

** Readers are invited to consult the caution note included in the Company's press releases*

Key events from January to September 2014

February	2013 annual results show a cash position of €16.9 million at December 31, 2013
March	Continuation of the clinical trial on the first bioprosthetic artificial heart
April	CARMAT participates in the 34th ISHLT annual meeting in San Diego
June	CARMAT participates in the 2014 French Touch Conference in New York
	CARMAT wins the Mechatronics Award of the decade
July	Approval to resume the first-in-man trial of CARMAT's bioprosthetic heart
September	Ongoing enrollment in the first-in-man trial of CARMAT's biprosthetic heart (following a 2nd implant).
	Eric Richez is appointed Head of Business Development
	CARMAT receives the Microns d'Or Honorary Award at the Micronora international microtechnology trade fair

Contents

The patient system: facts & figures

The patient system

The photo is of a staff member in our premises.

Total weight: **3.0 kg**, including the carrying bag.

Size of the bag (H x L x W): **23 x 28 x 13 cm**

Autonomy of the device: **4 hours***

Number of battery packs provided: **7**

Number of battery packs in the bag: **2** for redundancy

Weight of a battery pack: **460 g**

Displayed data: **7** (charge status for each battery pack, presence of a mains power supply, cardiac output, heart rate, electricity consumption, pressure)

Number of different trades involved in its development: **12**

** depending on the patient's activity; more if the patient is not very active.*

Focus on discharge from the hospital

- interview with André Maulet, project manager responsible for the patient system and equipments

How did you come to lead this project?

I'm an electronics engineer and my specialty at Matra was conducting tests for the aeronautical sector, and in particular for drones. Just like CARMAT's self-regulating bioprosthesis, a drone comprises "embedded intelligence" enabling it to be autonomous in various circumstances. I took charge of CARMAT's test team in May 2010 to undertake test benches. Our team increased from 3 to 8 staff in 2013 and we carried out the tests on the full system. It was therefore quite logical for CARMAT to entrust me with the patient system, a strategic project for the Company.

What is the patient system, and why is it so important for CARMAT?

It consists of all of the portable components that will allow patients to move around with the fewest possible restrictions, at home or outdoors, to live a social life that is as normal as possible. In the hospital, the bioprosthesis is powered and controlled by a patient-monitoring device. This is a large system with a touch screen to access every function that is required in the operating theater to start the prosthesis and then, after the operation, for detailed patient follow-up. This system is specifically designed for hospitals, and is far from ideal for patients at home. That is why CARMAT has quickly developed a specific system that is both light and portable. Quality of life will be pivotal to the adoption of the CARMAT heart by doctors and patients, and discharge from the hospital is key to the reimbursement. This device is therefore extremely important for CARMAT.

What components does the patient system consist of?

CARMAT's bioprosthesis has been designed to be self-regulating. All of the controls are "embedded" and there is no need for an external controller. The only component not included within the prosthesis or implanted is the power supply. The patient system thus includes the batteries and a small informative and warning device, no larger than a case for your eyeglasses, that provides the patient with all the information they require regarding the status of the power supply, i.e. the battery level or the presence of a mains supply, along with other information such as the heartbeat and cardiac output. This display is usually not visible so as to not unnecessarily disturb or worry the patient. It turns on automatically and emits a highly-audible sound when a battery needs changing. The batteries and the warning device are located in a small bag, and the entire patient system weighs 3 kg. Of course we will also provide the charger for the batteries, a number of battery packs and components to connect to the mains power supply, as well as a waterproof bag so that patients can shower in all peace of mind.

Device display

What sort of autonomy should patients expect?

In absolute terms, the autonomy is limited only by the number of charged batteries available. With the batteries in their bag, patients have a minimum of 4 hours – more if they are not very active, for example just sitting at a desk. The batteries are interchangeable and take three hours to recharge, so patients can increase their autonomy using the other battery packs supplied with the device: 2 packs on use in the bag for redundancy, other packs either fully charged or being charged. The alarm begins to go off when the batteries currently being used are down to 30%. If a patient is travelling, he or she can carry more battery packs with them. So as long as the patient plans ahead a bit, autonomy shouldn't be an issue. Patients can also plug the device directly into a mains socket whenever and wherever one is available, at a restaurant, when visiting friends, at work... and of course right through the night.

Why not simply implant the batteries?

Although there are technologies that enable recharging to be done through the skin, battery life is limited by the number of charge/discharge cycles. Batteries would therefore need to be changed frequently and the patient operated on again, a significant risk that we wanted to avoid. Furthermore, our work on fuel cell batteries is progressing well. This latter technology could increase current autonomy three or fourfold without having to change the batteries. Initially, we are using lithium-ion batteries, a proven technology used by all existing assist devices. To accelerate the availability of our first patient system, we started from an existing base that we have adapted to our specificities. For this project, we regularly worked with a subcontractor in the United States, an excellent opportunity to establish an initial partnership in that country. Development was also accelerated by the time difference between Europe and the USA, as requests we sent at the end of our working day were dealt with overnight and their response was already there when we arrived at work the next day.

What is your role as project manager?

Information & warning device

I was able to make extensive use of my experience with drones from the outset. In both cases, we require lightweight electronic design able to handle every environmental constraint (pressure, vibrations, temperature, etc.) without losing any of its reliability. Norms are particularly stringent and development procedures are identical. In CARMAT's case, there is also the human aspect, product-patient interaction, user friendliness and ease of use. As project manager, I work with all of the CARMAT teams: research office, tests, systems, software, clinical teams and subcontractors. Steering the project involves the dynamic exchanging of expertise, and communication is fundamental.

The 10 key points you should know

about CARMAT's project

1 The project was initiated in 1993 by Professor Carpentier and Airbus Group, with Truffle Capital coming onboard in 2008 when the company was founded.

Today, the three founders still account for 63% of the Company's capital, demonstrating their trust and confidence in this project.

2 It is the only self-regulating artificial heart project.

It will automatically and dynamically adapt, without any outside intervention to the patient's requirements in accordance with their level of activity. To do this, it contains 6 sensors, embedded electronics and software, and 2 mini-pumps controlled by a proprietary algorithm that continually adjusts both the heart rate and the cardiac output to the patient's needs.

3 It is the only bioprosthetic artificial heart project.

It uses 2 proprietary biosynthetic membranes and 4 biological valves, which do not cause rejection and aim to reduce the risk of hemorrhage or blood clot formation, the two main hurdles to the long-term use of existing products. In the CARMAT heart, the blood never comes into contact with the pumps or with mechanical components.

4 It is an electric heart, not a pneumatic heart.

The CARMAT heart is powered by electricity. The electric power makes no noise, and is supplied by rechargeable batteries or mains electricity via a simple cable. The only other product currently available uses compressed air, and requires an external compressor and two air inlet and outlet feeders.

5 The CARMAT project is not aiming to replace heart transplants.

It will not be aimed at patients who are awaiting a heart transplant. On the contrary, it will be aimed at those who are not eligible for a transplant and have little or no chance of becoming eligible. For these patients, its purpose is thus to become a long-term alternative.

6 The CARMAT project targets a very precise group of patients among the more than 20 million patients with heart failure[1].

This group comprises over 100,000 patients, those:

- with terminal heart failure,
- with biventricular heart failure or left only with a high risk of right heart failure,
- whose condition is life threatening in the short term,
- with no other therapeutic option,
- who are not eligible for a heart transplant,
- who are under 70, and
- whose thorax is large enough to host the prosthesis.

7 The ability to treat even a modest fraction of this patients' group would ensure the viability of the project.

According to the analysts' consensus, CARMAT may reach out to at least 10% of this subgroup.

8 The size of the current version of the CARMAT bioprosthesis is compatible with most targeted patients.

Under 70 years old, most of these patients are men. Indeed more than 80% of the patients implanted with the existing pneumatic product are male. The current volume of the CARMAT prosthesis is compatible with the thorax of 86% of men, which therefore does not significantly limit its initial coverage. Eventually, the development of smaller versions could extend this coverage, notably to more women.

9 This group of patients is growing fast.

A study by the National Institute of Health in the United States in September 2010[2] estimates that transplant needs (and not just waiting lists) exceed 50,000 patients per annum in the United States alone, whilst only around 2,200 transplants are effectively carried out each year.

10 CARMAT has already begun the clinical validation of its bioprosthesis.

A feasibility study (first-in-man trial) on 4 patients aimed at assessing the device's safety among very high-risk patients is currently at the halfway stage. Positive results would enable a second phase of trials to be launched.

1. In Europe and the United States

2. http://www.nhlbi.nih.gov/research/reports/2010-ctr-decade.htm

CARMAT and the stock market
at August 31, 2014

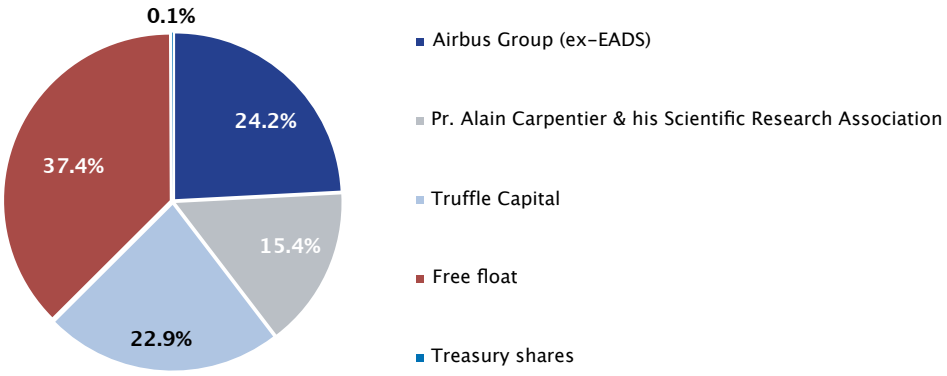
Share Price: **€76.00**
Total shares: **4,310,320**

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

ALCAR
LISTED
ALTERNEXT

Capitalization: **€327.6m**
+ High: **€118.16** (January 2, 2014)
+ Low: **€70.00** (July 2, 2014)
Liquidity: **8,332 shares a day** since January 1, 2014

Shareholders at August 31, 2014



Questions from shareholders

Why aren't you providing any details regarding the second patient, such as an interview?

CARMAT reiterates that it has never given any details about the patients taking part in its trials and does not intend to do so. This is not, as a French television report has suggested, some kind of concealment, an obsession with secrecy or dark financial manipulations. It is quite simply to comply with the laws and rules that apply to the Company with regard to conducting clinical trials and medical confidentiality issues. Infringing these rules would be contrary to the Company's interests – and therefore your interests.

The patients who accept to take part in these trials, and in particular a first-in-man feasibility study, are in a serious or critical condition. They often have no other choice. These are not public figures who can be harassed by the paparazzi. The legislator has strictly forbidden companies carrying out clinical trials from releasing patients' personal details, and notably their identity. Even in scientific publications, patient data has to be presented anonymously. Their age, however, may be disclosed as, for many pathologies, it can be an aggravating risk factor.

The only elements the Company is allowed to disclose during a trial are its progress – its start, interruption, resumption, completion – and its enrollment status. It is different if patients wish to express themselves; they are totally entitled to do so. However, they first and foremost have the right to be left alone.

Is your artificial heart too big?

The technological challenge, in terms of size, was to develop a totally self-regulating heart without compromising on the volume of blood a heart has to pump every heartbeat to supply the other organs with oxygen. If this volume is too small, the heart has to beat faster to compensate, which is unnatural and can have detrimental consequences over the long term. We therefore started from the volume a heart takes up in a person's thorax, and then reserved the volume of the two ventricles. It was in this small amount of remaining space that we designed the mini-pumps and all of the self-regulating electronics, thus arriving at a total volume that is compatible with a majority of patients. The current size has enabled us to industrialize the heart today, before extending the range in the future. The first version of the heart occupies a space in the thorax roughly the same as a sick heart. We validated its anatomical compatibility on more than 100 patients, and our heart is compatible with – at least – 14% of women and 86% of men. Now men represent by far the greatest proportion of patients aged under 70 years old, which is our target population. Indeed, of the 1,300 patients who have been implanted with the existing product, over 80% have been men despite this device size not being an issue.

Obviously doctors would like to treat as many people as possible, whether men, women, or even children... Our ambition is that future versions will help allow them to do this.

Why are you listed on the stock market when you don't have any revenue?

There are only two ways for a company to finance its development: shareholders' equity or debt. Debt (bank loans) is not feasible when you are not yet at the product's marketing stage, with the exception of specific public setups such as Bpifrance repayable loans. Thus far, we have benefited from the support of a core of stable shareholders and Bpifrance, this last being granted only if balanced by the support of private investors.

The stock market thus enables many innovative startups that have not yet reached the marketing stage to ensure their development.

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Schedule

October 11 – 15, 2014
EACTS at Milan

October 21, 2014
2014 half-year results

CARMAT in the foreign press

THE WALL STREET JOURNAL.

September 8, 2014

"CARMAT is halfway through a clinical trial testing the safety of its device - an artificial heart that is the first to be made of both synthetic and natural materials - in four patients suffering from end-stage heart failure."

REUTERS

5 septembre 2014

"An artificial heart made by the French company CARMAT has been successfully implanted for the second time."

The New York Times
INTERNATIONAL WEEKLY

September 5, 2014

"So far, human heart transplantation is the only treatment for chronic terminal heart failure, which affects an estimated 20 million people in the United States and Europe. But the supply of suitable donor organs meets only a small fraction of the need. The CARMAT device, called a "total artificial heart," [...] works like a normal heart [...] and is meant to be capable of doing away with the transplant altogether."

IRISH Mirror

September 4, 2014

"The device is designed to replace the real heart for as long as five years, mimicking nature's work using biological materials and sensors. It aims to extend life for thousands of patients who die each year while awaiting a donor."