

2019 Universal Registration Document

**Document**Including the Annual
Financial Report



#### **GENERAL REMARKS**

In this Universal Registration Document, the terms "CARMAT" or the "Company" shall mean CARMAT.

This Universal Registration Document contains information on the Company's objectives and its development priorities. This information is sometimes identified by the usage of the future, the conditional or terms such as "consider", "anticipate", "think", "aim", "expect", "understand", "should", "seek", "estimate", "believe", "wish", "can" or, where applicable, the negative form of these same terms, or any other variants or similar terminology.

The reader's attention is drawn to the fact that these objectives and development priorities are dependent on circumstances or facts that cannot be certain to occur or materialize.

These objectives and development priorities are not historical data and should not be interpreted as a guarantee that the facts or data will occur, that the assumptions will be proven correct or that the objectives will be achieved.

By their very nature, the objectives and development priorities contained in this Universal Registration Document could be affected by known and unknown risks, or by uncertainties linked specifically to the very nature of clinical trials, the regulatory, economic, financial and competitive environment or by other factors which could lead to the Company's future results, performance and achievements being significantly different from the objectives that have been formulated or suggested here.

In particular, these factors may include those set out in Chapter 2 "Risk factors", of this Universal Registration Document. It is therefore possible that these objectives and development priorities may not be achieved, and the statements or information in this Universal Registration Document may be erroneous. As such, the Company will under no circumstances be required to provide updates, subject, that is, to the applicable regulations and in particular the General Regulations for the French Financial Markets Authority (Autorité des marchés financiers – AMF).

This Universal Registration Document also contains information relating to the Company's business operations, as well as the market and industry in which it operates. This information specifically comes from studies carried out by internal and external sources (analysts' reports, specialist studies, sector publications and any other information published by market research companies, private companies, public bodies and learned societies).

The Company considers that this information presents a faithful picture of the market and the industry in which it operates, and that it faithfully reflects its competitive position. However, although this information is considered to be reliable, it has not been verified by an independent expert, and the Company cannot guarantee that a third party using different methods to gather, analyze or calculate data on the markets would obtain the same results.

Investors are invited to consider carefully the risk factors described in Chapter 2 "Risk factors" of this Universal Registration Document. If some or all of the risks materialize, this could have a negative impact on the Company's business, its position, its financial performance or its objectives.

In addition, other risks, not currently identified or considered as non-material by the Company, could have the same negative effect.

Drawings, images, charts and photographs used in this document are purely for illustration purposes, and shall in no case constitute a commitment of any kind on the part of CARMAT. The reproduction in any form of any part of this document is strictly prohibited.

To assist the reader's understanding, this Universal Registration Document has a glossary attached. Words identified by an asterisk "\*" when they first appear can be found in this glossary.



The French version of this Universal Registration Document (URD) was filed with the French Financial Markets Authority (AMF) on March 13, 2020, in its capacity as the competent authority under Regulation (EU) 2017/1129, without prior approval pursuant to Article 9 of the said Regulation.

The URD may be used for the purposes of a public offering of securities or the admission of securities to trading on a regulated market if it is supplemented by a securities note and, if applicable, a summary together with all amendments to the URD, approved by the AMF in accordance with Regulation (EU) 2017/1129.

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Items included in the Annual Financial Report are clearly identified in the table of contents by the symbol \*.

Items included in the Corporate Governance Report are available in sections 4.1, 5.6, 5.2.6 and 4.4.3.

# Q&A WITH THE CHAIRMAN



### JEAN-PIERRE GARNIER

How would you describe CARMAT's potential after more than a year as Chairman of the company?

More than ever, I am convinced that the CARMAT artificial heart is technological breakthrough with no equivalent on the market and that the Company has the potential to become a global leader. Given the low number of grafts available for patients suffering from heart failure, the CARMAT bioprosthesis was developed as a real alternative to transplants. This is the vision that continues to drive all of our teams. We are delighted that everyone's efforts are gradually turning into successes as the pivotal study progresses.

To date, the longest duration of individual support exceeds two years, which is particularly encouraging. Crossing this symbolic two-year milestone for a patient confirms the fundamentals of the prosthesis, namely its reliability and biocompatibility, and illustrates its potential to become a long-term solution for patients, in line with our objectives. We have been providing cumulative continuous support for more than seven years as part of our clinical studies, an exceptional achievement for such a complex medical device.

In addition, we have observed excellent results in patients eligible for transplants, five of whom have successfully received a human graft following the improvement in their health thanks to the initial support provided by the CARMAT artificial heart. This demonstrates that the prosthesis explanting process is well mastered and reproducible, thus opening the door to real development potential in bridge-to-transplant (BTT) therapy.

### What does this mean for the market access strategy?

Bridge-to-transplant therapy is a real opportunity to move quickly in receiving approval for the device in a real-life context and quickly establishing its credibility on the European – and subsequently global – markets. The data that we have obtained from our pivotal study clearly demonstrate the value of our artificial heart in a bridge-to-transplant (BTT) configuration.

This BTT option is in fact an extension of our initial vision, to make our artificial heart a destination therapy (DT) solution for patients not eligible for transplants. I would also like to add that the line between BTT and DT hardly exists anymore. We are already seeing this in the pivotal study when a patient eligible for a transplant receives our artificial heart but is not able to have a human graft following the transplant.

### Are the goals you set for the Company achievable?

When I took office a little over a year ago, we had clear objectives of making the prosthesis available to as many people as possible, progressing in the United States and successfully transforming CARMAT into an industrial and commercial company.

In this respect, CE marking expected this year will be a major achievement for CARMAT, and above all a dream come true for many European patients with no further therapeutic options.

As for our desire to go international, the recent positive moves with the FDA bring us decisively closer to the American market and we consider it realistic to start implantations as part of the feasibility study in the United States, in the fourth quarter of this year.

Finally, I am very satisfied with the Company's progress in its transformation into an industrial and commercial company, in particular with the transfer and increased reliability of all of our production activities at the new Bois-d'Arcy site in 2019.

# MESSAGE FROM THE CEO



### STÉPHANE PIAT

### What were the highlights for you in 2019?

2019 was a landmark year for CARMAT in several respects. First of all, we resumed production in May at the Bois-d'Arcy production site following final technical adjustments, making us particularly confident about the quality of the prosthesis, an essential criterion for its long-term reliability.

Following this, we gradually resumed the pivotal study with the approval of the competent authorities in Denmark, the Czech Republic and Kazakhstan. At the end of the year, the twelfth patient in the study benefited from our prosthesis, meaning that, to date, we have been providing cumulative continuous support of more than seven years. This record duration corroborates the intermediate results of the first part of the study and shows once again that the prosthesis fulfills its role perfectly, with no serious complications observed in the implanted patients.

At the same time, our very positive discussions with the US Food and Drug Administration (FDA) enabled us to obtain a conditional approval in September for a feasibility study in the United States. Since these talks, we have answered all of the FDA's remaining questions, obtaining full approval in early 2020, which will speed up discussions with the seven selected American hospitals, but also with the Centers for Medicare & Medicaid Services (CMSs) to obtain compensation for the costs of the study.

From an organizational point of view, the appointment of Alexandre Eleonore within our management team as Director of Manufacturing strengthens our market access strategy. His expertise will notably facilitate the ramp-up of the Boisd'Arcy production site, a continuation of CARMAT's strategy to transition into an industrial and commercial company.

Finally, in September 2019, we considerably improved our financial position thanks to a €60 million private placement with investors who share our long-term vision. These funds have provided us with financial visibility through to third-quarter 2021 and the necessary resources to look to the next phases of our project with great confidence.

### Will 2020 be the year you obtain CE marking?

We are committed to finalizing the pivotal study rapidly, and are working with Dekra, our certification agency, to obtain CE marking by the end of the year.

But CE marking is not an end in itself. It is important that our prosthesis can benefit the largest number of patients. With that in mind, we are delighted that in France, the French National Authority for Health (HAS) has deemed our device eligible, with a few observations, for a clinical study as part of the "Forfait Innovation" program. This program facilitates innovative device testing in France by covering the costs of the study. Provided our prosthesis demonstrates its benefits during this clinical study, we can positively envisage its reimbursement in the long term, in our country.

In the United States, the leading market for medical devices in the world, development is another important strategic priority for CARMAT in 2020. The protocol for the American feasibility study has been extended to ten patients eligible for transplants, enabling us to work with seven of the most renowned centers in the United States. If our discussions on covering the costs of the study with the CMSs are concluded quickly, American hospitals will be able to include the first patients in the study as early as the fourth quarter of this year.

Lastly, quality remains our number one priority. In 2020, we will continue to continuously improve our production processes, which must be perfectly aligned with commercial-scale production requirements.

### **PURPOSE AND VISION**

With its artificial heart, CARMAT is dedicated to providing physicians with innovative technologies to save lives and improve the quality of life of patients with terminal heart failure. Ultimately, the Company aims to become the number one provider of heart transplant alternatives. CARMAT relies on the commitment of its teams and the support of its shareholders.

The Company also aims to meet a major public health challenge related to cardiovascular diseases, namely heart failure, the leading cause of death in the world. More specifically, CARMAT aims to provide a lasting solution to the treatment of

terminal heart failure, a disease for which there are very few effective options today, the main one being heart transplants.

Heart failure is a progressive disease affecting 20 million patients in Europe and the United States. Within this population, tens of thousands of people are terminally ill. Each year, there are only 4,000 to 5,000 human grafts available. The CARMAT artificial heart provides a lasting solution to these patients with no further therapeutic options.

### **MARKET**

A fast-growing, high-potential market with more than 200,000 patients suffering from terminal biventricular heart failure each year ONLY 5,000 GRAFTS AVAIL-ABLE PER YEAR

### **CARMAT TEAM**

A multidisciplinary and highly qualified team of more than 100 people

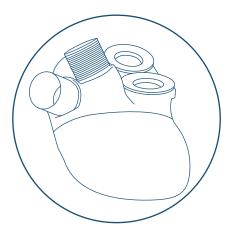
A Board of Directors chaired by Jean-Pierre Garnier, including nine directors, five independent directors and two internationally recognized cardiology experts

Stéphane Piat, as Chief Executive Officer, leads all of CARMAT's activities



Board members as at December 31, 2019 (Alain Carpentier is Honorary President of the Company, Karl Hennessee is missing from the photo)

### **CARMAT PROSTHESIS**



An innovative leadership position with strong intellectual property and significant barriers to entry thanks to the scientific stewardship of Professor Carpentier and the technological excellence of the Airbus

The first physiological cardiac bioprosthesis aimed at becoming a credible therapeutic alternative to heart transplants

### Prosthesis features:

- Highly biocompatible
- Self-regulating, automatically adapting to the patient's needs
- Pulsatile

- A nominal surgical technique easily reproducible by any heart surgeon
- A return to home for patients after implantation, ensuring good quality of life

### **NEW FINANCING IN 2019**



In September 2019, CARMAT raised €60.0 million from healthcare investors and strategic partners

# CARMAT CORPORATE PROFILE

Founded in 2008, after more than 15 years of research, CARMAT has developed a total artificial heart, which is orthotopic\*, bioprosthetic\*, self-regulating, pulsatile and implantable, as well as connected to an external power supply system.

The name CARMAT originated from the meeting in the early 1990s of Professor Alain Carpentier and Jean-Luc Lagardère, then Chairman of Matra Défense (Airbus Group). This meeting resulted in very active collaboration beginning in 1993 with the aim of designing a bioprosthetic artificial heart.

This unique partnership combines:

- the experience of more than 30 years of Professor Alain Carpentier, father of modern valvular heart surgery. Professor Carpentier developed treatments for biological animal tissues, which enabled him to design the most widely used biological valves in the world (Carpentier-Edwards® valves). He also developed restorative surgery and mitral valve annuloplasty\* techniques used today all over the world, on the principle that a device must always be associated with a reproducible procedure; and
- Matra Défense (Airbus Group) expertise in embedded systems and their constraints (reliability, harsh environments, mass and volume) enabling engineers to work on the concept using simulations, modeling and testing.

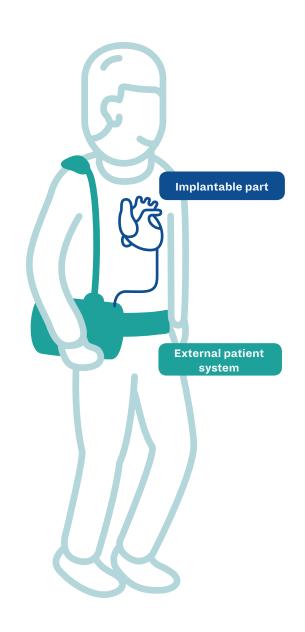
The Company's goal is to treat advanced heart failure, a global public health need and a harsh, progressive, and often fatal disease that is steadily rising in developed countries.

The CARMAT bioprosthetic artificial heart project aims to offer a long-term therapeutic solution to patients suffering from advanced biventricular heart failure, who are ineligible for or awaiting transplants, who have exhausted all treatment possibilities or to whom no satisfactory solution is currently offered.

To date, the CARMAT artificial heart highlights three major technical achievements, leading to undeniable competitive advantages compared to other medical devices on the market:

- the only artificial heart whose surfaces in contact with blood are made using biologically compatible materials to reduce thromboembolic risks;

- the first smart artificial heart to immediately and automatically adapt to the metabolic needs of the patient;
- special attention paid to patients' quality of life, with the development of lightweight external equipment and quiet operation.



CARMAT is initially aiming for CE marking in order to market its prosthesis in Europe soon. To this end, CARMAT submitted a file comprising technical and clinical parts to the Dekra certification agency for analysis and review. The clinical part of the file includes the clinical results obtained during the preclinical trials, the feasibility study relating to four patients finalized in early 2016 and the ongoing pivotal study initiated in August 2016.

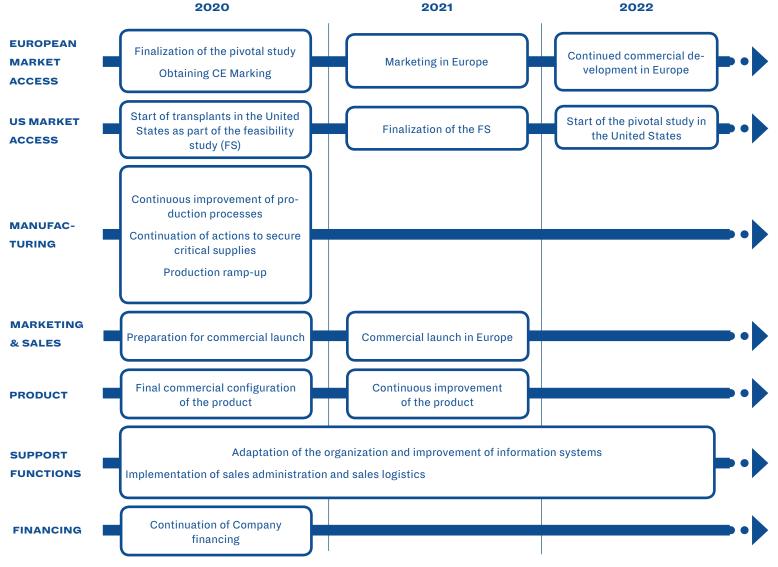
As a reminder, the pivotal study aims to validate the safety, efficiency and performance of the system and will contribute to the CE marking filing process. The Company's objective is to implant around 20 patients and demonstrate the survival of these patients over a six-month period.

CARMAT also aims to obtain pre-market approval (PMA) over the next few years, which would allow the Company to market its prosthesis in the United States. In this context, the Company obtained the

FDA's authorization in September 2019 to start a feasibility study in the United States on ten patients. If it is successful, this study would be followed by a larger pivotal study to obtain PMA.

CARMAT's clinical, industrial and commercial development will generate additional financial needs, which the Company estimates to date to exceed €100 million. Fundraising or other types of financing will therefore be required beyond, in particular, the fundraising of €60 million carried out in September 2019, and the drawing of the two remaining tranches of €10 million each of the loan conditionally granted by the EIB in December 2018.

### **BUSINESS AREAS**



Source CARMAT - Provisional project schedule

# **HISTORY OF THE** COMPANY

€5m

CARMAT receives €5 million in French research tax credits (RTCs) for 2012, in line with the Company's 2013 financing plan.

2014

2008

Creation of CARMAT by Matra Défense (Airbus Group), Truffle Capital and **Professor Alain** Carpentier.

€33m

€33 million in subsidies and repayable advances granted to CARMAT and its partners by Bpifrance under the Strategic **Industrial Innovation** scheme, the largest amount ever granted to a Young Innovative Enterprise by Bpifrance.

Professor Christian Latrémouille performs the first successful implantation on December 18, 2013 at the Georges Pompidou European Hospital.

**CARMAT** obtains authorization from the ANSM to conduct a feasibility study in France involving four patients.

2013

2012



Favorable opinion from

the Patient

Protection

preclinical

Commission

**CARMAT** presents

hemocompatibility

data to the 25th

**Annual Congress** 

of the European

Association for Cardio-Thoracic Surgery.

CARMAT wins a prize at the European Mediscience Awards in the Best Technology category.

Further items added to the ANSM file, including the results of the implants on animals and the intermediate results of the durability tests.

2009

Completion of modeling and optimization work on the artificial heart (900 grams) in anticipation of the assembly and implantation phase for the preclinical trials.

Marcello Conviti as CEO of CARMAT.



Appointment of

2010

**CARMAT** granted the status of "Innovation Enterprise" by **Bpifrance for Mutual Funds for Investment** in Innovation (FCPI).

€16m

Capital increase of €16 million, including share premium, on the occasion of CARMAT's flotation on Euronext's Alternext market in Paris.

Capital increase of €29.3 million (share premium included).

€29.3m

2011



Signing of an agreement with Edwards Lifesciences, the world leader in the heart valves sector and hemodynamic monitoring, for the use of Carpentier-Edwards biological valves in the CARMAT bioprosthetic artificial heart.

€5.3m

### **bpifrance**

CARMAT secures its future funding, reaching the 5<sup>th</sup> milestone of its agreement with Bpifrance and receiving €5.3 million.

Authorization received to recommence feasibility trials on the CARMAT bioprosthetic heart.

2015

€11m



CARMAT puts in place a new flexible equity financing arrangement with Kepler Cheuvreux, a mechanism enabling CARMAT to raise over €11 million during the year.

A third implantation of the CARMAT heart is carried out on April 8 by the heart surgery department at the Georges Pompidou European Hospital.

A fourth implantation of the CARMAT heart is carried out on December 22 by the team at La Pitié Salpêtrière on a patient suffering from severe biventricular failure.

2016

### €50m

At the end of April,
CARMAT raises
€50 million though a
private placement, with
the support in particular
of certain historical
shareholders as well as
new investors.

study relating to four patients completed, the experience gained allows CARMAT to start preparing the pivotal study, after receiving both ANSM and CPP authorizations.

With the feasibility

The patient receiving

implant at Nantes

Teaching Hospital on

August 5, 2014 went

home and benefited

from the prosthesis

for almost nine

died.

study.

months before he

In November, CARMAT

receives authorization

the CPP for completion

of the clinical feasibility

from ANSM and from

the CARMAT bioprosthetic heart

At the end of August,
the first implantation
under the pivotal study
is carried out. However,
the patient died at the end
of November. The analyses
showed no involvement of the
CARMAT prosthesis in the patient's
death.

€60m

In September 2019, CARMAT raises €60 million through a private placement, with in particular the participation of certain historical shareholders and the entry of new shareholders (family offices and entrepreneurs).

Full transfer of production to the Bois-d'Arcy plant.

Authorization received from the FDA to initiate a feasibility study (FS) in the United States.

2019

€30m

In December 2018, CARMAT is granted a conditional loan of €30 million by the European Investment Bank (EIB).

Banque européenne d'investissement Finalization, with positive results, of the first part (cohort 1 of ten patients) of the pivotal study. Implants begin in cohort 2.

The Bois-d'Arcy plant is certified and opened.

2018

Resumption in
May 2017 of the trials
corresponding to
the pivotal study
(after approval of
ANSM in France) and
extension in Europe
(Kazakhstan and
Czech Republic) of
this pivotal study.
Discussions are also
initiated in the United
States with the FDA.

€53m

In December
2017, CARMAT
receives more than
€50 million following
the completion
of a fundraising
exercise open to the
public, a transaction
carried out mainly
with the support
of two historical
shareholders (Pierre
Bastid and Antonino

2017

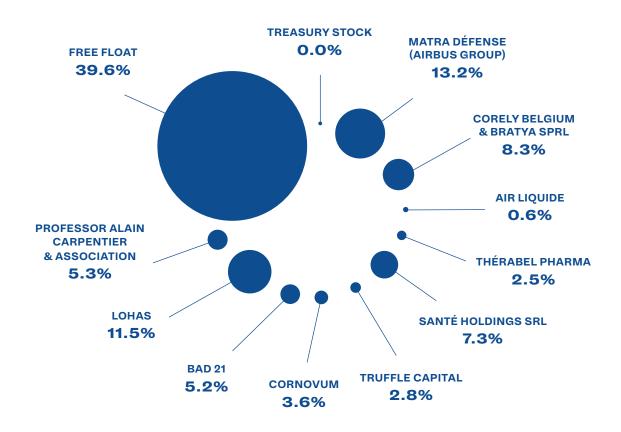


Stéphane Piat replaces Marcello Conviti as CEO to define and support CARMAT's commercial strategy to address the market.

# CARMAT AND ITS SHAREHOLDERS

### SHAREHOLDERS AS AT DECEMBER 31, 2019

(to the knowledge of the Company)



### ANALYSTS' COVERAGE

Broker/Analyst	Opinion	Target share price	Date of opinion
Gilbert Dupont	Accumulate	€24.00	February 12, 2020
Portzamparc	Buy	€22.90	February 12, 2020
Oddo BHF	Buy	€27.00	March 10, 2020
Edison	_ *	€68.01	September 27, 2019

<sup>\*</sup> Edison does not give recommendations but only an assessment of the company.

### INFORMATION ON THE CARMAT SHARE

Market	Number of shares out- standing (Decem- ber 31, 2019)	Ticker & ISIN code	Share price & market capitaliza- tion (December 31, 2019)	Average trading volume (in 2019, over 12 months)	Status
Euronext Growth	12,609,649	ALCAR	€19.28/share	8,186 shares/day	ELIGIBLE PEA
Edionext diowth	12,009,049	FR0010907956	€243.1m	o,ioo siiares/day	PME

### **CONTACTS**

Chairman	Chief Executive Officer	Chief Financial Officer and Head of Investor Relations	Registered office	Website
	Stéphane Piat	Pascale d'Arbonneau	36, avenue de l'Europe 78140 Vélizy-Villacoublay, France	www.carmatsa.com
Jean-Pierre Garnier		+ 33 1 39 45 64 50 contact@carmatsa.com		

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## 1 1 HEART FAILURE

### 1.1.1 PATHOLOGY AND ETIOLOGY\*

Heart failure occurs when the myocardium (cardiac muscle) can no longer carry out its essential function as a blood "pump" and provide a sufficient cardiac output to satisfy the metabolic needs of the organism. Failure of the left ventricle is called left ventricular failure; failure of the right ventricle is called right ventricular failure; failure of both ventricles, the left and the right, is called biventricular heart failure.

Essentially, the heart is unable to keep up with its work-load. The heart tries to make up for this by enlarging in an effort to pump faster and more vigorously to speed up the heart rate. The body also tries to compensate in other ways by making the blood vessels narrower and by diverting blood away from less important organs to favor key organs like the brain and kidneys.

These temporary measures mask the problem, but the muscle failure continues, at varying rates, until these compensatory measures are no longer effective. The patient then begins to experience the classic symptoms of heart failure in an ever-increasing way (see table on next page: NYHA classification).

The above is a description of the more common chronic condition, but heart failure can also occur acutely, most commonly as a result of a heart attack caused by coronary artery disease (CAD). Other causes of heart failure are listed in the table below.

Major causes of heart failure

Condition	Description
Ischemic heart disease	A buildup of fatty deposits on the walls of the coronary arteries that limits the supply of blood to heart muscle.
High blood pressure	A condition that increase the work that the heart needs to do, which leads to increased muscle mass and a need for more blood supply.
Cardiomyopathy	A group of heart muscle diseases leading to functional and structural damage. Diverse causes including inherited, infections, some cancer treatments and substance abuse.
Rhythm problems	Abnormal heart rhythms cause the heart to pump inefficiently. Types vary from relatively mild atrial (upper chamber) to disruptions of the ventricular (main pumping chamber). Can be treated by medication and/or pacemaker and automatic defibrillator devices. Often secondary to coronary disease.
Damage to heart valves	Valves can become stenosed (narrowed) or regurgitant (leaky) due to older age, infections, coronary disease, congenital defects, high blood pressure and diabetes. Consequently, heart function is compromised to an extent depending on the number and degree of valvular defects.
Congenital heart disease	Structural defects that develop in the womb before a baby is born. These can vary from a small "hole in the heart" to major structural deformities. Most can be partially or fully repaired but may cause problems in later life.
Substance abuse	Tobacco, alcohol and recreational drugs all cause damage to heart muscle and the vascular system. Some prescription drugs also have toxic side effects on the heart, depending on dosage and length of use.

#### **BUSINESS OVERVIEW**

Heart failure can affect the heart in different ways:

- The most common failure affects the left ventricle (the main pumping chamber), which can fail in two ways. It may lose its ability to contract forcefully enough (systolic failure) or it may not relax enough, in order to fill properly (diastolic failure).
- In the event of right heart failure, the weaker right ventricle is unable to pump enough blood through the lungs and since the left side relies on receiving blood from the right side, the entire pumping action of the heart is compromised. The right ventricle has much less resilience than the left and can therefore fail more easily. Right heart failure is most often secondary to left heart failure, because blood volume increases as a result of a compromised left function. Right heart failure may also be secondary to lung disease or an acute event such as an allergic reaction, infection or a blood clot that lodges in the lungs. Up to 30% of patients whose left heart failure is treated with a left ventricular assist device (LVAD) develop right heart failure  $^{01/02/03/04}$ .

Practitioners distinguish the severity of failure or extent of the impairment using the New York Heart Association (NYHA) Classification based on symptoms and including four classes.

There is also a number of other guidelines published by the various professional bodies such as the European Society of Cardiology: *Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure.* 

As heart failure is a progressive disease, the prognosis is poor: less than 50% survival five years after diagnosis <sup>05</sup>, and more than 40% of deaths within a year following initial hospitalization <sup>06</sup>.

A shift to class III is a decisive moment <sup>07</sup>:

- for the patient: it marks the passage between a virtually normal life and considerably reduced activity, very often involving a loss of autonomy;
- clinically, this translates to more aggressive therapies, a dependence on drugs, and, with class IV, the start of repeated hospitalization;
- for society as a whole, this represents an explosion in costs, particularly due to hospitalization: a class IV patient costs the community up to 15 times more than a class II patient<sup>08</sup>.

Class III and class IV patients represent between 20 and 35% of the total number of patients, with class IV representing up to 5% of heart failures.

NYHA	Class I	Class II	Class III	Class IV
Symptoms	No symptoms	Tiredness, palpitations, shortness of breath after a sustained effort	Symptoms and discomfort on the least effort	Symptomatic even at rest
Activity	No limitation	Modest limitation	Marked reduction	Inability for all activity, permanently confined to bed

- **O1** Dang NC et al. Right heart failure after left ventricular assist device implantation in patients with chronic congestive heart failure. J Heart Lung Transplant 2006; 25: 1-6.
- **O2** Boyle AJ et al. Predictors of poor RV function following LVAD implantation. J Heart Lung Transplant. 2003; 22: S205.
- O3 Kormos RL et al. Right ventricular failure in patients with the HeartMate II continuous-flow left ventricular assist device: incidence, risk factors, and effect on outcomes. The Journal of thoracic and cardiovascular surgery. 2010; 139(5):1316-24.
- **O4** Cordtz J et al. Right ventricular failure after implantation of a continuous-flow left ventricular assist device: early haemodynamic predictors. European Journal of Cardio-Thoracic Surgery. 2014; 45(5):847-53.
- **O5** Blackledge HM et al. Prognosis for patients newly admitted to hospital with heart failure: survival trends in 12,220 index admissions in Leicestershire 1993-2001. Heart. 2003; 89:615-620.
- **06** Stewart S et al. More 'malignant' than cancer? Five-year survival following a first admission for heart failure. Eur J Heart Fail. 2001; 3:315-322.
- **07** Launois R et al. Coût de la sévérité de la maladie ; le cas de l'insuffisance cardiaque. Journal d'économie médicale. 1990, T. 8, n° 7-8, p. 395-412.
- **08** Kulbertus HE et al. What has long medical treatment to offer and what does it cost. Eur Heart J 1987 (suppl F) 26-28.

# 1

### 1.1.2 EPIDEMIOLOGY, PREVALENCE AND INCIDENCE

The prevalence\* of heart failure is rising sharply in developed countries.

Prevalence can be estimated at 1% to 2% in the Western world while incidence\* is between 5 and 10 per 1,000 persons per year<sup>09</sup>. Both prevalence and incidence vary by country<sup>10</sup> (see Table 1 below).

In Europe, the disease affects approximately 2% of the general population 11/12, i.e., some 15 million people in

- O9 Mosterd A, Hoes AW. Clinical epidemiology of heart failure. Heart 2007; 93:1137-1146
- **10** Global public health burden of heart failure. Card Fail Review 2017 Apr; 3(1):7-11. Doi: 10.15420/cfr.2016:25:2.
- 11 Cowie MR, et al. The epidemiology of heart failure. Eur Heart J 1997; 18:208-225.
- **12** Davies MK et al. Prevalence of left ventricular systolic dysfunction and heart failure in the Echographic Heart of England Screening Study: a population based study. Lancet 2001; 358:439-444.

Europe <sup>13</sup>, <sup>14</sup>. Prevalence increases greatly with age <sup>15</sup>. A French epidemiological study has shown that it can affect nearly 12% of patients over the age of 60<sup>16</sup>.

- **13** Remme WJ et al. Public awareness of heart failure in Europe: first results from SHAPE. Eur Heart J 2005; 26:2413-2421.
- **14** McMurray JJ et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. Eur Heart J 2012; 33:1787-1847 (nombre incluant les 51 pays adhérents de la Société européenne de cardiologie).
- **15** Conrad N, et al. Temporal trends and patterns in heart failure incidence: a population-based study of 4 million individuals. The Lancet. 2018; 391(10120):572-80.
- **16** Saudubray T et al. Prévalence et prise en charge de l'insuffisance cardiaque en France : enquête nationale auprès des médecins généralistes du réseau Sentinelles. La revue de médecine interne 26 (2005) 845-850.

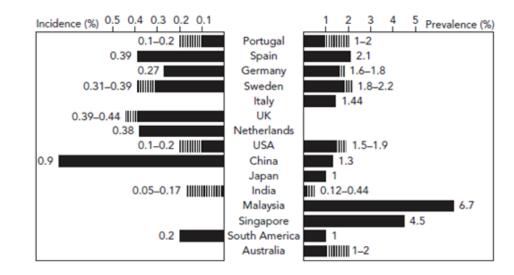
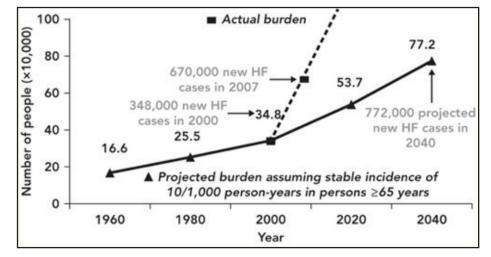


Table 1





Savarese G Global Public Health Burden of Heart Failure. Cardiac Failure Review 2017; 3(1):7-11. DOI: 10.15420/cfr.2016:25:2

### **BUSINESS OVERVIEW**

In the United States, over 5.8 million people were suffering from heart failure in 2012, with an annual incidence\* of more than 550,000 new patients each year. According to a new study published by a working group within the American Heart Association in May 2013, the prevalence of heart failure in the United States is expected to increase by 46% between 2010 and 2030 <sup>17</sup>, bringing the affected population to more than 8 million people.

A more recent publication in 2017 predicts the number of new cases of heart failures to reach 772,000 in the United States in 2040 (see Table 2 on previous page).

In addition, terminal chronic heart failure with reduced ejection fraction\*, which is a target market for CARMAT, is reported to affect 4.1 million people in Europe and the United States 18/19 (people under 75).

This change in the epidemiology is linked to the aging population, but also, for advanced heart failure, to improvements in survival after a heart attack and to the progress made in medicinal treatments, such as beta blockers\* and diuretics\* 20 as well as coronary stents.

- 17 Heidenreich PA et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013: 6:606-619.
- **18** The ECHOES study, Midlands, UK: Davies M, Hobbs F, Davis R, et al. Prevalence of left-ventricular systolic dysfunction and heart failure in the Echocardiographic Heart of England Screening study: a population based study. Lancet. 2001 Aug 11; 358(9280):439-44.
- **19** CARLA study, Sachsen-Anhalt, Germany: Tiller D, Russ M, Greiser KH, Nuding S, Ebelt H, et al. (2013) Prevalence of Symptomatic Heart Failure with Reduced and with Normal Ejection Fraction in an Elderly General Population.
- 20 Évaluation de l'assistance ventriculaire en attente ou en alternative à la transplantation cardiaque. Rapport de l'ANAES (Agence nationale d'accréditation et

The paradox is that the availability of these new medications and technologies has enabled more effective treatment of acute coronary syndromes and considerably increased patient survival after a heart attacks, the strongest predictor of left systolic dysfunction and the risk of heart failure. Patients no longer die immediately but receive long-term treatment, during which time the disease continues to develop. Consequently, the total number of people living with compromised heart function and with clinical heart failure will increase considerably in the coming decades 21. This change also leads to a population of older heart failure patients, suffering from various comorbidities, who are therefore even less likely to have access to transplants<sup>22</sup>. Out of the 8.5 million American people suffering from heart failure by 2030, as predicted by the AHA, only 2.5 million of these individuals will be under 65 years old.

Heart transplants are currently only available to some 5,000 patients per year, and durable Mechanical Circulatory Support (MCS) devices offer treatment to a further 8,000 patients, with variable results. This means that we currently do not have an effective therapy for the majority of patients. More than 30% of patients supported by a durable MCS system require biventricular support, currently only available with a Syncardia® TAH (see section 1.2.2).

d'évaluation de santé) – Avril 2001 – E.

- 21 Tendera M. Epidemiology, treatment, and guidelines for the treatment of heart failure in Europe. European Heart Journal Supplements (2005) 7 (Supplement J), .15-.19
- 22 Croft JB et al. Heart failure survival among older adults in the United States: a poor prognosis for an emerging epidemic in the Medicare population. Arch Intern Med 1999; 159:505-510.

### ECONOMIC CHALLENGES

Heart failure is a real public health challenge set to increase. In Western countries, the cost of heart failure is now one of the largest of all chronic diseases.

According to a study published by a working group within the American Heart Association in May 2013, the total cost of heart failure, which amounted to US\$31 billion in the United States in 2012, is estimated to be US\$70 billion by 2030. The direct costs (medical costs) of patient treatment is expected to increase by 250% between 2012 and 2030. Taking account of all the direct costs from resulting comorbidities, the cost is expected to reach US\$160 billion by 2030.

In addition, this study reveals that 80% of medical expenses are attributable to hospitalization.

There are no recent studies dealing with the cost of heart

failure on a European level. As an example, the direct cost of advanced chronic heart failure in France amounted to some €1.5 billion <sup>23</sup> (€3.3 billion for the long-term condition class combining serious cardiovascular diseases (ALD 5) in 2009, only for the French health insurance system, and was reported to affect over 730,000 people in 2011 (a 9% increase compared to the previous year).

In a statement released on May 7, 2010 for the European Heart Failure Awareness Day, the French Society of Cardiology and the French Federation of Cardiology announced some figures. In France, there are more than 100,000 new cases a year. 10% of these patients were hospitalized, the average length of hospitalization exceeding ten days and the rate of re-admission within six months being 20%. In 2008, heart failure was the main diagnosis for 195,800 hospital stays in France, for which the daily cost of

23 Régime général de l'Assurance maladie (French health insurance system) – www.ameli.fr/l-assurance-maladie/statistiques-et-publications/donnees-statistiques/affection-de-longue-duree-ald/.

### **BUSINESS OVERVIEW**

hospitalization in cardiac intensive care was over €2,000.

Overall, heart failure represents 2.5% of total healthcare expenditure in Western countries, with costs linked to hospitalization alone representing more than 70% of the

total cost of the disease<sup>24</sup>. Due to repeated hospitalizations, class IV chronic heart failure represents between 61% and 92% of the total cost of heart failure<sup>25</sup>.

**24** McMurray JJ, Stewart S. Epidemiology, aetiology, and prognosis of heart failure. Heart 2000: 83:596-602.

25 Clegg AJ et al. Clinical and cost effectiveness of LVAD for end stage heart failure – Health Technology Assessment NHS – 2005.

### 1.1.4 AVAILABLE TREATMENTS

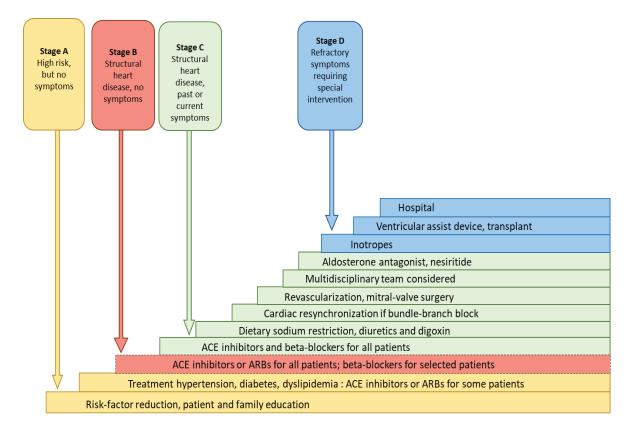
The onset of heart failure may be prevented or delayed by a certain number of measures, including treating high blood pressure. However, once this disease reaches the chronic phase, it is essentially incurable and the objectives of treatment are to improve clinical condition, functional capacity, quality of life, minimize hospital admissions and reduce mortality.

Heart failure can be classified according to its severity and associated treatment plans. In the chart below, four stages are identified, ranging from Stage A (high risk of developing heart failure) to Stage D (advanced heart failure)<sup>26</sup>.

26 Cardiac Failure Review 2017; 3(1):7-11. DOI: 10.15420/cfr.2016:25:2

Various national regulatory and professional bodies also produce guidelines and recommendations.

The four stages of heart failure and associated treatment plans



From Yancy, C. W., et. al. "2013 ACCF/AHA Guideline for the Management of Heart Failure:

A Report of the American College of Cardiology.

#### **BUSINESS OVERVIEW**

From Stage B onwards, treatment involves a personalized combination of medication and is known as Optimal Medical Therapy (OMT). Unfortunately, because of the many drug-related side effects, one of the constraints of OMT is compliance, with an estimated 40% of patients not respecting their treatment plans.

Stage C patients may be suitable for surgical procedures ranging from coronary stenting, coronary artery bypass surgery, valve repair/replacements and surgical re-modelling of the heart. Patients with heart rate problems can be treated with a variety of pacemaker-like devices, including those incorporating a defibrillator function.

Patients in Stage D typically require strong heart stimulating intravenous drugs (inotropes), and become candidates for assist devices or heart replacement therapy through a transplant or an artificial heart.

Patients in Stages C & D also commonly develop a number of comorbidities (other medical conditions) as a result of a chronic inadequate blood supply.

#### **MEDICATION**

At early stages (typically classes I and II of the NYHA classification), treatment is essentially drug-based <sup>27</sup> and, depending on the severity and symptoms, combines:

- anticoagulants\* and platelet agglutination inhibitors\* to prevent blood clots;
- angiotensin-converting enzyme inhibitors\* to reduce vascular resistance;
- beta blockers, which reduce the heart rate and cardiac output to decrease blood pressure;
- diuretics to remove excess fluids and lighten the burden on the heart to prevent pulmonary edema;
- vasodilators\*, which relax the blood vessels to increase the flow of blood and oxygen to the heart without increasing its workload;
- various other medications.

The complexity of treatment and the need for frequent adjustments leads to low patient compliance: 40% of patients do not take their treatment correctly after three months<sup>28</sup>.

Positive inotropes\* are generally also introduced at the most advanced stage of the disease. These drugs, administered intravenously in hospitals, increase cardiac contractility and allow, at least temporarily, critical situations of low cardiac output in episodes of acute decompensated heart failure\* or cardiogenic shock\* to be resolved. Dependence on inotropes marks the terminal phase of heart

27 American Heart Association – Heart Failure Medications – http://www. heart.org/HEARTORG/Conditions/HeartFailure/PreventionTreatmentof HeartFailure/Heart-Failure-Medications\_UCM\_306342\_Article.jsp.

**28** Benner JS et al. Long-term persistence in use of statin therapy in elderly patients. JAMA. 2002; 288:455-61.

failure with a mean survival of three and a half months 29.

#### **DEVICES**

From class III (NYHA classification), we consider surgical options and implanting supporting medical devices, such as:

- mono or biventricular pacemakers to prevent arrhythmias;
- implantable defibrillators to treat ventricular tachycardia and prevent sudden death;
- left ventricular reconstruction;
- restrictive mitral annuloplasty\*;
- implantable and non-implantable Mechanical Circulatory Support (MCS) devices, and artificial hearts.

For the most part, these options pursue the objective of recovering the heart's natural function. For example, biventricular pacemakers aim to reeducate the ventricles by synchronizing their contractions.

Restrictive mitral annuloplasty aims to reeducate the left ventricle by affecting its geometry. However, although these approaches temporarily relieve some patients, they do have major difficulties in patient selection <sup>30</sup> or technical implementation <sup>31</sup>, which restrict their application and do not stop the progression of the disease.

Finally, the use of stem cells to regenerate damaged heart muscle is a promising research approach, but remains relatively controversial <sup>32</sup>, in particular due to difficulties in collection, generation, administration (a large number of cells "die" during the injection), and the current lack of a clinical demonstration of long-term regeneration of the myocardium.

Mechanical Circulatory Support (MCS)

Mechanical Circulatory Support (MCS) systems are the systems considered to have the closest function and indication to the CARMAT artificial heart project. Their characteristics and evolution are detailed in section 1.2.2. "Technologies and market players". However, unlike artificial hearts, which replace both ventricles, MCS leaves the diseased heart in place, which can continue to deteriorate.

29 Hershberger RE et al. Care processes and clinical outcomes of continuous outpatient support with inotropes (COSI) in patients with refractory end-stage heart failure. J Card Fail. 2003; 9(3):180–7.

**30** Marwick TH. Restrictive Annuloplasty for Ischemic Mitral Regurgitation: Too Little or Too Much. J Am Coll Cardiol. 2008; 51(17):1702-1703.

**31** Strickberger SA et al. Patient Selection for Cardiac Resynchronization Therapy, Circulation. 2005; 111:2146-2150.

**32** Garbern J et al. Cell Stem Cell, Volume 12, Issue 6, 689-698, 6 June 2013.

### **BUSINESS OVERVIEW**

Patients with chronic or acute heart failure who cannot be stabilized with OMT are candidates for MCS. The devices are used to unload the failing heart and maintain an adequate blood supply to key organs. Typically, patients with acute cardiogenic shock\* are initially treated with a short-term assist device to enable a full assessment to be carried out while definitive therapy can be planned and administered. These decisions are guided by a categorization established by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). There are seven categories, including four suitable to MCS therapies (see below).

Although LVAD is the most frequently recommended MCS intervention, up to 30% of these patients will have failure of both ventricles (biventricular failure), thus giving rise to inferior outcomes. There is currently no biventricular (BiVAD) MCS device on the market, and given the only current Syncardia® artificial heart (TAH) has relatively poor outcomes, surgeons tend to test solutions such as implementing two LVADs.

INTERMACS level NYHA Classification		Description	Device
1. Cardiogenic shock	IV	Unstable despite maximum drug support and/or short-term MCS	ECLS* LVAD** TAH***
2. Progressive decline despite inotropic support	IV	Acceptable blood pressure but rapid deterioration of kidney function and nutritional state	ECLS* LVAD** TAH***
3. Stable but inotrope dependent	IV	Blood pressure stable but requiring intermittent inotropes	LVAD**
4. Symptomatic at rest	IV	Temporary cessation of inotropes but frequent treatment required for fluid overload	LVAD**

<sup>\*</sup> ECLS: Extracorporeal Life Support (short-term system connected to patient by tubes).

The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9<sup>th</sup> ed. Boston, Mass: Little, Brown & Co; 1994:253-256.

### MCS strategies

MCS devices can be used for a number of different strategies:

Acronym	Description	Application		
CPR	Cardio-Pulmonary Resuscitation	Short-term devices used to resuscitate and buy time		
BTD	Bridge to Decision	Short- or medium-term devices used to evaluate best therapeutic way forward		
BTR	Bridge to Recovery	Medium-term devices used to attempt functional heart muscle recovery		
ВТТ	Bridge to Transplant	Medium- to long-term devices used to suppor patient awaiting a transplant		
DT	Destination Therapy	Long-term device used for permanent heart replacement therapy		

<sup>\*\*</sup> LVAD: Left Ventricular Assist Device.

<sup>\*\*\*</sup> TAH: Total Artificial Heart.



#### **TRANSPLANTS**

Patients with NYHA IV can currently only be definitively treated by heart replacement therapy (transplant or artificial heart).

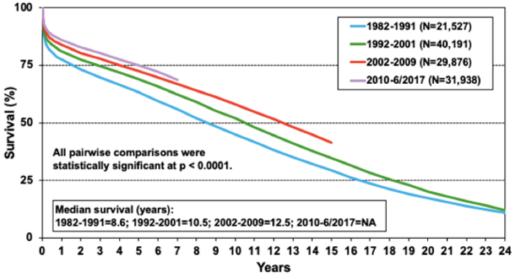
Although some LVADs and the only currently available TAH (Syncardia) are approved (or awaiting approval) for this chronic Destination Therapy (DT), they have yet to achieve the same results as heart transplants.

Professor Christian Bernard performed the first heart transplant in South Africa on December 3, 1967. The first transplant patients, with few exceptions, did not survive more than a few weeks after the operation, notably due to rejection (the host body's reaction against the transplant, which it considered as a foreign biological substance). Several important advances have increased patient survival:

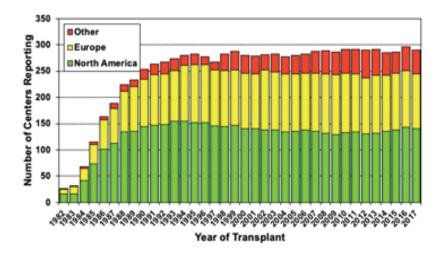
• the preservation of donor hearts thanks to refrigeration,

- allowing the removal at a distance from the place of transplantation;
- endomyocardial biopsy allowing early diagnosis of rejection: a probe is inserted, under radiological control and under local anesthesia, into a large vein and pushed until it is in the right ventricle, enabling a small piece to be harvested and analyzed under a microscope;
- finally, and above all, the arrival of ciclosporin, an immunosuppressant\* used as therapy, which provided great hope in organ transplants from the early 1980s by preventing acute rejection.

Today, some 4,500 transplants are carried out across the globe, with survival rates of 85% at one year and 69% at five years, in nearly 300 centers (see tables below). However, attrition rates do not improve significantly.



Survival rate after transplantation: ISHLT Registry 2018



Number of transplant centers worldwide: ISHLT Registry 2018

### **BUSINESS OVERVIEW**

The hopes placed on this treatment continue to face major problems limiting its generalization.

The first reason can be found in the very strict eligibility criteria both for harvesting the organ and the transplant. In theory, the donor 33 must be under the age of 61, brain dead, not a carrier of certain viruses such as HIV or hepatitis B and C, not be a drug addict or have a cancer and, of course, not be suffering from heart disease. This therefore limits the possibility of donation mainly to trauma deaths (in particular road accidents, which are constantly decreasing). Only 435 hearts were therefore harvested in France in 2012 and 397 were implanted 34.

In France, 41% of donors were over 60 years old in 2011 compared to 22% in 2007, which explains why not all of the transplants harvested can be used.

In light of this organ shortage, the eligibility criteria of the recipient are even stricter <sup>35</sup> in order to ensure the greatest chance of success with each transplant. Blood groups must be identical, weight and size equivalent. Irreversible pulmonary hypertension, an active infection or a cancer are formal contraindications. Other relative contraindications are also taken into account, such as diabetes, advanced lung or liver disease, renal impairment and morbid obesity.

A psychological assessment is considered to ensure that the patient understands and undertakes to adhere to complex life-long medical treatment. Patients with psychiatric disorders, or alcohol or drug addictions are not considered.

A particularly discriminating criterion, patients must be under 65, even if there is no particular legislation. Organs are therefore reserved for the youngest patients, while the vast majority of chronic heart failure patients are over 60 or suffering from comorbidities, which mean they are ineligible.

In addition, post-transplant survival decreases significantly with age. Only 80% of patients over 60 are still alive after one month, and 67% after one year<sup>36</sup>.

As a result, the number of transplants has been stable or declining in all developed countries for over ten years, while the prevalence of heart failure has considerably increased

Heart transplant waiting lists therefore do not reflect treatment needs, but simply the number of patients satisfying all the eligibility criteria, particularly age. The low diffusion of heart transplantation as treatment of choice for terminal heart failure is shown in the following table, which shows the small number of patients eligible for such treatment (see following table).

- **33** Latrémouille C et al. Transplantation cardiaque. EMC ©Elsevier, Techniques chirurgicales Thorax, 42-748, 2006.
- **34** Agence de la biomédecine Synthèse nationale de prélèvement et de greffe 2012 et annexe au bilan 2012.
- **35** Mehra MR et al. Listing Criteria for Heart Transplantation: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates. J Heart Lung Transplant 2006; 25:1024-42.

**36** Agence de la biomédecine – Rapport d'information au Parlement et au Gouvernement – septembre 2013 et bilan 2013: http://www.agence-biomedecine.fr/annexes/bilan2013/donnees/organes/03-coeur/synthese.htm.

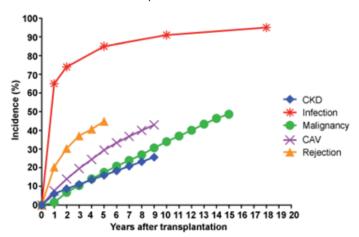
	France	United States	Germany****	U n i t e d Kingdom*****
Transplants	450*	3,244**	312	177
Patients on waiting list	364****	3,782***	703	246
* 2018 – Agence de la biomé	decine			
** 2017 - UNOS				
*** At January 17, 2019				
**** 2018 - EuroTransplant				

\*\*\*\*\* 2013 – Agence de la biomédecine – 2014 Annual Report http://www.agence-biomedecine.fr/annexes/bilan2013/donnees/organes/03-coeur/synthese.htm.

\*\*\*\*\* 2017 - NHS Organ Donation Annual Report

### **BUSINESS OVERVIEW**

There are also a number of serious complications associated with the transplants.



Post-transplant complication rate:
Alba A Int J Tx Res and Med 2016.

CKD = chronic kidney disease; CAV = cardiac allograft vasculopathy.

As patients require lifelong immunosuppression, they are susceptible to a range of side effects including an increased incidence of infection and malignancy, chronic rejection, development of graft coronary artery disease, hypertension and kidney disease.

Despite all of these issues, heart transplants are regarded as the gold standard in heart replacement therapy, so any potentially successful alternatives need to match or surpass their results. The International Society of Heart & Lung Transplantation (ISHLT) maintains a register and carries out extensive analyses of results, in order to guide recipient and donor selection, aimed at achieving the best outcomes with limited resources.

However, transplant rates are limited by the lack of donors and it is unlikely that an annual figure exceeding 6,000 will be achieved. The impact of changes to donation legislation, better donor management, innovative retrieval and storage techniques are offset by higher survival rates from road accidents and cerebral trauma.

Finally, heart transplants are heavy treatments at a very high price. The Milliman Institute has published a detailed report on the estimated cost of organ transplants in the United States. Its 2014 conclusions show a cost of US\$1,242,200 for heart transplants, including 30 pre-transplant days and 180 post-transplant days.

It is difficult to make international comparisons given the very different health funding systems and figures available covering different pre- and post-implantation periods.

## 1 2 ADDRESSABLE MARKETS AND MARKET PLAYERS

### 1.2.1 ADDRESSABLE MARKET FIGURES

CARMAT intends to market an artificial bioprosthetic heart for patients suffering from end-stage class IV heart failure, according to the NYHA Classification, that is either chronic or ischemic heart disease (including "acute myocardial infarction", which is only a sub-group) in the bridge-to-transplant indication, i.e., pending a transplant (see section 1.2.2 "Technologies and market players") and/or for Destination Therapy.

The figures below refer to the indication for destination therapy.

Chronic heart failure affects approximately 15 million European patients<sup>37</sup> and 5.8 million patients in the United States<sup>38</sup>, i.e., a total of approximately 20.8 million patients

**37** ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29, 2388-2442 (out of the 900 million inhabitants of the 51 member countries of the European Society of Cardiology).

**38** Heart Disease and Stroke Statistics – 2010 Update at a glance – American Heart Association and American Stroke Association.

in this geographical area.

Referring to the indications obtained by similar devices, this artificial bioprosthetic heart could be indicated for patients under 70 suffering from acute or chronic terminal heart failure who cannot be transplanted, without obvious contraindications such as cancer that reduce their life expectancy to less than six months.

### Considering that:

- each year, 2.3% of these patients will reach the terminal stage of the disease, involving the first hospitalization, i.e., approximately 478,400 patients<sup>39</sup>;
- 38% of these people are under 70 years old, i.e., approximately 182,000 patients<sup>40/41</sup>;
- **39** Jhund PS et al. Long-term trends in first hospitalization for heart failure and subsequent survival between 1986 and 2003: a population study of 5.1 million people. Circulation 2009; 119:515-523.
- **40** ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29, 2388-2442 (out of the 900 million inhabitants of the 51 member countries of the European Society of Cardiology).
- **41** Heart Disease and Stroke Statistics 2010 Update at a glance American

### **BUSINESS OVERVIEW**

- some 5,000 eligible patients are transplanted each year; and
- the anatomical compatibility of the CARMAT heart for men and women is 86% and 14% respectively (with a weighting of 80/20 between men and women). Note

Heart Association and American Stroke Association.

that the available clinical data indicate that these compatibility rates are set to increase in the near future.

There are approximately 126,700 potential patients in Europe and the United States for the indication class IV terminal chronic heart failure.

### 1.2.2 TECHNOLOGIES AND MARKET PLAYERS

Developing an artificial heart has long been the holy grail of medicine, and the first attempts date back to the 1930s in Russia, and then a series of developments in the United States in the 1960s. The first bridge-to-transplant (BTT) was carried out by Cooley in Texas in 1969, when an early device (Liotta Heart) was successfully used for 64 hours of support. One of the major innovators was Willem Kolff, who set up several teams to develop an artificial heart. One of Kolff's designs, developed by Robert Jarvik in 1982, was the first successful clinical implant. The patient lived for 112 days and then had four further permanent implants of the Jarvik 7 TAH, but the program was abandoned when it became clear that the therapy had too many complications and the equipment hindered decent quality of life.

Attention then turned to a simpler univentricular approach, when it became clearer that a significant number of heart failure patients could be adequately supported by just unloading the left ventricle, using an LVAD (left ventricle assistance device). These early partial success stories and the large unmet need, stimulated several commercial efforts to develop LVADs, driven by a steady improvement in engineering these devices, and patient selection and management.

While modern engineering has allowed major progress in pump design and fabrication, the weakness of these technologies remains the biological interface between the device and the patient, which results in significant complications, particularly coagulation control and infection. The design of CARMAT's artificial heart is aimed at overcoming these complications.

Although there have been many small companies involved in the development of these devices, today the principal market players are Thoratec® and Heartware® in the field of ventricular assistance, and Syncardia in the field of artificial hearts.

These devices are indicated in two main cases:

Pending transplants (bridge-to-transplant [BTT])

The device is implanted temporarily until an organ is available or until the patient's condition improves sufficiently to tolerate the operation. Given the thromboembolic or infectious complications of the available devices, they were, until recently, used mostly for this temporary indication.

Definitive treatment (Destination Therapy [DT])

This indication was, until recently, reserved for patients ineligible for a transplant, or who did not wish to have one. However, under the pressure of fast increasing prevalence and an organ shortage, many patients with temporarily implants actually become destination therapy patients.

The aim of Destination Therapy is to offer a system providing a real quality of life to the patient. This should include reasonable autonomy, returning to a home environment, and even normal social life and returning to work. Complications and the burden of system management should be minimal. In terms of symptoms, this would represent an improvement of at least 2 NYHA classes.

Thoratec® obtained the first approval for the use of their HeartMate II in Destination Therapy in 2010. The use of these devices as a permanent solution has increased considerably in the US and in Europe, such as in Germany, and in 2015, more than 50% of LVAD implants were for Destination Therapy.

(Note: The following information concerning the other devices has been taken exclusively from public sources such as the cited companies' websites, publicly accessible investor presentations or referenced scientific publications. Readers are encouraged to conduct their own research to form their own opinions. CARMAT accepts no liability concerning the accuracy of this information.)

### **VENTRICULAR ASSIST DEVICES 42**

These devices are often and incorrectly referred to by the media as artificial hearts.

However, as their name indicates, they are implanted to assist the native heart by supplementing its flow, meeting metabolic needs, but not replacing it.

Categories of Ventricular Assist Devices (VAD)

These devices can be categorized depending to their connection to the patient's vascular system (extracorporeal, paracorporeal, or intracorporeal):

- extra- and paracorporeal devices are used for shortto medium-term applications such as Rescue Therapy (RT), bridge-to-decision (BTD) and possibly, post-surgical bridge-to-recovery;
- modern VADs used for BTT or DT applications are intracorporeal and referred to as "durable" and implanted inside the body.

### Extracorporeal:

- Pump connected by long tubes
- Short-term support



### Paracorporeal:

- Pump located outside body
- Medium-term support

### Intracorporeal:

- Long-term/chronic support
- Intraventricular/Intrapericardial/ Abdominal pocket



The historical leader in VADs is Thoratec®, with its Heart-Mate II® and HeartMate III® devices. The HeartWare® LVAD, now owned by Medtronic, is the main competitor.

**42** Devices awaiting recovery (bridge-to-recovery [BTR]) are not mentioned here. Their indications and their technologies are very different. They can only provide limited assistance (approximately two liters/minute versus nine liters/minute for the CARMAT heart) for a very limited period (from a few hours to a few days) and are intended for patients without permanent ventricular deterioration, who need temporary hemodynamic support, for example after surgery or for post-traumatic

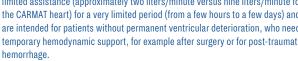
Thoratec® announced that it exceeded 18,000 implants for its HeartMate II® in 2014 (just five years after its FDA approval for definitive treatment), and it was on this basis particularly that the company was acquired by Saint Jude Medical in mid-2015 for €3.3 billion. In October 2015, the company announced that it had obtained CE marking for HeartMate III®.

More recently, in April 2016, the Abbott Group and Saint Jude Medical announced their merger, valuing Saint Jude Medical at approximately US\$25.0 billion. The company created as a result of this merger is positioned as a global leader in medical devices, with applications in the cardiac field, diabetes treatment and vision disorders.

Thoratec® products, an entity now belonging the Abbott Group, can theoretically assist the left ventricle (left ventricular assist device [LVAD]) or right ventricle (right ventricular assist device [RVAD]), or both ventricles. In the latter case, they are called biventricular assist devices (BiVAD). To date, however, there are no implantable devices approved for the right ventricle or biventricular application, as all of the devices have been designed for the left ventricle.

Right ventricular failure is a major complication of LVAD treatment of the left ventricle. Reported incidence varies from 3.9% to 53% using diverse definitions. However, BiVAD system results are significantly worse than those from LVAD alone, (50% versus 80% survival). To our knowledge, only Medtronic has expressed an intention to seek authorization for a right ventricular assist device (RVAD). RVAD or BiVAD design is different to LVAD design. This is because the right ventricle operates under very different conditions to the left ventricle. Operating pressures are much lower, the native muscle has much less resilience and unloading the left ventricle produces a change in the internal geometry of the heart. In addition, any BiVAD configuration requires the right and left flows to be carefully matched to avoid damage to the lungs.

LVAD designs have evolved over time, from first generation designs with large pneumatic or electromagnetic pumping chambers incorporating mechanical valves used in open heart surgery, to second and third generation devices, which are smaller and larger sophisticated described in the following paragraphs. They were connected to the heart via wide conduits and to an imposing control and power system via a percutaneous cable. Subsequent improvements to external systems allowed patients to be discharged from hospital while awaiting a transplant. However, these systems were relatively large, noisy, and had high levels of complications, including neurological attacks, infections and device failures.





The second-generation pumps were developed in the 1990s using rotary pump designs, after animal studies showed that the non-pulsatile flow and pressure profiles produced by this type of pumping action were compatible with chronic survival. This allowed the pump size to be significantly reduced, and avoided the inclusion of valves. The most frequently used device of this design was the HeartMate II®. Results were significantly better than with first-generation devices and the small size made for an improved patient quality of life. However, chronic loss of a pulse produced coagulation and abnormal blood vessel development complications, as well as issues with infection.

Third-generation designs comprise even smaller devices, such as HeartMate III® and HeartWare®, which are easier to implant right next to the heart, require less power, and can be controlled to produce a pseudo-pulse. Early results suggest that these designs have resulted in overall better outcomes with fewer complication rates. However, a recent INTERMACS annual report had the following conclusion: "adverse events continue to affect this field, contributing to death and an unacceptable high incidence of hospital readmissions".

### **TOTAL ARTIFICIAL HEARTS (TAH)**

Similar to the heart transplant procedure, total artificial hearts replace both failing ventricles. Placement is called "orthotopic" to distinguish grafts or implants placed elsewhere than at the position of the native heart in the thorax. The native ventricles are removed and the TAH is connected to the remaining atria of the human heart, the blood of which fills the device, and to the main blood vessels carrying blood to the lungs (pulmonary artery) and the rest of the body (aorta) by two conduits.

### Syncardia

The only total artificial heart currently on the market in Europe and the United States belongs to the private equity company Syncardia <sup>43</sup>. After facing financial difficulties ("Chapter 11"), the company was financed by private equity fund Versa Capital Management in September 2016.

The Syncardia® device was designed in the 1970s and implanted for the first time in 1982 under the name Jarvik 7. The patient survived for 112 days. In 1985, a patient reached the transplant stage for the first time after surviving for nine days with the artificial heart. In 1990, the FDA closed Symbion, Inc., which held the rights for Jarvik 7 and stopped the ongoing clinical study (IDE\*) due to regulation breaches. The technology was taken up again by the Health Sciences Center at University of Arizona under the name CardioWest™. A new clinical study restarted in 1992 in the United States and lasted ten years, resulting in FDA approval in 2004 for a bridge-to-transplant indication and CE marking. Meanwhile, a new privately funded company, Syncardia Systems, Inc., was created in 2001 to prepare and market the product<sup>44</sup>. Syncardia announced the 1000<sup>th</sup> implantation of its artificial heart in February 2012, 19 years after the first implant in December, 1982. Today, to our knowledge, the annual number of Syncardia implants is about 50.

This means that the only TAH on the market was designed more than 40 years ago. The two polyurethane ventricles are actuated by pneumatic pressure, and air pressure actuates the internal flexible membranes separating each ventricle into blood and air compartments. Forward flow is achieved with the use of four mechanical heart valves: Two percutaneous plastic pipes approximately 7 feet (2 meters) long connect the device to the external compressor, whose portable driver version, Freedom™, weighs 13.5 pounds (6.12 kilograms), excluding carrying accessories such as a backpack or carry case. It has an autonomy of three hours <sup>45</sup>.

**<sup>43</sup>** www.syncardia.com – all information concerning Syncardia is taken from the company's website, unless specifically stated.

**<sup>44</sup>** Historical information on Jarvik 7 can be found on the Jarvik Heart website www.jarvikheart.com.

**<sup>45</sup>** Jaroszewski et al. The SynCardia freedom driver: A portable driver for discharge home with the total artificial heart. J Heart Lung Transplant 2011 Jul 30(7):844-845.

Comparative table of different devices addressing heart failure

	CARMAT total artificial heart	Syncardia total artificial heart	Thoratec ventricular assis- tance device (Heart- Mate III®)	Heartware ventricular assis- tance device
Visual of the system				Driveline Buttery  Controller
Corporate information	Listed company €60 million last fundrais- ing in September 2019	Company supported by private equity fund Versa Capital Management since September 2016	Acquired by Saint Jude Medical in 2015 for \$3.3 billion, Saint Jude Medical acquired by Abbott in 2016 for \$25.0 billion	Acquired by Medtronic in 2016 for \$1.0 billion
Market access	Non-marketed product Pivotal study ongoing	Bridge to Transplant approval: 2004 (USA) and 1999 (CE marking Europe) Study for Destination Therapy: pending	Bridge to Transplant approval: 2017 (USA) Destination Therapy approval: 2015 (CE mark- ing Europe) and 2018 (USA)	Bridge to Transplant approval: 2012 Destination Therapy approval: 2017
Technology	Bioprosthetic artificial heart, biocompatible, autoregulated, pulsatile, hydraulic activation	Artificial heart, with pneu- matic technology (Jarvik 7)	Ventricular assistance device, with centrifugal pump	Ventricular assistance device, with centrifugal pump
Advantages	Biocompatible materials reducing adverse events  Autoregulation matching patient physiological needs  Pulsatile	Relatively simple technology Pulsatile Product already on the market	Small devices – large patient size compatibility Simple implantation Better complication rates than earlier devices or current TAH	
Disadvantages	Some patient size restrictions	Relatively high complication rates Limited automatic function Noisy	Left support only Relatively high complication rates Native heart problems impact Non-pulsatile Minimal autoregulation	

### **BUSINESS OVERVIEW**

### Other artificial heart projects

TAH research is a dynamic area of device innovation with, to our knowledge, five other devices in various stages of development, the most advanced of which is Bivacor.

CARMAT welcomes this investment by potential competitors as it underlines the belief in the potential and benefits of total artificial hearts.

Company	ReinHeart	RealHeart	SmartHeart	Bivacor	OregonHeart
Location	Aachen, Germany	Vâsteras, Sweden	Cleveland, USA	LA/Houston, USA	Seattle, USA
Development stage	Design improvements	Design improvements	Bench testing, animal studies	Animal studies	Design improvements
Visual of the prosthesis	TO SE				

# 1.3 THE FIRST PHYSIOLOGICAL HEART REPLACEMENT THERAPY\*

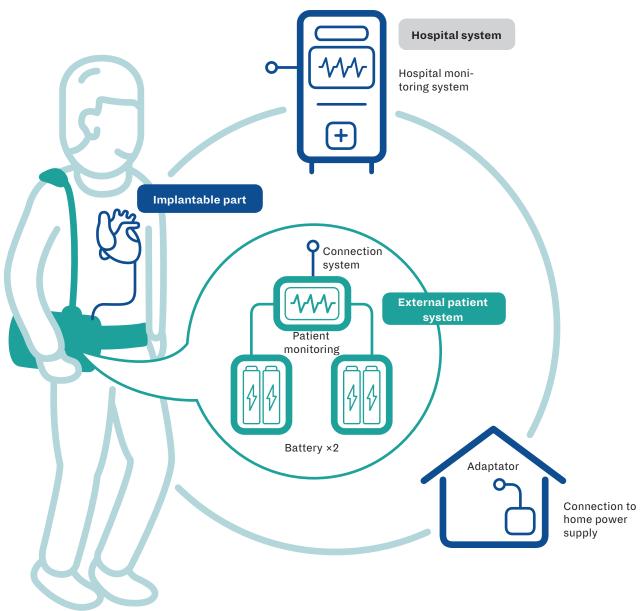
### 1 3 1 MARKET POSITIONING

The CARMAT artificial heart has been designed to offer a permanent solution to patients with terminal heart failure with no further therapeutic options due to the lack of human grafts or transplant illegibility.

The constraints on the adoption of assist devices as a major therapy, for the reasons detailed above, stimulated the design and development of the CARMAT artificial heart, with special emphasis on improving the biological interface, and subsequently reducing thrombotic and hemorrhagic complications.

A logical approach was to use the same materials already widely and successfully used in bioprosthetic heart valves. Incorporated into this design was also a novel electrohydraulic drive system, which simulates human physiological blood flow and pressure profiles, together with a control system to provide a normal response to exercise.

<sup>\*</sup> Hereafter PHRT.



Source: CARMAT - The complete CARMAT system

## 1.3.2 CARMAT PROSTHESIS TECHNICAL PROPERTIES

As presented on the above chart, the system consists of:

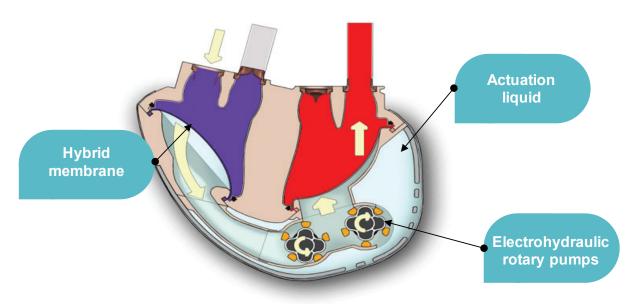
- an implantable part, the bioprosthetic artificial heart;
- external wearable equipment allowing patient autonomy and return to home;
- a hospital system allowing full prosthesis configuration and patient monitoring.

### **IMPLANTABLE PROSTHESIS**

The CARMAT prosthesis is a single-unit device with bio-prosthetic blood-contacting surfaces designed for orthotopic placement, with connection to an electrical supply (battery or mains power) via a percutaneous driveline.

Source: CARMAT - Overview of the full prosthesis





Each ventricle consists of two compartments, separated by a hybrid membrane. The membrane consists of processed bovine pericardial tissue, on the blood-contacting surface, and a polyurethane layer at the hydraulic silicone fluid contacting surface.

Two electrohydraulic rotary pumps create systolic and diastolic phases by rapidly reversing the direction of silicon fluid that alternately pushes and pulls the membranes.

Pressure sensors in each ventricle provide information on preload and afterload, while ultrasonic sensors measure the position of the membranes.

When they are implanted, and when required, physicians can adjust the beat rate (10 to 150 beats per minute), the left ventricular stroke volume (30 to 65 milliliters) and the right to left stroke volume ratio (to correct for the bronchial (lung) circulation) and alarm thresholds. The resulting pulsatile blood flow can range from two to nine liters per minute.

Once the patient is stable after implant, the device is switched to automatic mode, which automatically adjusts device performance to the patient's changing physiological needs.

The combination of membrane characteristics and hydraulic actuation provides for physiological pressure and flow profiles. Electronics and microprocessors are contained within the device.

Four Carpentier-Edwards® bioprosthetic valves (Edwards Lifesciences, Irvine, CA, US) are located at the inlet and outlet of each blood compartment to maintain unidirectional flow.

The prosthesis is partially surrounded by a flexible polyurethane compliance bag containing the hydraulic fluid.

### **Electrical connection**

Electrical energy is transferred from the monitoring console or portable batteries to the prosthesis via a flexible percutaneous driveline.

Its small diameter (8 millimeters) delivers power to the CARMAT prosthesis and retrieves information on device performance. The driveline connects to a wearable system, providing an electronic interface for displaying essential device data for the patient, and an uninterrupted power supply for the device. The clinician connects a hospital monitoring console to the wearable system for initial



set-up and for subsequent monitoring of the device and changes to the CARMAT prosthesis settings.

#### THE WEARABLE SYSTEM

The wearable system provides for autonomy and mobility, and allows for the patient to be discharged from hospital and return home with a good quality of life.

Once the patient is stable after implant, the hospital monitoring system is replaced by the wearable system. The patient then only uses the wearable devices, except during periods of outpatient reviews and for downloading data. Several ancillary bags and covers are available to use with the wearable equipment.

A stringent training and monitoring program are set up to ensure that the patient and companions fully understand the safe operating principles of the system.

The wearable system is made up of:

- a controller;
- two battery packs;
- a carry bag.

The entire system weighs three kilograms.

The batteries provide at least four hours of autonomy at a blood flow of six liters per minute.





Source: CARMAT - The patient's wearable system

### THE HOSPITAL MONITORING SYSTEM

The hospital monitoring system is only used in implantation centers by certified medical staff. It allows the medical team to configure and pilot the prosthesis during implantation, and to monitor progress during periodical check ups. It also enables new features or versions of prosthesis software to be downloaded.

The hospital monitoring system is used to:

- configure the prosthesis during device implantation;
- monitor prosthesis functions;
- display alarms;
- collect data from the prosthesis.



Source: CARMAT – The hospital monitoring system

### 1.3.3 INNOVATION AND COMPETITIVE ADVANTAGES

The CARMAT heart includes several innovative design features which, to our knowledge, are currently unmatched by any other MCS system on the market or planned for any device under development.

#### **HEMOCOMPATIBILITY**

The most original feature is the use of bioprosthetic materials similar to those that have been used for tissue heart valves for the past 35 years. This material is on the inner layer of the flexible membrane. The static surfaces of the ventricles are covered with polytetrafluorethylene, a material used in vascular surgery. Carpentier-Edwards bioprosthetic heart valves are used for the two inflow and outflow valves.

#### **PULSATILE**

The pumping action of the two ventricles is achieved by a viscoelastic movement driven by the embedded hydraulic pumps. This produces flow and pressure blood profiles that closely mimic those of the natural heart. This preserves valve durability and ensures optimal ventricular flow characteristics, avoiding damage to blood cells and proteins.

### Key features

· Biological:

Hemocompatible: biocompatible material for blood contact surfaces

Electronic:

Auto-regulated: automated response to the patient's physiological needs (activity adjustment, circadian rhythm)

Mechanical:

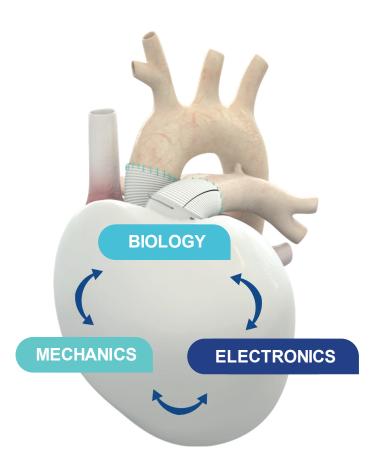
Pulsatile: hydraulic pumps mimic diastole and systole

#### **AUTOREGULATION**

Embedded electronics, microprocessors and ultrasonic sensors allow precise control and responses to changing patient physiological needs. In addition, they maintain an optimum balance between right and left pump flows.

### In summary:

- all surfaces that come into contact with blood are covered by proven biocompatible materials;
- biological valves, which have been in clinical use for many years, provide unidirectional flow;
- the pumping action closely mimics human heart dynamics;
- blood damage and the activation of pathological changes are avoided;
- an automatic function responds to changes in patient activity and needs.



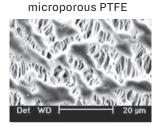
Source: CARMAT

Assessments of explanted clinical pumps confirm the efficacy of biocompatible surfaces (see picture below and section 1.4 "Clinical trials"). Patients were managed with a minimal anticoagulation therapy, which is likely to be reduced further in the future, to a level used for patients with vascular stents.

Biosynthetic membrane



Biosynthetic interface with the atria



Ventricle in

Carpentier-Edwards® pericardial valve



Source: CARMAT - Hemocompatible materials

### OTHER COMPETITIVE ADVANTAGES

Compatibility with human thoraxes/implantability

The shape and size of the CARMAT prosthesis have been adapted to the anatomy of the human thorax, in order to fit the largest number of patients. This involved making design adjustments to allow the ejection of a normal volume of blood with each beat, whilst using the minimum thoracic space.

Based on a sophisticated 3D simulation, an advanced virtual 3D implantation system has been developed to produce a reliable non-invasive method for patient selection.

3D virtual transplant simulator

Segmentation of CT image sections



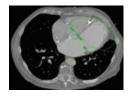
3D organ reconstruction

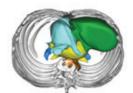


Insertion of the CARMAT 3D model



Assessment of compatibility







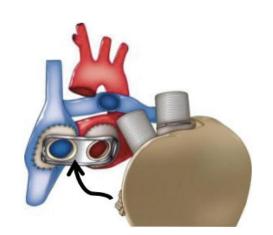


Source: CARMAT - 3D virtual transplant simulator

### Surgical experience

An implantable device can only be a valid therapeutic solution if the implantation is simple and reproducible. Under the supervision of Professor Carpentier, the CARMAT teams have therefore worked in tight collaboration with several surgeons, anesthesiologists, perfusionists and nursing personnel in the surgical community, to design and develop a procedure that any experienced heart surgery team can perform, even in emergency situations.

In particular, an original interface with the patient's atria (upper heart chambers) was developed, which allows the surgeon to have much more room to work, and ensures a better subsequent alignment of the prosthesis. Once this interface is sutured to the atria, the prosthesis can simply be clicked into place.



### **BUSINESS OVERVIEW**

Pivotal study experience also shows that the implantation times of the CARMAT prosthesis are similar to those encountered for a human transplant. The implantation procedure is also greatly facilitated by the fact that there is no adhesion of the tissues to the prosthesis.

# 1.4 GO-TO-MARKET PROCESS

As an active implantable device, the CARMAT total artificial heart (TAH) must gain approval from the competent authorities of the different countries where CARMAT wishes to sell it. The regulatory pathways differ from one country to another, but in all cases, for such a critical device, the manufacturer is required to demonstrate its

safety and efficacy through evidence collected in laboratory testing and clinical studies.

At present, CARMAT's objective is to get approval to commercialize its device both in Europe and in the United States.

### 1.4.1 GO-TO MARKET PROCESS FOR EUROPE

### **PROCESS OVERVIEW**

Council Directive 90/385/EEC relating to active implantable medical devices, modified by Directive 2007/47/EC defines the requirements to be met in order for the device to obtain CE marking.

in a technical file (TF), reviewed and audited by a certification agency. CE marking is granted by the certification agency once the TF has been successfully reviewed and audited.

The relevant process is described in the chart below (see Chapter 2 of this Universal Registration Document for a description of the risks associated with this process).

Evidence of safety and efficacy of the device is compiled

Full audit of the CARMAT quality system by the certification agency

- Design
- Production (management of the environment, process validation method, control tests)
- Management of anomalies
- Identification and management of risks
- Procurement (contracts, management and monitoring sub-contractors audits)
- Information systems
- Maintenance, metrology
- Human resources (skills, training)

ISO CERTIFICATION 13485-9001 obtained in July 2011, then renewed successfully, most recently in July 2017 Establishment of a technical file

- **File produced** (design, choice and validation of materials, plans, labels, leaflets, manuals, implantation procedures, etc.)
- Verification file for the full system, sub-assemblies and components
  - Biocompatibility
  - Tests on test systems (functional, endurance, etc.)
  - Electro-magnetic compatibility tests
    - Validation of sterilization
- Industrial validation on site and with the sub-contractors
- Risk management file (Analysis of types of failure and effects of their criticality (AMDEC) for the product and processes)
- Validation file: clinical studies

Audit of the technical file by the certification agency

- Analysis of the technical file

- Audit of the organization and all of the product-related processes:
  - on site
- with major sub-contractors
- Compliance opinion

Declaration of European Conformity

CE marking

Source: CARMAT – CE marking procedure

#### **BUSINESS OVERVIEW**

The CE marking authorizes the commercialization of the product throughout the European Union. However, certain member states have put in place additional conditions, such as registration or notification of market introduction.

The Council Directive concerning medical devices will be replaced by a new European medical device regulation from May 2020. This regulation strengthens the requirements to be met for a device to be granted CE marking. If CE marking is granted before May 26, 2020, it will remain valid until May 26, 2024, provided that there are no significant changes in the design or intended purpose of the device during this so-called "grace period", and the company complies with the requirements of the new medical device regulation relating to post-market surveillance, vigilance, and registration of economic operators and devices.

CARMAT announced that it had submitted its technical file (including the intermediate results from the pivotal study as described on the following page) to the Dekra certification agency in July 2019, and continues to take, in conjunction with the certification agency, all necessary steps to obtain CE marking in 2020.

Sections 1.4.1.2 and 1.4.1.3 describe the design and summarize the results so far of the clinical studies performed by CARMAT as part of the CE marking process.

#### PREPARATION OF CLINICAL TRIALS

Before clinical trials, the potential benefit of the device was assessed by literature research, aimed at comparing the device to existing therapies for terminal heart failure. A series of simulation tests, bench tests to assess device reliability, and animal implants were performed to identify and reduce potential risks for the patient prior to clinical trials.

An overview of these steps is provided below.

Clinical trials in Europe must be pre-approved before initiation by the competent authority in each participating country as well as the local ethics/patient protection committees.

#### **CLINICAL TRIALS**

#### Feasibility study

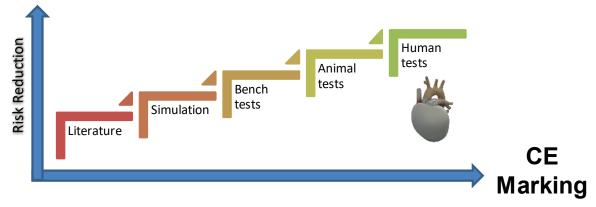
A first-in-man (FIM) study was conducted in France between 2013 and 2016 with a small cohort (n=4) of sick and elderly patients. During this early clinical stage, the surgical technique for device implantation was validated and the anatomic compatibility of the device confirmed. Technical improvements to the prosthesis were implemented following device failures in the first two implanted patients. The CARMAT TAH was capable of providing adequate blood flows, with cumulative support of 618 days, allowing two patients to return home and regain an almost normal quality of life. Results of the FIM study have been published in peer-reviewed medical journals such as *The Lancet* <sup>46</sup>, *The Journal of the American College of Cardiology* <sup>47</sup> and *The Journal of Heart and Lung Transplant* <sup>48</sup>.

#### Pivotal study

The feasibility study was followed by the pivotal study involving 20 patients (two cohorts of 10 patients). The objective of this study, which is still in progress, is to demonstrate the safety and performance of the CARMAT TAH in patients suffering from irreversible biventricular heart failure.

The pivotal study began enrolling patients in 2016 with authorizations in France (2016), Kazakhstan (2017), the Czech Republic (2017) and Denmark (2018) for a total of 20 patients (ClinicalTrials.gov - Identifier: NCT02962973).

- **46** Carpentier A, Latrémouille C, Cholley B, et al. First clinical use of a bioprosthetic total artificial heart: report of two cases. Lancet. 2015 Oct 17; 386(10003):1556-63.
- **47** Smadja DM, Bioprosthetic Total Artificial Heart Induces a Profile of Acquired Hemocompatibility With Membranes Recellularization. Journal of the American College of Cardiology 2017; 70:404-6.
- **48** Latrémouille C, et al. A bioprosthetic total artificial heart for end-stage heart failure: Results from a pilot study. J Heart Lung Transplant. 2018 Jan; 37(1):33-37.



Clinical trials are the last step in demonstrating device safety and performance

#### **BUSINESS OVERVIEW**

The primary assessment benchmark of the study is survival on a CARMAT device at 180 days post-implant or survival following a heart transplant if occurring before 180 days post-implant. The results are analyzed in the Clinical Evaluation Report, which is an integral part of the Technical File for the CE marking file.

Intermediate results of the pivotal study

CARMAT plans to communicate on the overall progress of CE marking and on significant milestones in the pivotal study. In accordance with good clinical practice and subject to regulatory requirements or special circumstances, CARMAT will not communicate on patient implants and the health of said patients individually.

CARMAT presented an update of the pivotal study in January 2019 and more recently in November 2019. The intermediate analysis presented in November included 11 patients, recruited between August 2016 and August 2018. In total, the pivotal study includes 20 patients with terminal biventricular heart failure.

Survival after implantation of the CARMAT TAH was 91% at one month, and 73% of patients achieved the primary objective of the study, namely six months of survival with the prosthesis or a successful heart transplant in the months following the CARMAT device implant. Nine patients were discharged from hospital to either a home setting or to a rehabilitation unit, where they spent more than 70% of their time.

Of the 11 patients included in the intermediate results, five patients eligible for transplants received donor hearts after 109, 155, 243, 304 and 308 days of CARMAT support without any procedure-related complications. In particular, there was no tissue adhesion around the device, a known procedural challenge with other circulatory support devices. In addition, explant analysis confirmed the early findings of ongoing endothelialization of all of the surfaces coming into contact with blood, which attests to the utility of using these particular biocompatible materials.

The experiment and the results of this cohort of 11 patients in the pivotal study have demonstrated a positive safety and performance profile, particularly in terms of the absence of hemocompatibility-related complications. This device compares favorably with the current TAH (Syncardia®) in terms of survival at six months (73% versus 64%), neurological complications (0% versus 23%), non-surgical bleeding (0% versus 20%), driveline infection (0% versus 22%), anticoagulation (low-dose versus complicated regimen), noise (quiet versus noisy pneumatics), physiological response (near normal versus limited) and has shown to facilitate safe and quick implant and explant surgery.

See the table below for a summary of the results obtained at this stage by CARMAT compared to other therapies at six months after transplant.

The overall cumulative experience in the pivotal study now exceeds 6.5 patient years. Out of the six patients supported for more than six months, three were transplanted as indicated above, and one has now been supported for

Device	Survival rate at 6 months	Stroke	Bleeding/ Reintervention	Gastrointestinal bleeding	Percutaneous cable-related infection
CARMAT Feasability study (n=4)	50%	0%	75%	0%	0%
CARMAT Pivotal study (n=11)	73%	0%	36%	0%	0%
SynCardia*	54%-62%	23%	41%	20%	22%
BIVAD**	46%-68%	7%	N/A	7%	7%

<sup>\*</sup> Arabia F et al, J Heart Lung Transplant, 2018; 37; 1304-1312. Demondion P et al, Eur J Cardiothorac Surg. 2013 Nov: 44(5):843-8.

Source: CARMAT - Intermediate results pivotal study

<sup>\*\*</sup> Lavee J et al, J Heart Lung Transplant 2018; 37; 1399-1402

#### **BUSINESS OVERVIEW**

nearly 24 months. In addition, bench tests have now been failure-free for more than five years.

The analysis of all information gathered from the experiment accumulated with the first cohort of the pivotal study and data recorded on test benches, prompted CARMAT to halt patient enrollment and production in October 2018 in order to implement a number of changes to its

manufacturing processes.

Subsequently, CARMAT restarted production in May 2019 and received approval to resume the Pivotal Study in Denmark (August 2019), the Czech Republic (November 2019) and Kazakhstan (December 2019), with an implant in the Czech Republic in November 2019, marking the enrollment of the twelfth patient.

## 1.4.2 GO-TO-MARKET PROCESS FOR THE UNITED STATES

Selling the CARMAT heart in the United States is subject to obtaining a pre-market approval (PMA) awarded by the US Food and Drug Administration (FDA).

In order to submit a PMA application to the FDA, CARMAT is required to supplement its existing clinical evidences with additional clinical results from a new multicentric clinical study performed on a larger population. Conducting this study in the United States requires an Investigational Device Exemption (IDE) to be obtained from the FDA following a successful review of all of the pre-clinical data (technical studies, animal studies, etc.) and clinical data obtained in other countries.

In October 2013, the FDA published a guidance document on early feasibility studies (EFS). This approach to feasibility studies was designed to allow for acquisition of initial clinical knowledge when additional non-clinical testing methods are not available or are not sufficient to initiate a pivotal study. These studies may be initiated before the design of the device is finalized and may be justified on the basis of less evidence than for other types of clinical studies. This EFS approach was chosen by CARMAT.

In 2014, the Company began preliminary work to support its regulatory strategy for the United States. In August 2018, CARMAT submitted an EFS to the FDA.

In September 2019, the FDA granted conditional approval to CARMAT's application, allowing CARMAT to initiate the patient enrollment process for its EFS in the United States.

On February 5, 2020, CARMAT announced that it had obtained the full FDA approval required to launch its clinical feasibility study with its artificial heart. The approval was granted for a study limited to ten patients.

Upon successful completion of the feasibility study, CAR-MAT will submit another application to initiate a pivotal study in the United States, the results of which will support its PMA application. This strategy would allow for the integration into the PMA application of certain clinical data obtained in Europe, thereby limiting the size of the pivotal study to be conducted in the US.

See Chapter 2 of this Universal Registration Document for a description of the risks associated with obtaining a PMA from the FDA.

# 1.5 COMPANY STRATEGY

## 1.5.1 REGULATORY STRATEGY

Firstly, CARMAT is currently looking to obtain CE marking, which will allow it to market its prosthesis in Europe; and secondly, pre-market-approval (PMA), to enable the Company to market its prosthesis in the United States.

CE marking is issued by Dekra, CARMAT's certification agency, while PMA is issued by the US FDA.

CE marking and PMA processes are specified in section 1.4 of this document, as is CARMAT's progress in this area.

## 1.5.2 MARKETING STRATEGY

#### **EUROPE**

The Company will be able to market its product throughout Europe as soon as CE marking is obtained, subject to the application of national systems covering the cost of the device (see Chapter 2 of this document for a description of the risks associated with reimbursement and management of the system).

To date, the Company intends to market its prosthesis through a direct sales force in the main European countries, and where appropriate, distributors or agents carefully selected in countries deemed less strategic, or when this method seems more appropriate given the local context.

A direct sales force was chosen in two ways:

- thorough selection of the indications and the need for technical and clinical support for each implantation.
   This support is provided primarily by the Company in the training and launch phase;
- a concentric approach strategy to the market involving focusing initially on the target heart, i.e., the active heart transplantation centers (at least 20 heart transplants per year) followed by the less active centers, then the centers with teams dedicated to heart failure (surgery and cardiology) but who are not approved for transplantation and finally, if the local regulations permit, all heart surgery centers.

The sales force will therefore initially consist of very clinical profiles to ensure the training and adoption of therapy by the medical and surgical community, an approach expected to enable progressive investments.

Given the very limited number of human grafts, the number of truly active heart transplant centers – those that

obtain approval and perform a sufficient amount of transplants to keep teams available and trained – is very low, i.e., less than ten in each large country. For example, fewer than ten centers in France and Germany perform more than 20 transplants per year.

The Company therefore considers that, to cover this target made up solely of centers of excellence, a direct sales force is the most appropriate response in the first phases of commercial development (three to five years after commercial launch in Europe). In the longer term, when the Company has a larger clinical and medico-economic data base and once implantation centers have adopted its product(s), CARMAT's several centers may be gradually expanded.

The order in which the different European countries will be approached will depend on the prevalence of cardiovascular diseases, the size of the centers, and the national systems for covering the cost of the device. To date, taking into account these elements, the first target market for CARMAT's prosthesis after obtaining CE marking is likely to be Germany.

With regard to the pricing policy, the price targets for the CARMAT bioprosthetic artificial heart are consistent with current reimbursement practices for available devices. For example, an implantable device for left mono-ventricular assistance is currently reimbursed in Europe between €60,000 and €110,000 excluding taxes (approximately €90,000 excluding taxes in France) <sup>49</sup>. As the CARMAT heart treats both parts of the heart and is made up of a system that includes an implantable part as well as external parts and associated pre- or post-operative services, the pricing variables are numerous and could make it possible to adapt to the volume and reimbursement conditions specific to each center or each market, while maintaining overall price consistency at European level.

**49** List of reimbursable products and services – LPP (ameli.fr): regulated unit price (decision of 11/29/2012) of the monoventricular HeartMate II® is €87,565.

#### **BUSINESS OVERVIEW**

There are multiple and varying reimbursement procedures in each country. For that reason, the Company will call upon the services of local reimbursement experts, where necessary, to optimize and accelerate the management of its device. It also assembles the medico-economic data necessary to support the reimbursement and care procedures.

The Company considers that the absence of reimbursement would not be synonymous with the total absence of sales and income, in particular insofar as hospitals in certain countries have their own budgets to finance innovation, but would not allow the development of sales in line with its financial objectives.

Finally, it should be noted that Stéphane Piat, who joined CARMAT in September 2016 as Chief Executive Officer, has considerable experience in the field medical devices marketing, in particular within Johnson & Johnson Cordis and Abbott.

#### **UNITED STATES**

The development of a commercial approach to the American market is premature at this stage. However, CARMAT currently intends to apply the same fundamentals as in Europe, both in terms of commercial structure and development, reimbursement and prices.

## 1.5.3 INDUSTRIAL STRATEGY

#### **CHOICE OF INTEGRATION MODEL**

The Company designs or specifies all of the components in the CARMAT artificial heart, including its external components as well as all the ancillary tools, packaging, systems and methods intended for the validation (bench testing) and production of components, sub-assemblies and systems (clean room). It has also developed strong intellectual property rights for all of these components. Nevertheless, considering the very high number of specialties and expertise involved in each component and sub-assembly of the system, it was impossible to develop and produce them all internally.

The Company has therefore adopted the following model of integration: it designs and specifies, but entrusts the manufacturing of most of the components to specialized subcontractors, recognized in their field and selected following rigorous consultation. These components are then integrated at its production site.

CARMAT integrates the components and sub-assemblies provided by manufacturers of very different sizes, methods and areas of expertise. The Company has hundreds of component manufacturers and service providers for the CARMAT heart.

The challenge for a company such as CARMAT involves federating these companies with different origins and methods (some are large sub-contracting groups in the aerospace industry and others are very small specialist companies) with common strict processes as are required in the field of medical technologies and by regulatory authorities. This coordination relates to technical aspects, logistics and in particular, quality. The Company has made great efforts to validate and qualify these suppliers, so that each one of them complies with the very high level of quality standards required for active implantable medical devices.

CARMAT's mode of operation, its methods and its integration process are therefore identical to those of a large group in the management of a project as complex as that of the bioprosthetic artificial heart.

In parallel, the Company actively pursues a strategy of developing a secondary source of supplies, in particular the transformation of critical raw materials or the supply of key components. Initiating a second source involves selecting of a new supplier, helping to produce its first parts, then qualifying them while ensuring that each part comes from a source that is strictly identical to those coming from another source, including the documentation with them in particular to satisfy the imperatives of quality and traceability. It is important and vital work to reduce the dependency of the Company with regards to their suppliers, and so that CARMAT can have materials and components in sufficient volumes, and at the level of quality required, to meet its needs both in the development phase and in the marketing phase of its prosthesis.

## INTERNALIZED PRODUCTION AND PRODUCTION CAPABILITIES

However, the Company has kept and retained the production of the biosynthetic components of the prosthesis (ventricular biomembrane, ventricular coverings and atrial connection interfaces) internal, protected by numerous patents and by industrial secrets.

2017 was marked by the construction of a new dedicated production site to manufacture several hundred units per year. The site was opened and certified in 2018, and has an area of 1,600 square meters, is located in Bois-d'Arcy in Greater Paris, has a 270-square-meter clean room in compliance with ISO 7 standards. The manufacture, integration and sterilization of prostheses are carried out in a controlled environment, by specialized and highly qualified staff. Prostheses are now entirely produced at this site.

#### **BUSINESS OVERVIEW**

Manufacturing a device as complex as the CARMAT heart remains a challenge, particularly on a large scale. Industrially, in addition to its actions of securing supplies, the Company constantly pursues the improvement of its information systems, and the adaptation of its production processes

with an objective of reliability and better replicability, and, in particular, quality. These improvements also aim to increase production capacities, in particular with a view to marketing the prosthesis. In 2019, CARMAT successfully carried out more than 50 changes to its production processes.

# 1.5.4 INNOVATION AND R&D MANAGEMENT

#### **APPLYING SKILLS**

Thanks to its historical artificial bioprosthetic heart project and its teams, CARMAT benefits from an exceptional and unique double know-how stemming from more than 15 years of development and collaboration between the medical and aerospace fields in the implementation of biomaterials and advanced technologies applied to the artificial bioprosthetic heart field.

In addition, contributions specific to the medical and aerospace fields, the Company also knew how to bring together talents never before used on such a complex project, allowing them to acquire know-how specific to these fields.

Emboldened by this unique capacity to create synergies between industrial and medical skills, CARMAT may, in the future, and beyond bioprosthetic artificial hearts, develop new applications of its know-how in the cardiovascular field. Original simple devices derived from CARMAT's existing research and patents, in particular with regard to hemocompatible biomaterials, may also be developed. Products derived from patents already been submitted – particularly in the field of digital simulation and ancillary implantation materials – may also result in commercial marketing or sale of rights. Original services may also be commercialized.

However, at this stage, the Company does not plan to devote resources to these potential applications, and remains focused on finalizing the development and improving the reliability of its artificial heart with a view to its future commercialization. On the other hand, it pursues an aggressive policy of protection of its intellectual property and ensures permanent technological monitoring of the technologies and methods corresponding to its fields of activity.





#### **BUSINESS OVERVIEW**

#### **INTELLECTUAL PROPERTY**

#### - Patents

Patents and other intellectual property rights are of fundamental importance in the medical devices sector. CARMAT regularly files patent applications to protect its innovations.

CARMAT's portfolio of patents is made up of 11 patents held in the Company's name and classified in two categories: firstly, patents associated with the architecture of the bioprosthetic artificial heart project and secondly, patents linked to the hemocompatible materials and sub-assemblies of the prosthesis.

Details of these patents are set out below:

Title	Geographical area	Submission/Publication no.	Date of submission	Status
	France	FR0605333	June 15, 2006	Granted on Sept. 5, 2008
		FR2902345	Julie 15, 2006	Expiring on June 15, 2026
"One-piece heart pros-	Europa	EP07290725.6	lune 44, 0007	Granted on July 15, 2009
thesis implantable in an anatomical position"	Europe	EP1867352	June 11, 2007	Expiring on June 11, 2027
anacomoa posteron	International	PCT/FR2007/000962	lune 44, 0007	Dublished on Dec 04 0007
	international	WO2007/144497	June 11, 2007	Published on Dec. 21, 2007
	France	FR200800184	lon 14 0000	Granted on Jan. 22, 2010
	France	FR2926223	Jan. 14, 2008	Expiring on Jan. 14, 2028
"Implantable one-piece	F	EP09290009.1	I 7 0000	Granted on Jan. 12, 2011
heart prosthesis"	Europe	EP2078533	Jan. 7, 2009	Expiring on Jan. 7, 2029
		PCT/FR2009/00008	I 7 0000	Published an Oant 47 0000
	International	WO2009/112662	Jan. 7, 2009	Published on Sept. 17, 2009
"0	France	FR0511430	N 40, 0005	Granted on Jan. 22, 2010
"Composite hemocompatible	France	FR2892939	Nov. 10, 2005	Expiring on Nov. 10, 2025
material and the process		EP06291657.2	0-4 05 0000	Granted on Sept. 23, 2009
through which this is	Europe	EP178515	Oct. 25, 2006	Expiring on Oct. 25, 2026
obtained"	14	PCT/FR2006/002471	Nav. 7, 0000	Dublish ad a 1 May 40, 0007
	International	WO2007/054637	Nov. 7, 2006	Published on May 18, 2007
	_	FR0604206		Granted on Jan. 1, 2010
	France	FR2900988	May 12, 2006	Expiring on May 12, 2026
"Reduced radial volume		EP7290571.4		Granted on Jan. 28, 2009
rotatory volumetric pump"	Europe	EP1855005	May 7, 2007	Expiring on May 7, 2027
hamb	International	PCT/FR2007/000778 WO2007/135261	May 7, 2007	Published on Nov. 29, 2007

Title	Geographical area	Submission/Publication no.	Date of submission	Status
	_	FR0605331	Iver- 45, 0000	Granted Sept. 5, 2008
"Rapid connection	France	FR2902343	June 15, 2006	Expiring on June 15, 2026
device between a totally	Firmer	EP07290723.1	l 44, 0007	Granted Sept. 24, 2008
implantable cardiac pros-	Europe	EP1867350	June 11, 2007	Expiring on June 11, 2027
thesis and natural atria"	International	PCT/FR2007/000959	June 11, 2007	Published on Dec. 21, 2007
		WO2007/144495		
	France	FR0605332	June 15, 2006	Granted Sept. 5, 2008
"Connection device		FR2902344		Expiring on June 15, 2026
"Connection device between a cardiac pros-	Europe	EP07290724.9	June 11, 2007	Granted Sept. 24, 2008
thesis and natural atria"		EP1867351		Expiring on June 11, 2027
	International	PCT/FR2007/000960 WO2007/144496	June 11, 2007	Published on Dec. 21, 2007
	France	FR0703339	May 10, 0007	Granted on June 4, 2010
"Process for producing	France	FR2915903	May 10, 2007	Expiring on May 10, 2027
a hemocompatible item	Former	EP08290405.3	April 28, 2008	Granted on May 6, 2015
with a complex configuration and item thereby	Europe	EP1992369		Expiring on April 28, 2028
obtained"	International	PCT/FR2008/000607 WO2008/145870	April 28, 2008	Published on Dec. 4, 2008
		FR1001724		Granted on July 13, 2012
	France	FR2959134	April 22, 2010	Expiring on April 22, 2030
"Process for obtaining a composite hemocompat-	Europe	EP11161291.7	April 6, 2011	Granted Sept. 12, 2012
ible material and material		EP2380608		Expiring on April 6, 2031
obtained"	International	PCT/FR2011/050768	April 6, 2011	
	international	WO2011/131887	April 6, 2011	Published on Oct. 27, 2011
	France	FR1152364	Mayab 00, 0044	Granted on July 4, 2014
	France	FR2972919	March 22, 2011	Expiring on March 22, 2031
"Process to ensure the	Firmer	EP12158011.2	Manual E 0040	Granted on Nov. 2, 2016
connection of an anatom- ical duct"	Europe	EP2502577	March 5, 2012	Expiring on March 5, 2032
	International	PCT/FR2012/050449 WO2012/127145	March 5, 2012	Published on Sept. 27, 2012
"Tissue endoprosthesis and the process through		•		Granted on March 24, 2017
	France	FR1500457	March 10, 2015	Expiring on March 10, 2035
	Europe	EP16159051.8	March 7, 2016	Published on Sept. 14, 2016
which this is produced"	International	PCT/FR2016/050525 WO2016/142617	March 7, 2016	Published on Sept. 15, 2016



Title	Geographical area	Submission/Publication no.	Date of submission	Status
	France	FR1756847	July 19, 2017	Granted on July 26, 2019
"Flexible barrier mem-			July 19, 2017	Expiring on July 19, 2037
brane and method of manufacturing the flexi- ble barrier membrane"	Europe	EP18179971.9	June 26, 2018	Published on Jan. 23, 2019
	International	PCT/FR2018/051562	luna 00, 0040	Dublished on May 01, 0010
	International	WO2019/102085	June 26, 2018	Published on May 31, 2019

#### - Exclusive license agreements

Exclusive license agreements with Pierre and Marie Curie University

Under the terms of an exclusive license agreement dated June 17, 1993, modified by amendment no. 1 of June 27, 1995 and amendment no. 2 of November 12, 1997, Pierre and Marie Curie University gave Matra Défense the rights to use patent no. 8800381 to plan studies and further development with a view to creating prototype artificial hearts implantable into human beings.

Although Matra Défense initially used the intellectual property rights granted, the benefit of this license was subsequently assumed by CARMAT, to which Pierre and Marie Curie University consented by way of an agreement duly signed by Pierre and Marie Curie University, Matra Défense, the Scientific Research Association of the Alain Carpentier Foundation and CARMAT. Under this agreement, (i) Pierre and Marie Curie University expressly waived any benefit from all intellectual property rights linked to or resulting directly or indirectly from the work on the bioprosthetic artificial heart project and

acknowledged that CARMAT was the sole owner of all intellectual property rights that could have been attributed to Pierre and Marie Curie University; and (ii) in return, the Scientific Research Association of the Alain Carpentier Foundation granted at no cost, on its behalf and account and in the interest of Matra Défense, 400 CARMAT shares (equivalent to 10,000 CARMAT shares following the 25:1 stock split) to the benefit of Pierre and Marie Curie University.

Patent No. 8800381 expired in 2008. However, the exclusive license agreement stipulates that it will be valid for five years from the date of the first marketing of the product implementing the patent claims for the European countries as well as other countries and will be tacitly renewable for two successive five-year periods, unless one or the other party cancels one year before each deadline.

#### - Trademarks

The Company has registered the "CARMAT" trademark in the countries and regions below.

Registration number	Status	Date filed	Renewal date	Regions	Classes
023184827	Filed	Sept. 23, 2002	Sept. 23, 2022	France	9, 10, 42
007374821	Filed	Oct. 29, 2008	Oct. 29, 2028	Community (Euro- pean Union)	10, 42
				International	
1022720	Filed	June 19, 2009	June 19, 2029	Designations: China, Japan, Switzerland, Russia	9, 10, 42
3663230	Filed	Jan. 7, 2009	Aug. 4, 2029	United States (USA)	10, 42
1442665	Filed	June 25, 2009	Sept. 27, 2026	Canada	10, 42
200911637	Renewal in progress	June 24, 2009	June 24, 2029	South Africa	10
200911638	Renewal in progress	June 24, 2009	June 24, 2029	South Africa	42
1838058	Renewal in progress	July 9, 2009	July 9, 2029	India	10, 42



#### - Domain names

The Company has registered the following domain names:

Domain name	Date reserved	Renewal date
aeson.eu	Aug. 22, 2019	Aug. 22, 2024
aeson.fr	Aug. 22, 2019	Aug. 22, 2024
aeson.uk	Aug. 27, 2019	Aug. 27, 2024
aeson-phrl.com	Aug. 26, 2019	Aug. 26, 2024
carmat.tel	March 23, 2009	March 22, 2029
carmatsas.com	Oct. 29, 2008	Oct. 29, 2028
carmatsas.fr	Oct. 29, 2008	Oct. 29, 2028
carmatsas.eu	Oct. 29, 2008	Oct. 31, 2028
carmatsa.tel	April 29, 2010	April 29, 2021
carmatsa.fr	April 29, 2010	April 29, 2021
carmatsa.com	April 29, 2010	April 30, 2021
carmatsa.eu	April 29, 2010	April 29, 2021

## 1.5.5 PROVISIONAL PROJECT SCHEDULE

CARMAT made very significant progress in 2019, including:

- In terms of access to the European market:
- the submission of the CE marking technical file in July;
- confirmation in November of the positive interim results of its pivotal clinical study, based on the first 11 implanted patients; with in particular 73% of the patients having reached the primary objective of the study, and the confirmation of the very good profile of the device as regards safety (see details of the results in section 1.4.3 of this Universal Registration Document).
- In terms of market access in the United States: the authorization (conditional approval) received in September from the US Food & Drug Administration (FDA)

to start an early feasibility study (EFS) in the United States.

- In terms of manufacturing: finalization of the transfer of all production from the old Vélizy site to the Bois d'Arcy site, and the implementation of more than 50 process changes, intended to improve production reliability and quality, as well as to facilitate the ramp-up.
- In terms of CARMAT's transforming into an industrial and commercial company: strengthening the Company's IT systems, continuing to prepare for the commercial launch, and strengthening the team, particularly in the areas of production and IT systems.
- In terms of financing: fundraising of €60 million and the drawing of the first tranche (€10 million) of the loan granted in December 2018, under conditions, by the European Investment Bank.

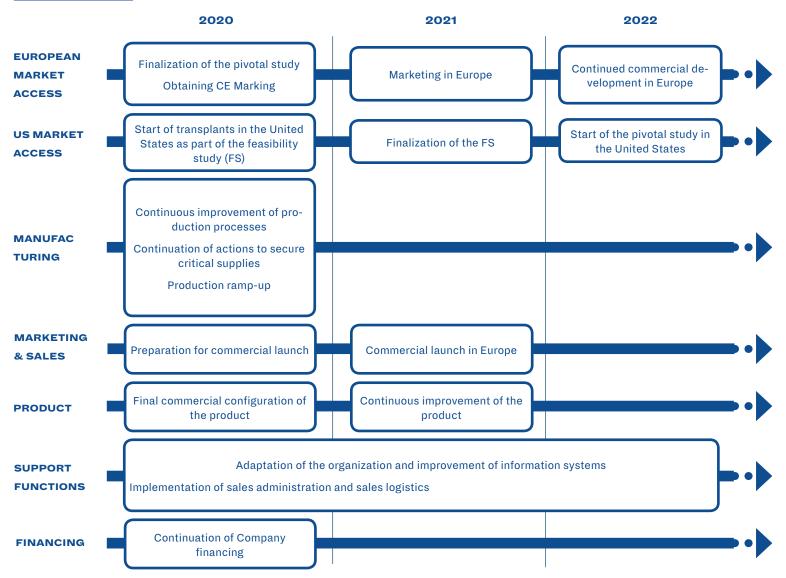
In view of this progress, the CARMAT project schedule is

#### **BUSINESS OVERVIEW**

updated as shown below.

Readers are invited to refer to Chapter 2 "Risk factors" of this Universal Registration Document to make an informed assessment of this schedule, as well as to the Company's regular press releases on project progress.

#### **BUSINESS AREAS**



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# **RISK FACTORS**



#### **RISK FACTORS**

#### Note

Investors are invited to consider all information contained in this Universal Registration Document, including the risks and uncertainties described in this chapter.

When preparing this Universal Registration Document, the Company carried out a review of the risks likely to have a significant unfavorable impact on its business, financial position, performance, development or prospects, and it considers that there are no other material and specific risks than those presented.

However, investors' attention is drawn to the fact that other risks, which are either unknown or not considered material and specific at the date of filing this document, can and could exist.

# 2 1 METHODOLOGICAL APPROACH

#### 9 1 1 PREAMBLE

As part of the new Prospectus 3 regulations applicable from July 21, 2019, CARMAT has redesigned this Risk Factors chapter in order to simplify the presentation of

information relating to risks and to continue to improve its readability.

In application of this new regulation, this chapter only presents material and specific risks to the Company.

## 2.1.2 RISKS IDENTIFICATION AND CLASSIFICATION

In 2019, the Company identified and ranked its risks. The result of this analysis was presented to the Audit Committee on February 5, 2020 and is reflected in this Universal Registration Document.

Methodology and risk assessment

The risks were identified with the assistance of all members of the management team. The risks fall into 5 categories:

- financial risks;
- industrial risks (supply chain);
- market access risks;
- human, organizational and regulatory non-compliance risks;
- IT, data and transaction risks.

The level of criticality of a risk is assessed using two criteria:

 the impact, estimated on a scale <sup>01</sup> from 1 (immaterial) to 5 (critical); the probability of occurrence, estimated on a scale <sup>02</sup> from 1 (almost zero probability) to 4 (highly likely).

The combination of these two criteria makes it possible to give each risk a score and therefore classify the risks into four levels of criticality <sup>03</sup> (criticality = impact x probability): critical, major, moderate, minor.

The level of criticality is a "net" level, i.e., after taking into account the measures implemented by the Company to prevent and mitigate the risk.

Following this analysis, CARMAT considered 12 risks to be material and specific, which are summarized in section 2.2.

CARMAT also assessed the trend for each risk, which can be positive, negative or neutral, depending on whether CARMAT considers that the risk level increased, decreased, or remained more or less the same, between 2019 and 2018.

**02** Probability scale: 1 = almost zero probability, 2 = possible, 3 = probable, and 4 = highly probable.

O3 Risks are considered critical when their score is equal to or higher than 16, major between 10 and 15, moderate between 7 and 9, and minor between 0 and 6.

**01** Impact scale: 1 = immaterial, 2 = minor, 3 = moderate, 4 = major and 5 = critical.



# 2 2 SUMMARY OF MATERIAL AND SPECIFIC RISKS

The table below summarizes the Company's material and specific risks, presented by category. Within each category, the most material risk, if applicable, is mentioned first.

The name, probability and potential impact levels, criticality (from the two previous elements) and trend are mentioned for each risk.

Each risk is presented in more detail in section 2.3.

	Probabil-	Criticality Probabil- Potential					
	ity	impact	Critical risk	Major risk	Moderate risk	Minor risk	Trend*
<u>Financial risks</u>							
Funding risk	2	5		Major risk			+
Risk of economic and financial unviability	2	5		Major risk			=
ndustrial risks (supply chain)							
Risk associated with the supply of materials and components	4	3		Major risk			=
Risk associated with production quality	2	5		Major risk			+
Risk associated with production volumes	3	3			Moderate risk		=
Market access risks							
Risk associated with obtaining CE marking in Europe	2	5		Major risk			=
Risk associated with obtaining PMA in the United States	2	5		Major risk			+
Risk associated with reimbursement on European markets	2	5		Major risk			=
Risk associated with reimbursement on the American market	2	5		Major risk			=
luman, organizational and regulatory no	n-compliance	<u>risks</u>					
Organizational and regulatory non-compliance risks	3	3			Moderate risk		=
Human resources risks	3	2				Minor risk	=
T, data and transaction risks.							
IT, data and transaction risks	2	4			Moderate risk		=

<sup>\*</sup> The + sign indicates a positive trend, i.e., a decrease in risk.



# 2.3 DETAILED PRESENTATION OF MATERIAL AND SPECIFIC RISKS

2.3.1 FUNDING RISK

Financial risks	Description of risk	Potential impacts
Funding risk	Risk that the Company does not have the financial resources required to carry out its development project at the desired pace or to the point of self-financing.	Requirement to slow down or temporarily interrupt all or part of the Company's operations. In the final stage, requirement to end the Company's operations.

Taking into account, on the one hand, the financial resources at its disposal (see section 3.1.1 of this document), and in particular the available cash position of €55.5 million at December 31, 2019, the fundraising of €60 million carried out in September 2019, the balance of €20 million of the loan granted under conditions by the EIB in December 2018, the progress of its project, and all the information at its disposal, the Company estimates that at this stage, the probability that it will not be able to find the funding needed to complete its project is relatively low, but this possibility cannot be excluded.

The financial resources available (as described in section 3.1.1) will enable the Company to finance itself until the third quarter of 2021; excluding the Kepler Cheuvreux equity line contracted in September 2018.

The Company considers that by this deadline, the conditions, in particular in terms of project progress, will be met to raise new funds, provided that unforeseen and material events do not occur.

The Company is constantly pursuing an active investor relations policy, and is seeking new investors both in France and abroad. It also believes it can count on the support of certain existing shareholders for its next fundraising.

The Company has also specifically assessed its liquidity risk and believes it will be able to fund operations for more than 12 months.

2.3.2 RISK OF ECONOMIC AND FINANCIAL UNVIABILITY

CARMAT's ability to deliver positive cash flow and a net profit over time requires reaching a certain level of sales, controlling expenditure and investments, as well as controlling device production costs. Although the Company

Financial risks	Description of risk	Potential impacts
Risk of economic and financial unviability	could also be due to higher than expected necessary	Negative impact on the market valuation of the Company. Requirement to slow down or temporarily interrupt the Company's operations. Requirement to find additional funding (fundraising, loans, etc.).  In the final stage, requirement to end the Company's operations.

#### **RISK FACTORS**

considers its assumptions and estimates to be reasonable, it cannot guarantee that all of its objectives will be achieved within the expected timeframe.

The Company is still at clinical stage and has not yet obtained authorization to market its device in Europe and the United States (see sections 2.3.6 and 2.3.7). The device represents an expensive therapy, and there is no guarantee that it will be reimbursed at the levels expected by the Company (see sections 2.3.8 and 2.3.9).

Furthermore, since the CARMAT heart is a unique and innovative therapy, there is no guarantee that adoption by healthcare professionals and patients will be in line with CARMAT forecasts.

Finally, CARMAT's profitability requires it to produce its device at a competitive cost despite the complexity of the product and the level of quality required. It is possible that CARMAT may have to face expenses and investments not anticipated to date, for example in the event that the authorities ask for additional clinical studies.

This risk is further accentuated by the fact that CARMAT is only targeting the marketing of one product at this stage (namely its artificial heart) and is therefore dependent on its success.

# 2.3.3 RISK ASSOCIATED WITH THE SUPPLY OF MATERIALS AND COMPONENTS

Industrial risks (supply chain)	Description of risk	Potential impacts
Risk associated with the supply of materials and components	Risk that the Company will not be able to obtain from its suppliers, in sufficient quantities or within the required time or to required quality standards, the various materials or components necessary for the production of prostheses. In particular, this may be due to the fragility of certain suppliers and/or the limited capacity of certain suppliers, and/or the fact that CARMAT sources certain components or materials from one single supplier, and/or the obsolescence of sourced products. This may also be due to an insufficient quality of CARMAT's forecasts.	CARMAT's inability to produce prostheses in sufficient quantities, which could lead to a delay or an interruption in its development, and/ or an inability to meet the needs of the market, therefore constituting a negative financial impact.

As indicated in section 1.5.3 of this document, to manufacture its device, the Company depends on a large number of suppliers and subcontractors of extremely diverse sizes, some more solid than others, and some able to ramp-up more quickly than others. It cannot be excluded that certain components or materials must be substituted or modified to for reasons of obsolescence or in the context of continuous improvement of the artificial heart. In addition, validating new suppliers or subcontractors is a long and costly operation, and the quality requirements imposed by CARMAT are high.

In order to secure its supplies, CARMAT regularly conducts a review of its supplier portfolio and assesses its needs in terms of materials and components. In this context, a "double-sourcing" policy, modification of sourcing and/or capacity building at critical suppliers, is gradually being implemented. However, despite the implementation of this policy, the risk of temporary insufficient supply of certain components or materials remains a material risk for CARMAT, especially when the volume of prostheses necessary to meet the needs of clinical trials and the commercial phase is growing.



## 2.3.4 RISK ASSOCIATED WITH PRODUCTION QUALITY

Industrial risks (supply chain)	Description of risk	Potential impacts
Risk associated with production quality	Risk that the Company will not be able to routinely produce prostheses that meet the required quality standards, in particular due to manual or sub-optimal production processes and procedures, or due to the lack of competent resources, or due to an inadequate IT system or organization.	CARMAT's inability to produce prostheses meeting the required quality criteria, which may cause a delay or an interruption in its development, and/or an inability to respond to market needs, therefore constituting a negative financial impact. Potentially, the patient's life is at stake in the event of an unexpected failure of an implanted prosthesis, with consequently a potential financial risk if CARMAT is called into question.

CARMAT complies with the highest quality requirements and has set up a quality management system (QMS) certified ISO 13485-9001 in July 2011. The certification has been successfully renewed regularly since, most recently in July 2017. Based in particular on its internal audit results and the audits carried out by Dekra, the Company considers that this system enables it in particular to quickly identify any critical quality defects and implement appropriate preventive and corrective actions.

However, and taking into account in particular the complexity of its artificial heart, the large number (several hundred) of materials and components used in its manufacture, the number of operations necessary for the manufacture of the heart, and the very high degree of precision required, it cannot be excluded on the one hand that the Company has to face quality challenges likely to temporarily slow down its production, and on the other hand to deal exceptionally with a product incident due to a quality defect.

## 2.3.5 RISK ASSOCIATED WITH PRODUCTION VOLUMES

Industrial risks (supply chain)	Description of risk	Potential impacts
Risk associated with production volumes	Risk that the Company will not be able to produce a sufficient number of prostheses to meet its needs (in the pre-marketing phase or in the post-marketing phase), in particular due to manual or sub-optimal production processes and procedures, and/or the lack of production capacities and resources, and/or an inadequate IT system; and also in the event of unavailability of the sole production site, caused, for example, by damage.	CARMAT's inability to produce prostheses in sufficient quantities, which could lead to a delay or an interruption in its development, and/or an inability to meet the needs of the market, therefore constituting a negative financial impact.

In the medical technology sector as a whole, and more particularly for a product as complex as the CARMAT artificial heart, producing large series remains a challenge. Although the Company has an industrial tool (Bois d'Arcy production site) allowing it to produce several hundred devices per year, the production process remains complex, and is based in part on very high precision manual operations.

The Company has already made, in particular in 2019, several dozen modifications to its production processes, and will continue its continuous improvement and automation actions in the coming years to make production operations more reliable and facilitate ramp-up.

However, the Company considers it possible that the rate of ramp-up of its production may not be high enough to prevent demand from exceeding its production capacities, particularly in the short term.

# 2.3.6 RISK ASSOCIATED WITH OBTAINING CE MARKING IN EUROPE

Market access risks	Description of risk	Potential impacts
Risk associated with obtaining CE marking in Europe	Risk that the Company will not obtain (or obtain later than expected) CE marking, i.e., authorization to market its prosthesis in Europe. Risk that the indications obtained are less broad than those anticipated. This may in particular be due to clinical data deemed insufficient, and/or to a technical file and/or to audits deemed unsatisfactory, and/or to changes in the regulatory framework.	Inability for CARMAT to market its prosthesis in Europe and in other countries recognizing CE marking (or delayed marketing compared to forecasts), resulting in the absence of sales (or delayed or lower sales compared to forecasts) in these regions.

In order to market its artificial heart in Europe, CARMAT must first obtain "CE marking" (European declaration of conformity), issued by a notified body. The process to obtain this CE marking is described in section 1.5.1 of this document.

The Company considers that it has made considerable progress with this process, and in particular announced that it had submitted its technical file to the Dekra in July 2019. Taking into account these advances and the quality of its clinical results in particular (see section 1.4.2), CARMAT considers it reasonable to obtain CE marking for its artificial heart by the end of 2020.

However, the artificial heart being a unique device, and the decision to issue CE marking being in the hands of the notified body, and therefore not controlled by the Company, CARMAT cannot guarantee that CE marking will be obtained within this timeframe or will even be ultimately obtained.

In addition, the entry into force in May 2020 of the Medical Device Regulation (MDR), which replaces the Medical Device Directive (MDD), may potentially delay obtaining CE marking.

# 2.3.7 RISK ASSOCIATED WITH OBTAINING PMA IN THE UNITED STATES

Market access risks	Description of risk	Potential impacts
Risk associated with obtaining PMA in the United States	Risk that the Company will not obtain (or obtain later than expected) PMA, i.e., authorization to market its prosthesis in the United States. This may in particular be due to clinical data deemed insufficient, and/or to a technical file and/or audits deemed unsatisfactory.	Inability for CARMAT to market its prosthesis in the United States (or delayed marketing compared to forecasts) resulting in the absence of sales (or delayed or lower sales compared to forecasts) in this region.

#### **RISK FACTORS**

In order to market its artificial heart in the United States, CARMAT must first obtain Pre-Market Approval (PMA), issued by the US Food & Drug Administration (FDA). The process to obtain PMA is described in section 1.5.1 of this document.

In September 2019, the Company announced that it had obtained conditional approval to start an Early Feasibility Study (EFS) in the United States, which is the first step in the process of obtaining PMA. Given, in particular, this

progress, the quality of its clinical results (see section 1.4.2) and its discussions with the FDA, CARMAT considers it reasonable obtain PMA in the United States within a few years.

However, as the decision to issue PMA is in the hands of the FDA, and the process for obtaining it is at any early stage, CARMAT cannot guarantee that the PMA will be obtained within this period, or even in the long term.

# 2.3.8 RISK ASSOCIATED WITH THE REIMBURSEMENT OF THE PROSTHESIS ON EUROPEAN MARKETS

Market access risks	Description of risk	Potential impacts
Risk associated with the reimbursement of the prosthesis on European markets	Risk that despite having obtained CE marking, CARMAT will not obtain reimbursement for its prosthesis in one or more of the targeted European markets, or that the level of reimbursement obtained will be lower than forecast by the Company.	Prosthesis sales levels may be much lower than forecast on the markets considered, with a potential impact on the economic viability of the Company.

The Company's ability to generate turnover with its artificial heart depends in part on the conditions of reimbursement in the countries where it intends to market its products, since many patients will not be able to self-fund this relatively expensive therapy.

The CARMAT artificial heart will be, in terms of price, at the top of the range of all cardiological medical devices. The Company's ability to reach acceptable levels of reimbursement from government authorities, private health insurers and any other organization will therefore have an impact on its ability to successfully market its products. In Europe, the processes for obtaining reimbursement and support, as well as their levels differ in each country.

Given various parameters, including the quality of its clinical results (see section 1.4.2) and the reimbursement of existing devices and therapies (see section 1.5.2), CARMAT considers it reasonable to obtain reimbursement levels in line with its assumptions in the European countries targeted for the marketing of its prosthesis (it being recalled that Europe is the first geographic area in which CARMAT intends to market its prosthesis, and will remain so for a few years).

However, the Company cannot be sure of obtaining and maintaining optimal reimbursement in all the European countries concerned, in particular because there is constant economic, regulatory and political pressure to limit healthcare costs.

## RISK ASSOCIATED WITH THE REIMBURSEMENT OF THE **OSTHESIS ON THE AMERICAN MARKET**

**Market access** risks

#### **Description of risk**

#### **Potential impacts**

Risk related to the reimbursement of the prosthesis on the American market

Risk that despite having obtained PMA from the FDA, CARMAT will not obtain reimbursement for its prosthesis than forecast on the American market, with a in the United States, or that the level of reimbursement obtained will be lower than forecast by the Company.

Prosthesis sales levels may be much lower potential impact on the economic viability of the Company.

The Company's ability to generate turnover with its artificial heart depends in part on the conditions of reimbursement in the countries where it intends to market its products, since many patients will not be able to self-fund this relatively expensive therapy.

The CARMAT artificial heart will be, in terms of price, at the top of the range of all cardiological medical devices. The Company's ability to reach acceptable levels of reimbursement from government authorities, private health insurers and any other organization will therefore have an impact on its ability to successfully market its products.

Given various parameters, including the quality of its clinical results (see section 1.4.2) and the reimbursement of existing devices and therapies, CARMAT considers it reasonable to obtain reimbursement and management levels in line with its assumptions in the United States, which currently represents the largest target market for the marketing of its prosthesis.

However, the Company cannot be sure of obtaining and maintaining optimal reimbursement in this country, in which CARMAT intends to start marketing its prosthesis in a few years.

### 3.10 ORGANIZATIONAL AND REGULATORY **NON-COMPLIANCE RISKS**

Human, organizational and regulatory non-compliance risks

#### **Description of risk**

#### **Potential impacts**

Organizational and regulatory non-compliance risks

Risk that the Company will fail to set up or maintain a sufficiently adapted and robust organization, processes and systems (including IT systems) to support its objectives and growth and meet legal and regulatory requirements.

Difficulty for CARMAT to achieve some of its objectives on time, with a possible negative financial impact. Failure to meet all legal and regulatory obligations, which may result in the delay in achieving certain objectives (for example obtaining CE marking or PMA in the United States, or even impossibility for the Company to be listed on the desired market), and/or financial penalties.

The Company plans to grow significantly, and is gradually expanding its activities, initially limited to R&D and clinical trials, to production, marketing and sale of its artificial heart. It is also increasing its geographic presence and intends to continue to do so both in terms of clinical trials and marketing.

CARMAT must therefore constantly adapt its structure, organization, procedures and processes, as well as its systems, which is a challenge and may potentially mobilize a significant amount of resources. At the same time, the Company is subject to strong operational pressure associated with the delivery of its objectives, and to a binding and constantly evolving legal and regulatory framework (regulatory obligations linked to obtaining CE marking and PMA in the United States, regulatory obligations related to



#### **RISK FACTORS**

conducting clinical trials, quality-related regulations, obligations as a listed company, GDPR regulations, "Transparency" law in France, etc.).

The Company strives to meet all of these imperatives by mobilizing the appropriate resources and systems. CAR-MAT ensures constant legal and regulatory monitoring and calls on external consultants and specialists to assist it on those matters and implement appropriate measures. However, it cannot be excluded that CARMAT, on an ad hoc basis, will experience organizational defects and/or does not comply with all of its legal and regulatory obligations, which could have an unfavorable impact on the achievement of its operational and financial objectives.

## 2.3.11 HUMAN RESOURCES

Human, organizational and regulatory non-com- pliance risks	Description of risk	Potential impacts
Human resources risks	Risk that the Company will fail to hire or retain critical people necessary to achieve its objectives. This can in particular result from people deemed to be key or difficult to replace leaving the Company, and/or the difficulty in acquiring certain skills or levels of experience due to the characteristics of the Company (for example, 'start-up' considered potentially risky).	Difficulty for CARMAT to achieve some of its objectives on time, with a possible negative financial impact.

CARMAT's success is largely based on the quality of its management and teams, which means being able to attract and retain the appropriate talent and human resources. CARMAT believes that it takes the necessary actions in terms of its hiring, compensation and other policies to remain an attractive employer. The Company also uses the services of external resources, particularly consultants, as and when necessary.

However, in terms of talent acquisition and retention, CARMAT is in competition with a number of other companies, some with more means or potentially certain assets (career development possibilities or work environment, for example) that CARMAT is not in a position to guarantee. In addition, certain skills, particularly technical (in electronics and IT, for example) are in high demand on the job market.

Finally, given the size of the Company, certain skills are provided by a very limited number of employees, sometimes just one person.

In this context, it is possible that the Company may temporarily face difficulties in attracting talent for certain positions or retaining the people necessary to achieve CARMAT's objectives.



## 2.3.12 IT, DATA AND TRANSACTION RISKS

IT, data and transaction risks	Description of risk	Potential impacts
IT, data and transaction risks	Risk of vulnerability of the IT system to cyber attacks, risk of loss or theft of sensitive data, risk of unauthorized transactions or operations (carried out internally or externally).	Direct financial losses (in the case of fraud for example) or indirect (in the case of unauthorized use of sensitive research or production data). Potentially negative consequences on the reputation of the Company.

The Company is highly dependent on its IT systems to conduct its business, and it manages a large amount of data relating to its research, clinical trials, intellectual property, financial data, etc., some of which are particularly sensitive and are stored physically and/or electronically.

Access to the Company's IT resources is granted to employees depending on their needs, but also, where appropriate, to external service providers or consultants working for the Company, some of which are based remotely (for example, hubs located overseas where clinical trials are conducted).

The loss or theft of sensitive and/or confidential data for unauthorized purposes, the carrying out of unauthorized transactions and the corruption of data or systems rendering them unfit for use, temporarily or definitive, are all events likely to cause operational (for example temporary production stoppage) and financial (for example in the event of a fraudulent transaction) damage to CARMAT. The impacts of such an event could also be accentuated by the media exposure of CARMAT, in particular if patient data were at stake.

The Company has implemented a systems & data security, access and protection policy to limit the above risks.

However, CARMAT cannot fully exclude the risk of external cyber attacks or malicious acts, carried out internally or externally.

#### **RISK FACTORS**

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# FINANCIAL INFORMATION



## 3.1 2019 FINANCIAL REVIEW

## 3.1.1 SELECTED FINANCIAL INFORMATION

Simplified income statement	Year ended	Year ended	Year ended
(in thousands of euros)	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017
Net revenue	0	0	0
Other operating income	702	722	28
Operating expenses	(43,096)	(43,489)	(31,063)
NET OPERATING INCOME (EXPENSE)	(42,394)	(42,766)	(31,035)
Net financial income (expense)	(1,787)	(945)	(472)
RECURRING INCOME (EXPENSE) BEFORE TAX	(44,181)	(43,711)	(31,507)
Net non-recurring income (expense)	(104)	(2)	(56)
Research tax credit	1,636	1,984	2,335
NET PROFIT (LOSS)	(42,649)	(41,729)	(29,228)
Simplified cash flow statement	Year ended	Year ended	Year ended
(in thousands of euros)	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017
NET PROFIT (LOSS)	(42,649)	(41,729)	(29,228)
Cash flow from operations before change in working capital	(40,028)	(39,863)	(27,227)
Net cash from (used in) operating activities	(40,245)	(38,174)	(24,279)
Net cash from (used in) investing activities	(636)	(2,308)	(3,709)
Net cash from (used in) financing activities	71,085	5,059	57,547
Change in cash and cash equivalents	30,204	(35,421)	29,560
CASH AND CASH EQUIVALENTS AT	25,302	60,723	31,163

## CHANGE IN THE COMPANY'S ACTIVITY IN THE FINANCIAL YEAR

CARMAT recorded no revenue during the year 2019, its artificial heart being still in clinical development.

The operating loss for the year amounted to €42.4 million, a slight improvement compared to the previous year (operating loss of €42.8 million in 2018).

During 2019, CARMAT devoted the main part of its operating resources to:

- studies and tests carried out as part of the process of obtaining CE marking on the one hand, and obtaining authorization to start a clinical study in the United States (Early Feasibility Study – EFS) on the other hand;
- the improvement in reliability of its production processes and the preparation of the ramp-up in the Bois d'Arcy production site;
- the further transformation of the Company into an industrial and commercial company.

This translates into operating expenses of €43.1 million, slightly down by €0.4 million compared to the previous year, CARMAT having made a major effort to rationalize its expenses, especially in the second half of the year.

The net financial expense of €1.8 million, down by €0.8 million compared to 2018, is explained by the increase in loan interests, the Company having proceeded at the end of January 2019 to draw the first tranche (i.e., €10 million) of the €30 million loan granted under conditions by the European Investment Bank (EIB) in December 2018.

After taking into account non-recurring expenses of €0.1 million and the research tax credit of €1.6 million, the net loss for the 2019 financial year comes to €42.6 million, compared to a net loss of €41.7 million in 2018.

#### **FINANCIAL INFORMATION**



#### Industrialization and production

During the first half of 2019, CARMAT finalized the transfer of all its production activities to its new industrial site in Bois d'Arcy.

Following the analysis of the information gathered from the experience accumulated during cohort 1 of the pivotal clinical trial, and the data recorded on test benches, CARMAT proceeded to review its production processes, with the aim of strengthening the reliability of its artificial heart. This analysis and the changes decided upon following this review led to a shutdown of production from October 2018 to May 2019. Production resumed on the site in May 2019.

From now on, all the prostheses produced will come entirely from the Bois d'Arcy production site, and the Company will focus on continuous improvement of its processes, securing its supplies and ramping up its production with a view to marketing its artificial heart.

Clinical development and market access

#### Access to the European market

Following the resumption of production at the Bois d'Arcy site in May 2019, and the authorizations received during the third and fourth quarters to resume recruitments as part of the pivotal study in Denmark, the Czech Republic and Kazakhstan, CARMAT announced in December 2019 that it had implanted a twelfth patient in the context of this trial (10 for the first cohort of 10 patients, and 2 for the second cohort of 10 patients).

The positive results of the first cohort of the pivotal clinical trial, presented in January 2019, were confirmed and reinforced with the presentation in November 2019 of the results of the trial on the first 11 implanted patients.

73% of these patients achieved the primary objective of the trial, either surviving 6 months with the prosthesis or receiving a successful heart transplant within 6 months of the device being implanted. The data collected from patients confirm the biocompatibility of the prosthesis, particularly its very good safety profile (absence of stroke, gastrointestinal bleeding and related infection to the percutaneous cable), which has never been achieved by other technologies.

In parallel, the Company confirmed that it submitted its CE marking technical file to the certification agency Dekra in July 2019.

The CE marking is necessary for the Company to market its artificial heart in Europe.

#### Access to the United States market

After filing in 2018, CARMAT received, in accordance with its roadmap, authorization (conditional approval) from the US Food & Drug Administration (FDA) in September 2019 to start an Early Feasibility Study (EFS) in the United States. The implantation of the first patient, as part of this study, is planned for 2020.

The authorization to start this clinical trial in the United States is the first step in the process which could ultimately give CARMAT the authorization to market its prosthesis in the United States.

Transformation into an industrial and commercial company

In view of the commercial launch of its prosthesis in Europe (post-CE marking) and the necessary ramp-up in production, CARMAT also continued in 2019 to adapt its organization and its information systems, and prepare its commercial launch, while expanding its teams as necessary.

In 2019, a new Director of Manufacturing, Alexandre Eléonore, who joined the CARMAT management team in November, and a Director of IT Systems were recruited.

#### Governance

Professor Alain Carpentier left his position as director of CARMAT at the end of the Shareholders' Meeting held on March 28, 2019. He was appointed Honorary President of the Company, and as such continues to be involved in the life of the Company and to attend meetings of the Board of Directors, without taking part in the votes.

In June 2019, Karl Hennessee, Senior Vice-President of Airbus, replaced Anne-Pascale Guédon, as permanent representative of Matra-Défense (Airbus Group) on the Board of Directors.

#### STRENGTHENED FINANCIAL POSITION

At December 31, 2019, the Company's cash position stood at €55.5 million compared to €25.3 million at December 31, 2018.

This significant strengthening of cash position can be explained in particular by:

- fundraising of €60 million carried out in September 2019 through a private placement;
- drawing the first tranche of €10 million of the EIB loan at the end of January 2019;
- obtaining the last tranche of the €1.5 million BPI repayable advance in June 2019;
- using the flexible Kepler Cheuvreux equity line for €2 million in 2019.

#### FINANCIAL INFORMATION

Net cash from operating and investing activities stood at a negative €41 million during the year, as the Company is not yet generating commercial income.

In addition, CARMAT also has at its disposal:

- two tranches of EIB loans of €10 million each, which can be drawn down when certain technical stages are reached:
- a drawdown possibility of €21.9 million until the end of September 2020, on the flexible Kepler Cheuvreux equity line contracted in September 2018.

Combined, and excluding the Kepler Cheuvreux equity line, all of these financial resources allow CARMAT to finance its activities, according to its business plan, until the third quarter of 2021.

In addition, the fundraising carried out in September 2019 enabled the entry into the capital of renowned entrepreneurial shareholders, in particular the family offices of the Gaspard family, owners of the Lyreco group (Corely Belgium SPRL and Bratya SPRL) and Pierre-Edouard Stérin, founder of Smartbox (BAD 21 SPRL), who have indicated their intention to support CARMAT in the long term. Historical shareholders have also renewed their confidence in the CARMAT project by participating in the fundraising, in particular the Airbus Group, the family offices of Pierre Bastid (Lohas) and Dr. Ligresti (Santé Holdings SRL), as well as the Therabel Group.

Given these elements, the Company is confident in its ability to carry out the clinical development of its prosthesis and the preparation of the commercial phase.

## 3.1.2 COMPLETED OR FUTURE INVESTMENTS

## MAIN INVESTMENTS COMPLETED IN THE LAST THREE FINANCIAL YEARS

Over the 2019 financial year, the Company spent €0.7 million on investments, breaking down as follows:

- €701k on property, plant and equipment;
- €36k on intangible assets.

Investments are down compared to the previous two years, which were marked by the establishment of the Bois d'Arcy production site.

In the 2018 financial year, the Company recorded €2.3 million in investments including €2.2 million in property, plant and equipment related to the installation of the Bois d'Arcy

site and €0.1 million in intangible assets.

In 2017, the Company recorded €3.5 million in investments, including €2.8 million in fitting out the new production site at Bois d'Arcy.

## PROPERTY, PLANT AND EQUIPMENT IN PROGRESS

Property, plant and equipment in progress at the end of the 2019 financial year amount to €0.6 million and will be used for production once activated.

#### MAIN PLANNED INVESTMENTS

The main investments to come in the short term concern production equipment and tools to further streamline the production process and increase capacity.

# 3.1.3 PROGRESS MADE AND DIFFICULTIES ENCOUNTERED DURING THE FINANCIAL YEAR

Following the analysis of the information gathered from the experience during phase 1 of the pivotal clinical trial, and the data recorded on test beds, CARMAT proceeded to review its production processes, with the aim of strengthening the reliability of its artificial heart. This analysis and the changes decided upon following this review led to a shutdown of production from October 2018 to May 2019. Production resumed on the site in May 2019. From now on, all the prostheses produced will come entirely from the Bois d'Arcy production site.

# 3.1.4 ANTICIPATED DEVELOPMENTS, OUTLOOK AND SIGNIFICANT EVENTS AFTER THE REPORTING DATE

CARMAT intends to continue to focus its efforts and resources on its strategic priorities:

- finalizing the pivotal study with the short-term completion of recruitments for the second cohort of patients;
- obtaining CE marking in 2020;
- starting an Early Feasibility Study (EFS) in the United States, following the agreement received from the Food & Drug Administration (FDA) in September 2019;
- continuously improving its production processes;
- transforming CARMAT into an industrial and commercial company, with a view to the commercial launch of the prosthesis by 2021.

## SIGNIFICANT EVENTS AFTER THE REPORTING DATE

On February 5, 2020, CARMAT announced that it had received full approval from the FDA to launch its clinical feasibility study with its artificial heart in the United States and that the study population had been increased to 10 patients.

## MAIN TRENDS SINCE THE END OF 2019 FINANCIAL YEAR

The Company does not have any significant change to report in its financial position since December 31, 2019.

#### **PROFIT FORECASTS OR ESTIMATES**

The Company does not intend to make any profit forecasts or estimates.

## 3.1.5 FIVE-YEAR FINANCIAL SUMMARY

## STATEMENT OF RESULTS FOR THE PAST FIVE FINANCIAL YEARS

(in euros)	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2016	Dec. 31, 2015
Share capital at year end					
Share capital	504,385.96	371,036.76	360,661.76	241,277.76	183,117.40
Number of existing ordinary shares	12,609,649	9,275,919	9,016,544	6,031,944	4,577,935
Maximum number of future shares to be created					
- by conversion of bonds	-	-	-	-	-
- by exercise of subscription rights	1,314,700	1,246,750	943,025	852,140	466,610
Operations and earnings					
Revenue excluding tax	0	0	0	0	0
Net profit (loss) before tax, profit sharing, depreciation/amortization and provisions	(43,339,319)	(42,784,848)	(30,020,856)	(25,378,370)	(20,229,406)
Income tax	1,636,019	1,983,916	2,334,690	2,817,116	3,148,534
Employee profit sharing	-	-	-	-	-
Net profit (loss) after tax, profit sharing, depreciation/amortization and provisions	(42,648,672)	(41,729,066)	(29,227,910)	(22,980,178)	(17,545,761)
Distributed earnings	-	-	-	-	-
<u>Earnings per share</u>					
Earnings (loss) after tax and profit sharing, but before depreciation/amortization and provisions	(3.31)	(4.40)	(3.07)	(3.74)	(3.73)
Earnings (loss) after tax, profit sharing, depreciation/amortization and provisions	(3.38)	(4.50)	(3.25)	(3.81)	(3.83)
Dividend per share	-	-	-	-	-
Personnel					
Headcount at year end	107	90	70	56	48
Total payroll for the year	8,364,741	6,819,510	5,220,243	4,371,200	4,069,741
Total benefits for the year	4,453,860	3,906,890	2,163,452	1,803,184	1,611,888

#### **FINANCIAL INFORMATION**

## 3.1.6 PROPOSED APPROPRIATION OF NET PROFIT (LOSS)

We propose the approval of the annual financial statements (balance sheet, income statement and notes) as presented.

These financial statements show a net loss of €42,648,672.

We propose the appropriation of this loss to "Losses carried forward", taking the balance of that item from negative €187,480,075 to negative €230,128,747.

#### DIVIDEND PAYMENT HISTORY

In accordance with the provisions of Article 243 of the French General Tax Code (Code général des impôts), it is recalled that no dividends have been paid for the last three financial years.

There are no plans to adopt a policy of paying dividends in the short term, taking into account the Company's stage of development.

## 3.1.8 PROPERTY, PLANT AND EQUIPMENT

The Company carries out its activities in the premises it rents under leases entered into at market prices and conditions with companies which have no direct or indirect link with its executives. CARMAT does not own any property.

For the current financial year at the date of this Universal Registration Document, the Company considers that it has suitable premises which should enable it to support the planned growth and its workforce.

As a reminder, the transfer of production from the Vélizy site to the Bois d'Arcy site was finalized in 2019.

#### **ENVIRONMENTAL ISSUES**

As part of the search for non-thrombogenic materials\*, CARMAT decided to follow an original path with Professor Alain Carpentier's biological valve experiment, using chemically treated animal pericardium to make it inert and biologically stable, which avoids rejection by the human body.

Premises used by the Company as at December 31, 2019

Lessee	Address	Nature of premises	Surface area	Lease start date	Lease expi- ration date
CARMAT SA	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy-Villacoublay	Business premises	1,053 sq.m	Feb. 1, 2009	Jan. 31, 2027
CARMAT SA	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy-Villacoublay	Business premises	595 sq.m	Oct. 1, 2010	Sept. 30, 2028
CARMAT SA	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy-Villacoublay	Business premises	595 sq.m	July 1, 2011	March 31, 2022
CARMAT SA	9, rue René Clair Batiment G Sis parc Spirit Meliers III 78390 Bois d'Arcy	Business premises	1,558 sq.m	Dec. 7, 2017	Dec. 6, 2027

#### FINANCIAL INFORMATION

In the design and manufacture of the bioprosthetic artificial heart, the Company is therefore subject to chemical and biological risks. CARMAT therefore implements prevention and protection measures for its teams and to efficiently manage waste in accordance with the regulations in force. CARMAT considers that it complies with these regulations, taking into account the use, storage, handling and disposal of hazardous materials.

CARMAT entrusts two specialized subcontractors with waste management, including the traceability of processed materials. In addition, a risk analysis is updated annually. Each risk situation is assessed according to quantified criteria of occurrence and severity, which gives rise to the implementation of appropriate prevention measures. Specific training is given to those exposed.

# 3.1.9 INFORMATION ON PAYMENT TERMS

## INFORMATION ON PAYMENT TERMS FOR ACCOUNTS RECEIVABLE

Not applicable.

## INFORMATION ON PAYMENT TERMS FOR ACCOUNTS PAYABLE

In accordance with the provisions of Articles L.441-6-1 and D.441-4 of the French Commercial Code, we bring your attention to the following information concerning supplier payment terms:

As at December 31, 2019, accounts payable totaled €2,376,881. A comparison of the figures from the financial statements is set out below:

(in euros)	Dec. 31, 2019	Dec. 31, 2018
Trade notes and accounts payable shown under liabilities	5,345,899	7,615,547
Less: Amounts receivable from suppliers shown under assets	0	0
Less: Accrued expenses included in this item	(2,969,018)	(4,334,470)
Amounts payable on non-current assets and other	0	0
Accrued expenses included in this item	0	0
TOTAL	2,376,881	3,281,077

The breakdown of this amount by maturity date is shown below, based on the payment terms negotiated with suppliers:

(in euros)	Dec. 31, 2019	Dec. 31, 2018
Due (including amounts receivable from suppliers)	316,519	404,414
Falling due on January 31	2,060,363	2,876,663
Falling due on February 28	0	0
Falling due on or after March 31	0	0

Breakdown of payables due at the end of the financial year:

Article D.441	I1: Invoices	received and di	ue but not settl	ed at the end of	the period	
(in euros)	0 days	1 to 30 days	31 to 60 days	61 to 90 days	> 90 days	Total
(A) Days late						
lumber of invoices	50					
otal amount of invoices (incl. taxes)	170,625	0	0	0	0	0
ercentage of total purchases for the eriod (incl. taxes)	0.50%	0	0	0	0	0
(B) Invoices excluded from (A)	relating to conte	sted payables				
lumber of invoices		1 invoice	e for an amount of €	145,894 incl. taxes		

#### **FINANCIAL INFORMATION**



## 3.1.10 MATERIAL CONTRACTS

The material contracts to which the Company is a party are as follows:

- a royalties agreement signed on June 24, 2008 and amended on February 5, 2010, between CARMAT, Professor Alain Carpentier and Matra Défense (an Airbus Group subsidiary): please refer to section 5.6 "Related-party agreements";
- an exclusive license agreement with the Pierre and Marie Curie University relating to patent no. 8800381: please refer to section 1.5.4 "Innovation and management of R&D";
- an agreement with Edwards Lifesciences for an initial period of one year, renewable automatically each year, concluded in the 4th quarter of 2010 between CARMAT and Edwards Lifesciences, world leader in the segment of heart valves and in hemodynamic monitoring, for the use and the supply of Carpentier-Edwards biological heart valves in the CARMAT bioprosthetic artificial heart project;
- a 12-year agreement with Invibio Limited concluded in the 3rd quarter of 2012 between CARMAT and Invibio Limited for the supply and use of PEEK-OP-TIMA® polymeric material. This material is used by CARMAT for its biocompatibility characteristics, which are certified as long-lasting implantable, and for its mechanical properties. The structural subsets of the prosthesis are processed with this material;
- a framework aid agreement for the CARMAT Industrial Strategic Innovation (ISI) project and an agreement in support of the CARMAT project entered into on July 24, 2009 for a total sum of €33.0 million granted by Bpifrance;
- a non-dilutive financing agreement concluded in December 2018 with the European Investment Bank for an amount of €30.0 million.

These last two agreements are detailed below:

## FRAMEWORK AGREEMENT WITH BPIFRANCE

#### Initial conditions of the agreement

On July 24, 2009, the Company signed a framework agreement with Bpifrance to secure aid for the CAR-MAT Strategic Innovation (ISI) project. Under the terms of the agreement, Bpifrance undertook to pay a total amount of €33.0 million, of which €18.5 million as subsidies and €14.5 million as refundable advances, payable upon achievement of the key milestones set out in the agreement.

The Company acts as project leader, thus receiving all of the refundable advances and €17.4 million in subsidies,

i.e., €31.9 million, the remaining €1.1 million to be paid to the four partners of the project: Dedienne Santé, Paxi-Tech, Vignal Artru Industries (Pack'Aero Group) and Iréis (formerly HEF R&D).

Under the Bpifrance Innovation framework agreement, each of the partners has undertaken to provide the resources necessary to complete the development project for the bioprosthetic artificial heart and its components. In return, Bpifrance will pay its subsidies and repayable advances as certain phases and milestones described below are completed.

#### Accounting and financial conditions

The subsidies accrue to the Company as of right and so will not be repayable in the event of success of the project.

Accordingly, they are accounted for in the "Operating subsidies" line of the income statement.

Repayable advances will have to be repaid by CARMAT according to the arrangement set out in the paragraphs below. Repayable advances are therefore accounted for on the liabilities side of the balance sheet under the "Other equity – Conditional advances" line.

The corresponding interest is shown on the liabilities side of the balance sheet under the "Sundry loans and borrowings" line.

By addendum to the initial contract, signed in September 2013, the Parties agreed to calculate the amount of the financial returns due by CARMAT based on thresholds of revenue generated by the products and services created by the project (reference products and services).

Threshold S1 (cumulative sales of reference products and services) is set at €38 million.

Threshold S2 (cumulative sales of reference products and services) is set at €2 billion.

If threshold S1 (as defined above) is reached, CARMAT will pay Bpifrance the following flat fees by June 30 of each year following the reference year:

Year 1 by June 30	€184,000
Year 2 by June 30	€368,000
Year 3 by June 30	€1,472,000
Year 4 by June 30	€2,784,000
Year 5 by June 30	€8,316,000
Year 6 by June 30	€11,300,000

The amounts will be reimbursed as indicated above, based on CARMAT's operating income from the project's products, in light of the annual income statement.

Should threshold S1 not be reached, CARMAT will not pay Bpifrance the amounts above.

From year 2 and for the remaining years, in case of a fall in revenue exceeding 20% of the updated forecasts (in 2013), as defined in the amendment signed in September 2013,

#### **FINANCIAL INFORMATION**

these amounts would be then capped.

In this scenario, CARMAT will generate new forecasts allowing it to draw up a new timetable for the reimbursements to Bpifrance.

Should sales of the reference products and services be in excess of the forecasts, the flat fees defined above will not be affected.

In any case, in the event that no reimbursement is due pursuant to this Article over a period of 10 years from payment of the last subsidy as set out in the agreement providing for a repayable advance, CARMAT will be released from any obligation to pay financial returns. Moreover, this agreement will be terminated ipso jure with no other formalities, provided that CARMAT has complied with all its obligations. CARMAT will be bound to pay specific fees as defined above, should threshold S1 be reached before this date, and until said date is reached.

If the advance payment has been reimbursed in accordance with the provisions above, CARMAT will pay Bpifrance during the year after the date said reimbursement is completed and provided sales of the reference products and services (excluding taxes) have reached at least  $\ensuremath{\in} 2$  billion, 2.5% of the yearly revenue generated the previous year by sales of the Project's products and services.

The corresponding amounts will be payable on any generated revenue, subject to a maximum financial return of €50 million at nominal value, if achieved within 8 years.

Amounts received and still to be received at December 31, 2019

The Bpifrance agreement provides for the payment of a total of €17.4 million in subsidies, all of which was received at the end of the 2019 financial year.

It also provides for the payment of a total sum of €14.5 million for repayable advances, all of which were received at the end of 2019 (the last €1.5 million due having been paid in June 2019).

## EUROPEAN INVESTMENT BANK (EIB) FINANCING AGREEMENT

The financing agreement signed with the EIB allows CAR-MAT to borrow up to €30 million via three tranches of €10 million each.

Within the context of the positive interim results of the first part of the pivotal study, published by CARMAT on January 15, 2019 the Company carried out the drawdown on the first tranche of the EIB loan, i.e., €10 million, on

January 31, 2019.

The drawdowns on the second and third tranches are subject to certain technical and financial milestones, including the successful execution of clinical trials and/or the raising of additional funds.

The amounts borrowed bear an average fixed interest rate of 8% for the first tranche, 8% for the second tranche and 5% for the third tranche. The reimbursement of each tranche will take place at the end of the loan period (bullet payment), i.e., five years from the date of the drawdown on this specific tranche.

The loan contract provides for certain information and operational commitments (such as limits on authorized debt, approval for external growth operations, etc.). Failure to comply with these conditions would give the EIB the right, if deemed necessary, to demand an early reimbursement of the loan.

The occurrence of certain changes in the shareholding structure or a change in management not approved beforehand by the EIB would also allow the latter, if deemed necessary following discussions with the Company, to demand an early reimbursement of the loan.

The loan is not secured. Any new Group subsidiary becoming material with respect to the financial agreement would be personally liable for the Company. To date, CARMAT has no subsidiaries.

In addition, the Company has signed a royalties agreement with the EIB providing for the payment of additional compensation to the EIB depending on the commercial performance of the Company. This agreement is valid for 13 years from the year during which the cumulative sales of CARMAT reach €500,000. The Company can decide to terminate the royalties agreement at any time by paying a lump sum (net of any royalties already paid), based on the amount borrowed and the year during which the decision is taken.

Upon the occurrence of certain events (in particular should the EIB demand the early repayment of the loan or should a new shareholder reach 33% of the voting rights of CARMAT), the EIB could, if deemed necessary, demand from CARMAT an advance payment of royalties up to a certain percentage of the amount of the loan effectively used (this percentage would range from 100% of the borrowed amount if the event occurs during the first four years of the financial contract to 160% if the event occurs after the eleventh year).

# 3.2 2019 FINANCIAL STATEMENTS

3.2.1 FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019

#### **INCOME STATEMENT**

Income statement	Year ended Dec. 31, 2019			Year ended Dec. 31, 2018
(in euros)	France	Export	Total	Total
OPERATING INCOME				
Sale of goods for resale				
Production sold - goods				
Production sold - services				
Net revenue				
Inventoried production				
Capitalized production				
Operating subsidies (note 3.2.2.5)			14,000	14,000
Reversals of impairment, depreciation/amortization and pro-	visions, expense	transfers	688,472	708,481
Other income				
TOTAL OPERATING INCOME (I)			702,472	722,481
OPERATING EXPENSES				
Purchases of goods for resale				
Change in inventories (goods for resale)				
Purchases of raw materials and other supplies			7,397,143	6,523,753
Change in inventories (raw materials and other supplies)				
Other purchases and external expenses			20,901,665	24,148,661
Taxes, duties and other levies			365,293	372,399
Wages and salaries			8,364,741	6,819,510
Social security contributions			4,453,860	3,906,890
Depreciation/amortization and impairment				
- of non-current assets: depreciation/amortization (note 3.2.	2.4)		1,163,537	919,829
- of non-current assets: impairment				
- of current assets: impairment				
Additions to provisions (note 3.2.2.4)			382,592	716,786
Other expenses			67,452	81,059
TOTAL OPERATING EXPENSES (II)			43,096,284	43,488,886
1 - NET OPERATING INCOME (EXPENSE) (I - II)				(42,766,405)
SHARE IN INCOME FROM JOINT VENTURES				
Income allocated or loss transferred (III)				
Loss incurred or income transferred (IV)				
FINANCIAL INCOME				
Investment income				
Income from other marketable securities and non-current as	set receivables			
Other interest income				
Reversals of impairment and provisions, expense transfers				
Foreign exchange gains			40,786	41,149
Net income on sales of marketable securities				
TOTAL (V)			40,786	41,149



#### **FINANCIAL INFORMATION**

Income statement	Year ended Dec. 31, 2019			Year ended Dec. 31, 2018
(in euros)	France	Export	Total	Total
FINANCIAL EXPENSES				
Depreciation/amortization, impairment and provisions				
Interest expense			1,782,149	937,512
Foreign exchange losses			45,572	48,425
Net expenses on sales of marketable securities				
TOTAL (VI)			1,827,721	985,937
2 - NET FINANCIAL INCOME (EXPENSE) (V - VI)				(944,788)
3 - RECURRING INCOME (EXPENSE) BEFORE TAX (I-II+III-I\	V +V - VI)		(44,180,747)	(43,711,193)
NON-RECURRING INCOME (NOTE 3.2.2.5)				
Non-recurring income on management transactions				
Non-recurring income on corporate actions			46,794	60,198
Reversals of impairment and provisions, expense transfers				
TOTAL (VII)			46,794	60,198
NON-RECURRING EXPENSES (NOTE 3.2.2.5)				
Non-recurring expenses on management			2,513	3,424
Non-recurring expenses on corporate actions			60,767	58,564
Depreciation/amortization, impairment and provisions			87,458	
TOTAL (VIII)			150,738	61,987
4 - NET NON-RECURRING INCOME (EXPENSE) (VII			(103,944)	(1,789)
Employee profit-sharing (IX)				
Income tax (X) (note 3.2.2.5)			(1,636,019)	(1,983,916)
TOTAL INCOME (I+III+V+VII)			790,052	823,829
TOTAL EXPENSES (II+IV+VI+VIII+IX+X)			43,438,724	42,552,895
5 - NET PROFIT (LOSS) (total income - total expenses)				(41,729,066)



#### **FINANCIAL INFORMATION**

#### **BALANCE SHEET**

Assets	Dec. 31, 2019			Dec. 31, 2018	
(in euros)	Gross	Depreciation, amortization and impairment	Net	Net	
UNCALLED SUBSCRIBED CAPITAL (TOTAL I)					
Non-current assets					
Intangible assets (note 3.2.2.4)					
- Start-up costs					
- Development costs					
- Licenses, patents and similar rights	2,014,253	1,986,534	27,718	89,777	
- Goodwill*					
- Intangible assets not yet available for use					
- Advances and downpayments					
Property, plant and equipment (note 3.2.2.4)					
- Land					
- Buildings					
- Technical plant, equipment and tooling	9,670,507	6,590,283	3,080,224	2,327,214	
Other property, plant and equipment	2,810,222	1,394,484	1,415,737	1,629,202	
- Property, plant and equipment in progress	614,209		614,209	1,606,508	
- Advances and downpayments					
Financial assets** (note 3.2.2.4)					
- Equity-accounted investments					
Other equity interests					
- Other long-term investments					
- Loans	470 500		470 500	405.077	
Other financial assets	473,503	0.074.004	473,503	485,877	
TOTAL II Current assets	15,582,693	9,971,301	5,611,392	6,138,578	
Inventories and work in progress					
- Raw materials, supplies					
- Work in progress – goods					
- Work in progress – goods - Work in progress – services					
- Semi-finished and finished goods					
- Goods for resale					
Advances and downpayments on orders	494,132		494,132	375,721	
Receivables***	404,102		404,102	010,121	
- Trade notes and accounts receivable					
Other receivables (note 3.2.2.4)	2,943,016		2,943,016	4,579,872	
Share capital subscribed, called and unpaid					
Marketable securities					
Cash instruments					
Cash	55,505,492		55,505,492	25,301,658	
Prepaid expenses*** (note 3.2.2.4) TOTAL III	121,610		121,610	433,318	
	59,064,250		59,064,250	30,690,569	
ACCRUAL ACCOUNTS					
Deferred loan issuance costs (IV) Bond redemption premiums (V)					
Unrealized foreign exchange losses (VI)					
GRAND TOTAL (I+II+III+IV+V+VI)	74,646,944	9,971,301	64,675,643	36,829,147	
* Including lease rights			107.000	444.050	
** Of which are due in less than one year			127,386	141,359	

Equity and liabilities	Dec. 31, 2019	Dec. 31, 2018
(in euros)		
EQUITY (notes 3.2.2.3 and 3.2.2.4)		
Share capital (of which paid-up: 504,386)	504,386	371,037
Additional paid-in capital	254,053,133	194,560,697
Revaluation adjustments		
Reserves		
- Legal reserve		
- Statutory or contractual reserves		
- Untaxed reserves		
- Other reserves	38,476	29,840
Retained earnings (losses carried forward)	(187,480,075)	(145,751,009)
Net profit (loss) for the year	(42,648,672)	(41,729,066)
Investment subsidies		
Tax-driven provisions		
TOTAL1	24,467,248	7,481,498
OTHER EQUITY		
Proceeds from issues of equity securities		
Conditional advances (note 3.2.2.6)	14,507,309	13,056,577
TOTAL II	14,507,309	13,056,577
PROVISIONS		
Provisions for contingencies		
Provisions for losses (notes 3.2.2.4 and 3.2.2.5)	685,560	991,440
TOTAL III	685,560	991,440
LIABILITIES*		
Debt		
- Convertible bonds		
- Other bonds		
- Bank loans and borrowings	10,733,333	
- Bank overdrafts		
- Sundry loans and borrowings (note 3.2.2.4)	5,681,519	4,651,634
Advances and downpayments received on orders in progress		
Accounts payable (note 3.2.2.4)		
- Trade notes and accounts payable	5,345,899	7,615,547
- Tax and social security payables	3,254,774	2,985,907
Amounts payable on non-current assets and other		
Other payables		46,544
ACCRUAL ACCOUNTS		
Prepaid income*		
TOTAL IV	25,015,525	15,299,631
Unrealized foreign exchange gains		
TOTAL V		-
GRAND TOTAL (I+II+III+IV+V)	64,675,643	36,829,147
* Liabilities and prepaid income due in loss than one year	0 600 672	10 647 000
Liabilities and prepaid income due in less than one year	8,600,673	10,647,998



#### **CASH FLOW STATEMENT**

Cash flow statement	Year ended Dec. 31, 2019	Year ended Dec. 31, 2018
(in euros)		
Net profit (loss)	(42,648,672)	(41,729,066)
Depreciation/amortization and provisions	1,546,129	1,636,615
Reversals of depreciation/amortization and provisions	(688,472)	(708,481)
Gains or losses on disposals of assets		
Investment subsidies transferred to income		
Other income and expenses with no cash impact	1,763,219	937,484
CASH FLOW FROM OPERATIONS BEFORE CHANGE IN WORKING CAPITAL	(40,027,796)	(39,863,448)
Tax and social security payables	268,867	866,933
Trade accounts payable	(2,269,648)	1,790,159
Other payables	(46,544)	46,544
Prepaid income		
Inventories and work in progress		
Advances and downpayments on orders	(118,411)	(194,015)
Other receivables	1,636,856	(754,231)
Trade receivables		
Prepaid expenses	311,708	(65,826)
CHANGE IN WORKING CAPITAL	(217,172)	1,689,564
NET CASH FROM (USED IN) OPERATING ACTIVITIES	(40,244,968)	(38,173,884)
Acquisition of property, plant and equipment	(613,158)	(2,176,599)
Acquisition of intangible assets	(35,568)	(116,780)
Acquisition of financial assets	12,374	(13,335)
Proceeds from disposals of financial assets		
NET CASH FROM (USED IN) INVESTING ACTIVITIES	(636,352)	(2,306,714)
Capital increase	133,349	10,375
Bonds redeemable in shares/share warrants		
Share premium and reserves	59,501,072	5,048,893
Capitalization of current accounts		
Borrowings and conditional advances	11,450,732	
NET CASH FROM (USED IN) FINANCING ACTIVITIES	71,085,154	5,059,268
CHANGE IN CASH AND CASH EQUIVALENTS	30,203,834	(35,421,330)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	25,301,658	60,722,988
CASH AND CASH EQUIVALENTS AT END OF YEAR	55,505,492	25,301,658

### 3.2.2 NOTES TO THE 2019 FINANCIAL STATEMENTS

Notes to the balance sheet for the year ended December 31, 2019, which shows total assets of €64,675,643, and to the income statement for the year ended December 31, 2019, presented in list form and showing zero revenue resulting in a net loss of €42,648,672.

The financial statements cover the 12-month period to December 31, 2019, and the comparative 12-month period to December 31, 2018.

The notes and tables presented below are an integral part of the financial statements for the year ended December 31, 2019 as approved by the Board of Directors on February 10, 2020. They are presented in euros unless otherwise stated.

### 3.2.2.1 SIGNIFICANT EVENTS DURING THE YEAR

The Company's business is devoted to the development of an artificial heart that responds to the challenges of terminal heart failure. The product is currently in the pivotal study phase.

During the year, the Company led a fundraising campaign, approved by the Board of Directors on September 18, 2019 on delegation of authority from the Combined Shareholders' Meeting of March 28, 2019. This operation resulted in a capital increase of €126,316, with a gross share premium of €59,873,689, for a total amount of issue proceeds of €60,000,005.

This capital increase led to the creation of 3,157,895 new shares, with a par value of 0.04. Taking into account the costs related to the capital increase, in the amount of 3,044,708, which are deducted from the share premium in application of the preferential accounting method, the net amount of the share premium of this capital increase is 56,828,981 (or 56,955,297 including the capital increase).

As part of the equity line agreement concluded with Kepler Cheuvreux in September 2018, fourteen subscriptions were made between January and December for a total of 105,000 share warrants (BSA), allowing the capital to be increased by €4,200, by issue of 105,000 ordinary shares with a par value of €0.04, issued at an average price of €21.46 per share, with a gross share premium of €2,269,980. Taking into account the costs related to the capital increase, amounting to €43,035, which are deducted from the share premium in accordance with the preferential accounting method, the net amount of the

share premium for this capital increase is €2,226,945 (or €2,231,145 including the capital increase).

Fifteen company founder share warrant (BCE) exercises were carried out between January and December coming to a total of 1,245 BCE 2009-2, making it possible to increase the capital by an amount of €1,245, by issuing 31,125 ordinary shares with a par value of €0.04, issued at a price of €8 per share, or with a share premium of €7.96 per share.

An exercise of 904 BSA share warrants was carried out on June 10, 2019, making it possible to increase the capital by an amount of €904, by issuing 22,600 ordinary shares with a par value of €0.04, issued at a price of €8 per share, or with a share premium of €7.96 per share.

Three capital increases totaling €684.40 were recorded between January and December, as a result of the vesting of 17,110 free preference shares (AGAP) which had provisionally been allocated in 2018.

All of the capital increases carried out during the financial year made it possible to increase the share capital by an amount of €133,349, by creating 3,333,730 new ordinary shares. The share capital of the Company was thus increased from €371,037 to €504,386. The total amount of additional paid-in capital was increased from €194,560,697 to €254,053,133.

The Company proceeded at the end of January 2019 to draw down the first tranche of €10 million from the loan granted under conditions by the European Investment Bank (EIB) in December 2018. This loan for a total amount of €30 million consists of three tranches of €10 million, two of which remain to be drawn down provided that the technical and financial conditions are met.

On June 28, 2019, the Company received a total amount of €1,450,732.07 from BPI France, as a repayable advance, recognized on the "Conditional advances" line under liabilities in the balance sheet.

The Company maintains the option for the Research Tax Credit for the year 2019. The first option was exercised for the calendar year 2009 and renewed each year until 2019.

### **(3**)

#### FINANCIAL INFORMATION

The Research Tax Credit relating to the year 2019 has been recognized for €1,636,019 on the "Income tax" line in the income statement (details in note 3.2.2.5) and appears on the "Other receivables" line of the balance sheet.

The status of the project and the significant activities of the Company are detailed in section 3.1 "2019 financial review" of this document.

### 3.2.2.2 SIGNIFICANT EVENTS AFTER THE REPORTING DATE

No events occurred after the reporting date that are liable to alter the presentation or the valuation of the financial statements as approved by the Board of Directors.

#### 3.2.2.3 SIGNIFICANT ACCOUNTING POLICIES

The methods used for measuring accounting items for the year remain unchanged from the previous financial year.

#### General principles and conventions

The financial statements for the period have been prepared and are presented in accordance with the applicable French accounting regulations and the principles laid down in Articles 120-1 et seq. of the French General Chart of Accounts.

The historical cost method is used as the basis for measuring accounting items.

The accounting conventions have been applied in accordance with the provisions of the French Commercial Code (Code de commerce), the Accounting Decree of November 29, 1983 and the CRC regulations concerning the new French General Chart of Accounts applicable as at the end of the period.

The financial statements for the year ended December 31, 2019 have been prepared in accordance with French generally accepted accounting principles, including the principles of prudence and accrual-based accounting. They are presented on a going concern basis and accounting methods have been applied consistently from one year to the next.

The Board of Directors has assumed that the business is a going concern, having taken the following points in particular into account:

- available cash and cash equivalents as of December 31, 2019, in a total amount of €55.5 million;
- the possibility of using the flexible equity financing set up in September 2018 with Kepler Cheuvreux, whose balance at December 31, 2019 is equal to €21.9 million;
- non-dilutive financing granted by the European

Investment Bank (EIB) under conditions on December 17, 2018, of which the amount remaining to be drawn on December 31, 2019 amounts to €20.0 million.

The Company's clinical, industrial and commercial development, even beyond obtaining the CE marking, will generate additional financial needs: financing of recurring operations, continuation of R&D efforts, commercial launch, clinical trials in the United States, the working capital requirement linked to the development of sales, and investments (especially in production). The Company currently believes that these additional needs could exceed €100 million. Fundraising will therefore be necessary beyond the use of the available balance of the Kepler equity financing lines and the EIB loan.

#### Additional information

Applied research and development costs

Research and development costs are recognized as expenses in the year in which they are incurred.

#### Intangible assets

Patents, licenses and other intangible assets have been measured at their cost of acquisition, excluding the expenses incurred in acquiring them. The methods and periods of amortization used are as follows:

Category	Method	Useful life
Licenses and software	Straight line	1 to 3 years
Patents	Straight line	15 years

#### • Property, plant and equipment

The gross value of property, plant and equipment corresponds to their initial book value, inclusive of any expenditure required to render the items usable but excluding costs incurred in their acquisition. The methods and periods of depreciation used are as follows:

Category	Method	Useful life
Fixtures and fittings	Straight line	9 to 10 years
Technical plant	Straight line	3 to 10 years
Equipment and tooling	Straight line	2 to 6 years
Furniture	Straight line	8 years
IT equipment	Straight line	3 years

#### Financial assets

#### OTHER LONG-TERM INVESTMENTS

In 2010, the Company entered into a liquidity agreement, the purpose of which was to improve the liquidity of transactions and regularize the CARMAT share price, without impeding the normal operation of the market and without misleading third parties. To this end, the Company made €300,000 available.

On May 19, 2016, the Company transferred the liquidity agreement to Gilbert Dupont for a period of 12 months, renewable by tacit agreement.

Treasury shares acquired through the implementation of this liquidity agreement are recorded under financial assets at their purchase price. If necessary, an impairment loss is recognized based on the average official stock market price for the final month prior to the end of the reporting period.

#### OTHER FINANCIAL ASSETS

These comprise:

- guarantee deposits paid, which are shown at face value; and
- the unused balance of sums made available under the liquidity agreement for the acquisition of treasury shares.

#### Receivables and payables

Receivables and payables are measured at face value. Where applicable, receivables are impaired via provisions to take into account any collection difficulties they may potentially face. Any provisions for impairment are determined by comparison between the acquisition value and the probable realizable value.

Receivables and payables in foreign currencies are converted into euros on the basis of the exchange rate at the date of the invoice.

#### Inventories

The equipment held in inventory is not measured at end of the financial year as it is intended to be integrated into the prostheses used for the pivotal study. Its net realizable value is therefore nil.

#### Cash in euros

Cash on hand or at bank is recorded at face value.

#### • Cash in foreign currencies

Cash in foreign currencies is converted into euros at the exchange rate prevailing at the reporting date. Translation differences are recognized directly in profit or loss for the period as foreign exchange gains and losses.

#### Cash instruments

These comprise term deposit accounts, shown under assets at their acquisition cost, plus accrued interest at the reporting date.

#### • Cash and cash equivalents

For the purposes of the cash flow statement, cash and cash equivalents are defined as being the sum of the "Cash instruments" and "Cash" items under assets, less the "Bank overdrafts" liability item, to the extent that cash instruments are available in the very short term and do not present a risk of a loss in value in the event of a change in interest rate. An analysis of cash according to this definition is provided in the footnote of the cash flow statement.

#### Repayable advances made by public bodies

Advances received from public bodies to finance the research activities of the Company and which are subject to repayment are shown under liabilities under "Other equity – Conditional advances". The corresponding interest is shown in balance sheet liabilities under "Sundry loans and borrowings".

#### Operating subsidies

Subsidies are recorded as soon as the corresponding receivable becomes certain, taking account of the conditions set at the time the subsidy was granted. Operating subsidies are recorded under income taking into account, if necessary, the corresponding rate of expenditure in order to adhere to the principle of matching expenses with revenue.

#### • Retirement benefits

Future payments for benefits to members of staff are measured according to an actuarial method based on assumptions concerning changes in salaries, retirement age and mortality; the resulting valuations are then discounted to their present value. These obligations are covered by provisions in the balance sheet liabilities.

#### Sub-contracting expenses

The progress of third-party sub-contract agreements for certain research services is assessed at the end of each reporting period in order to allow the cost of services already rendered to be recorded under accrued expenses.

#### Share issue costs

In application of the reference method (ANC 2018-01), share issue costs are recorded in the balance sheet as deductions from the share premium.

### 3.2.2.4 ADDITIONAL INFORMATION ON THE BALANCE SHEET

Movements in non-current assets

(in euros)	Gross value at	Increases		
	start of period	Line to line transfers	Acquisitions	
Licenses, patents and similar rights*	1,978,684	35,568		
Intangible assets not yet available for use				
TOTAL	1,978,684	35,568		
Technical plant, equipment and industrial tooling**	8,068,236	1,199,230	490,499	
General plant, sundry fixtures and fittings	2,430,861			
Office and IT equipment, furniture	376,175	3,185		
Property, plant and equipment in progress	1,606,508		245,684	
TOTAL	12,481,781	1,202,415	736,183	
Other financial assets***	485,876		2,515,417	
TOTAL	485,876		2,515,417	

GRAND TOTAL	14.946.342	1.237.983	3.251.600

	Decre	Decreases		Revaluation of
(in euros)	Line to line transfers	Disposals	at end of period	original value at end of period
Licenses, patents and similar rights*			2,014,252	
Intangible assets not yet available for use				
TOTAL			2,014,252	
Technical plant, equipment and industrial tooling**		87,458	9,670,508	
General plant, sundry fixtures and fittings			2,430,861	
Office and IT equipment, furniture			379,360	
Property, plant and equipment in progress	1,237,983		614,209	
TOTAL	1,237,983	87,458	13,094,938	
Other financial assets***		2,527,791	473,503	
TOTAL		2,527,791	473,503	
GRAND TOTAL	1,237,983	2,615,248	15,582,693	

<sup>\*</sup> This item includes a sum of €411,284, recognized in respect of the share of the contribution in kind made on September 30, 2008, with a total value of €960,000, corresponding to the contribution of patents.

<sup>\*\*</sup> This item includes the commissioning of the clean room at a total cost of €943,582. The item also includes a sum of €548,716 recognized in respect of the share of the contribution in kind of €960,000 made on September 30, 2008, corresponding to the contribution of equipment and tooling.

<sup>\*\*\*</sup> This item includes the 4,170 treasury shares held in connection with the liquidity agreement, valued at €74,201, and (i) the liquidities not invested in treasury shares as at the end of the period under the liquidity agreement for €53,185 and (ii) guarantee deposits of €346,117, mainly comprising deposits under premises lease contracts.

#### Movements in depreciation and amortization

Positions and movements for the period (in euros)	Value at start of period	Additions for the period	Decreases Reversals	Value at end of period
Licenses, patents and similar rights	1,888,907	97,627		1,986,534
TOTAL	1,888,907	97,627		1,986,534
Technical plant, equipment and industrial tooling	5,741,430	849,261		6,590,691
General plant, sundry fixtures and fittings	855,287	200,839		1,056,126
Office and IT equipment, furniture	322,140	15,811		337,950
TOTAL	6,918,857	1,065,910		7,984,767
GRAND TOTAL	8,807,764	1,163,537		9,971,301

#### Movements in provisions

Provisions (in euros)	Value at start of period	Increases Additions	Decreases Utilized amounts	Decreases Surplus amounts	Value at end of period
Sundry risks					
Pension and similar obligations*	302,968	110,938			413,906
Payroll taxes on AGAP free preference shares**	688,472	271,654	688,472		271,654
TOTAL	991,440	382,592	688,472		685,560
Impairment of other long-term investments					
TOTAL	0	0	0		0
	00/ //0	200 500	000 170		005.500

 GRAND TOTAL
 991,440
 382,592
 688,472
 685,560

 Of which operational additions and reversals:
 382,592
 688,472

Of which financial additions and reversals:

#### Receivables and payables by maturity

Receivables	(in euros)	Gross amount	Due within 1 year	Due beyond 1 year
Staff and related receivables		5,132	5,132	
Social security receivables		32,380	32,380	
Income tax*		1,715,376	1,715,376	
Value-added tax		1,110,898	1,110,898	
Sundry receivables		78,730	78,730	
TOTAL		2.943.016	2.943.016	

<sup>\*</sup> The receivable corresponds to: - the French research tax credit (CIR) for 2019 for an amount of €1,636,019;

<sup>\*</sup> See note 3.2.2.6.

<sup>\*\*</sup> See note at the end of section 3.2.2.4.

<sup>-</sup> the balance on the CIR for 2018 for an amount of €79,357 (collective deduction of 4% collected by Predirec as part of the CIR 2018 mobilization).



Payables (in euros)	Gross amount	Due within 1 year	Due in 1 to 5 years	Due beyond 5 years
Bank loans and borrowings*	10,733,333		10,733,333	
Sundry loans and borrowings**	5,681,519		5,681,519	
Trade notes and accounts payable	5,345,899	5,345,899		
Staff and related payables	1,707,234	1,707,234		
Social security payables	1,412,384	1,412,384		
Value-added tax	31,717	31,717		
Other taxes, duties and levies	102,939	102,939		
TOTAL	25,015,525	8,600,673	16,414,852	

<sup>\*</sup> Loan from the European Investment Bank (EIB): the EIB loan contract provides for certain information and operational commitments (such as limitations on authorized debt, authorized external growth operations, transfers of assets, etc.), the non-compliance of which would allow the EIB, if it deemed it necessary, to demand an early repayment of the loan. The occurrence of certain changes in the shareholding structure or a change in management not approved beforehand by the EIB would also allow the latter, if deemed necessary following discussions with the Company, to demand an early repayment of the loan. To date, CARMAT complies with all of the commitments required by the EIB.

#### Capital

#### Composition of the share capital

Classes of shares	Par value in		Number	Number of shares	
Classes of Shares	euros	Opening Created Rede	Redeemed	Closing	
Ordinary shares	0.04	9,275,919	3,316,620		12,592,539
Preference shares	0.04		17,110		17,110
TOTAL		9,275,919	3,333,730		12,609,649

The capital increase further to the fundraising in September 2019 resulted in the creation of 3,157,895 ordinary shares, with a par value of €0.04.

The capital increase further to the exercise of share warrants (BSA) by Kepler Cheuvreux in 2019 resulted in the creation of 105,000 ordinary shares, with a par value of €0.04.

The capital increase further to the exercise of company founder share warrants (BCE) in 2019 resulted in the creation of 31,125 ordinary shares, with a par value of €0.04.

The capital increase further to the exercise of BSA share warrants in 2019 resulted in the creation of 22,600 ordinary shares, with a par value of 0.04.

The capital increase further to the vesting of free preference shares (AGAP) in 2019 resulted in the creation of 17,110 preference shares, with a par value of €0.04.

#### Changes in equity

EQUITY AT START OF THE PERIOD	7,481,498
Capital increase following the fundraising carried out	56,955,297
Capital increase through the exercise of BCE share warrants	249,000
Capital increase through the exercise of BSA share warrants	180,800
Subscription of BSA share warrants	18,180
Capital increase through the exercise of Kepler BSA share warrants	2,231,145
Profit (loss) for the period	(42,648,672)
EQUITY AT END OF THE PERIOD	24,467,248

<sup>\*\*</sup> This amount corresponds to the accrued interest expected at year-end on the repayable advances from Bpifrance (details in section 3.2.2.6).

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#### FINANCIAL INFORMATION

#### Stock options

#### 2018 stock options

On the authorization of the Combined Shareholders' Meeting of April 5, 2018, the Board of Directors decided, on December 3, 2018, to grant 46,000 options to subscribe to ordinary shares, breaking down as follows: 23,000 A options and 23,000 B options. These options entitle holders to subscribe to 46,000 new shares, following the achievement of attendance and/or performance criteria, representing 0.37% of the existing capital as of December 31, 2019, at a price of €20.35 per share, share premium included.

#### 2019 stock options

On the authorization of the Combined Shareholders' Meeting of March 28, 2019, the Board of Directors decided, on April 1, 2019, to grant 46,000 options to subscribe to ordinary shares. These options entitle holders to subscribe to 46,000 new shares, following the achievement of attendance and/or performance criteria, representing 0.37% of the existing capital as of December 31, 2019, at a price of €22.70 per share, share premium included.

#### Preference shares (AGAP)

#### 2017 plans

On the authorization of the Combined Shareholders' Meeting of April 27, 2017, the Board of Directors' meeting decided, on May 15, 2017, to allocate provisionally 5,250 preference shares, breaking down as follows: 270 AGAP 2017-01, 1,800 AGAP 2017-02, 3,180 AGAP 2017-03; and on September 25, 2017, to allocate provisionally 560 preference shares, breaking down as follows: 50 AGAP 2017-01, 200 AGAP 2017-02, 310 AGAP 2017-03.

These preference shares may be converted based on the achievement of the performance criteria into a maximum of 421,000 ordinary shares: 32,000 ordinary shares under AGAP 2017-01, 40,000 ordinary shares under AGAP 2017-02, and 349,000 ordinary shares under AGAP 2017-03.

#### 2018 plans

On the authorization of the Combined Shareholders' Meeting of April 5, 2018, the Board of Directors' meeting decided, on April 16, 2018, to allocate provisionally 12,080 preference shares, breaking down as follows: 580 AGAP 2018-01 and 11,500 AGAP 2018-02; then on September 27, 2018, to allocate provisionally 370 preference shares (AGAP 2018-03); then on February 11, 2019, to allocate provisionally 370 preference shares (AGAP 2018-03).

These preference shares may be converted based on the achievement of the performance criteria into a maximum

of 301,500 <sup>01</sup> ordinary shares: 58,000 ordinary shares under AGAP 2018-01, 169,500 ordinary shares under AGAP 2018-02, and 74,000 ordinary shares under AGAP 2018-03.

#### 2019 plans

On the authorization of the Combined Shareholders' Meeting of March 28, 2019, the Board of Directors' meeting decided, on April 1, 2019, to allocate provisionally 11,900 preference shares, breaking down as follows: 4,760 AGAP 2019-01, 4,760 AGAP 2019-02 and 2,380 AGAP 2019-03; then on September 23, 2019, to allocate provisionally 4,700 preference shares, breaking down as follows: 2,240 AGAP 2019-01, 2,240 AGAP 2019-02 and 220 AGAP 2019-03; then on December 2, 2019, to allocate provisionally 3,000 preference shares, breaking down as follows: 1,000 AGAP 2019-01, 1,000 AGAP 2019-02 and 1,000 AGAP 2019-03.

These preference shares may be converted based on the achievement of the performance criteria into a maximum of 193,000 <sup>02</sup> ordinary shares: 78,800 ordinary shares under AGAP 2019-01, 78,800 ordinary shares under AGAP 2019-02, and 35,400 ordinary shares under AGAP 2019-03.

#### Share warrants (BSA)

#### BSA 2009-1

At the Shareholders' Meeting and the Board of Directors' meeting of July 8, 2009 and following the Board of Directors' meeting of September 8, 2011, 3,096 BSA 2009-1 share warrants were issued; of these 556 were canceled following the resignation of one of the directors and 2,540 were exercised.

#### BSA Kepler Cheuvreux

In accordance with the Board of Directors' decision of December 9, 2014, as authorized by the Combined Shareholders' Meeting of April 2, 2014, then in accordance with the Board of Directors' decision of December 12, 2016, as authorized by the Combined Shareholders' Meeting of June 28, 2016, a total number of 900,000 BSA share warrants were issued, 742,600 of which had been exercised as at July 20, 2018, the expiration date of the contract. The 157,400 BSA warrants not exercised on the same date became expired.

By decision of the Board of Directors on September 27, 2018, as authorized by the Combined Shareholders' Meeting of April 5, 2018, 400,000 BSA share warrants were issued, of which 139,000 BSA warrants were exercised

**01** These figures take into account the departure of an AGAP 2018-02 beneficiary and the non-achievement of a performance criterion attached to AGAP 2018-02.

 ${f 02}$  These figures take into account the departure of an AGAP 2019-01, 2019-02 and 2019-03 beneficiary.

#### FINANCIAL INFORMATION

on December 31, 2019. The 261,000 BSA warrants not exercised on the same date confer subscription rights to 261,000 new shares, representing 2.07% of the existing capital as at December 31, 2019, at a price per share defined contractually between CARMAT and Kepler Cheuvreux, the holder of the BSA warrants, as being equal to the average share price at the time of the drawdown, less a discount of not more than 6%.

#### BSA 2017

By decision of the Board of Directors dated May 15, 2017, 12,000 share warrants were issued as authorized by the Combined Shareholders' Meeting of April 27, 2017, none of which had been exercised as at December 31, 2019. The 12,000 BSA warrants not exercised on the same date confer subscription rights for 12,000 new shares, representing 0.10% of the existing capital as at December 31, 2019, at a price of €30.10 per share.

#### SUMMARY TABLE OF BSA SHARE WARRANTS

#### BSA 2018

By decision of the Board of Directors dated June 11, 2018, 10,000 BSA share warrants were issued pursuant to a delegation of authority granted by the Combined Shareholders' Meeting of April 5, 2018, none of which had been exercised as at December 31, 2019. The 10,000 BSA warrants not exercised on the same date entitle them to subscribe to 10,000 new shares, representing 0.08% of the existing capital as at December 31, 2019, at a price of €20.93 per share.

#### BSA 2019

By decision of the Board of Directors dated June 24, 2019, 6,000 BSA share warrants were issued pursuant to a delegation of authority granted by the Combined Shareholders' Meeting of March 28, 2019, none of which had been exercised as at December 31, 2019. The 6,000 BSA warrants not exercised on the same date entitle them to subscribe to 6,000 new shares, representing 0.05% of the existing capital as at December 31, 2019, at price of €20.21 per share.

	Issued	Sub- scribed	Expired	Reserve	Exercised	Balance	Expiry date
BSA 2009-1 SM of July 8, 2009	3,096	3,096	556	0	2,540	0	July 8, 2019
BSA Kepler Cheuvreux (old tranches)	900,000	900,000	157,400	0	742,600	0	July 20, 2018
BSA Kepler Cheuvreux (new tranches)	400,000	400,000	0	0	139,000	261,000	Sept. 26, 2020
BSA 2017	12,000	12,000	0	0	0	12,000	May 15, 2027
BSA 2018	10,000	10,000	0	0	0	10,000	June 11, 2028
BSA 2019	6,000	6,000	0	0	0	6,000	June 24, 2029

#### Company founder share warrants (BCE)

#### BCE 2009-1

At the Shareholders' Meeting and the meeting of the Board of Directors of July 8, 2009 and following the Board of Directors' meeting of September 8, 2011, 3,108 fully assigned and subscribed BCE-2009-1 company founder share warrants were issued, exercised.

#### BCE 2009-2

At the Shareholders' Meeting and the meeting of the Board of Directors of July 8, 2009 and following the Board of Directors' meeting of September 8, 2011, 7,566 fully assigned and subscribed BCE-2009-2 company founder share warrants were issued, 4,475 of which have been exercised and 3,091 of which have expired and been canceled.

#### BCE 2012-1

In accordance with the Board of Directors' decision of June 27, 2012, as authorized by the Combined Shareholders' Meeting of April 26, 2012, 56,500 fully assigned and subscribed BCE 2012-1 company founder share warrants were issued, of which 45,000 have expired and been canceled. The 11,500 BCE 2012-1 warrants subscribed and not exercised as at December 31, 2019 confer subscription rights to 11,500 new shares, representing 0.10% of the existing capital as at December 31, 2019, at a price of €108.483 per share.

#### BCF 2012-2

In accordance with the Board of Directors' decision of November 8, 2012, as authorized by the Combined

Shareholders' Meeting of April 26, 2012, 6,700 fully assigned and subscribed BCE 2012-2 company founder share warrants have been issued. The 6,700 BCE 2012-2 warrants subscribed and not exercised as at December 31, 2019 confer subscription rights to 6,700 new shares, representing 0.06% of the existing capital as at December 31, 2019, at a price of €122.003 per share.

	Issued	Sub- scribed	Expired	Exercised	Balance	Expiry date
BCE 2009-1 SM of July 8, 2009	3,108	3,108	0	3,108	0	Sept. 9, 2019
BCE 2009-2 SM of July 8, 2009	7,566	7,566	3,091	4,475	0	July 8, 2019
BCE 2012-1 SM of April 26, 2012	56,500	56,500	45,000	0	11,500	June 27, 2022
BCE 2012-2 GM of July 26, 2012	6,700	6,700	0	0	6,700	Nov. 8, 2022

#### Other balance sheet details

#### Conditional advances

The conditional advances item comprises repayable advances received from Bpifrance, the total amount of which was €14,507,309 as at the end of the financial year. Note 3.2.2.6 below specifies the repayment conditions of these advances.

They are interest-bearing at the contracted rate of 5.59%. The interest accrued, calculated using the capitalization method, stood at €5,681,519 at the year-end and appears in liabilities under "Sundry loans and borrowings".

#### Accrued income

Value of accrued income included in the following balance sheet items	Value
Other receivables	76,111
Total	76,111

#### Accrued expenses

Value of accrued expenses included in the following balance sheet items	Value
Bank loans and borrowings	733,333
Sundry loans and borrowings	5,681,519
Trade notes and accounts payable	2,968,394
Tax and social security payables	2,547,493
Total	11,930,739

#### Prepaid expenses and deferred income

Prepaid expenses	Value
Operating expenses	121,610
Total	121,610

Prepaid expenses comprises the share of subscriptions, software license royalties and insurance premiums for the period after December 31, 2019, totaling €121,610.

Prepaid income	Value
Operating income	None
Total	None

#### Information on related companies

The following balance sheet items include sums in connection with related companies:

Trade notes and accounts payable 145,818

#### **Provisions**

Four preference share allocation plans, approved on February 11, 2019, April 1, 2019, September 23, 2019 and December 2, 2019, allowed for the provisional allocation of 19,970 preference shares, which can be converted based on the achievement of the performance criteria to a maximum of 233,000 ordinary shares. The vesting dates for these preference shares are fixed at February 11, 2020 for 370 preference shares, at April 1, 2020 for 11,900 preference shares, at September 23, 2020 for 4,700 preference shares and at December 2, 2020 for 3,000 preference shares. At the end of the year, the Company booked a provision for losses corresponding to the amount of the employer contributions of 20% to be due in 2020, on a pro

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#### FINANCIAL INFORMATION

rata basis of the vesting period and based on the estimate of the value of the ordinary shares that could be converted at the end of the vesting period.

The calculation assumptions made were as follows:

- determination of a percentage of achievement of each of the performance criteria;
- value of a ordinary share of €19.70;
- employer contribution rate of 20%.

### 3.2.2.5 ADDITIONAL INFORMATION ON THE INCOME STATEMENT

#### Operating subsidies

The Company received the sum of €14,000 as an operating subsidy from the Association nationale de la recherche et de la technologie (national research and technology association) to employ 1 PhD student.

#### Applied research and development costs

Research and development costs are recognized under expenses. They amounted to €29,368,163 in 2019, compared to €27,193,406 in the previous year.

#### • Research tax credit

The income statement for the year shows a research tax credit amounting to €1,636,019, corresponding to the amount calculated for the year 2019.

In addition, the research tax credit claim for 2018 was sold to Prédirec, which collected it at the end of 2019. This operation generated a cost for CARMAT of €36,930 in 2019 (including commissions and interest).

#### Statutory Auditors' fees

The total amount of Statutory Auditors' fees paid over the year is €112,000 excluding taxes and disbursements and breaks down as follows:

Total amount excl. taxes (€)	PwC	LCA	Total
Statutory Auditors' fees	50,500	35,000	85,500
Non-audit services fees			
- Non-audit services required	3,500	3,500	7,000
- Other non-audit services	9,750	9,750	19,500
Total	63,750	48,250	112,000

#### Non-recurring income and expenses

Туре	2019	2018
Non-recurring income		
- Disposal of assets		
- Disposal of treasury shares	46,794	60,198
Total	46,794	60,198
Non-recurring expenses		
- Disposal of assets		
- Disposal of treasury shares	60,767	58,564
- Fines and penalties	2,513	3,424
- Non-recurring depreciation	87,458	
Total	150,738	61,987

Non-recurring items relate to:

- disposals of treasury shares carried out under the liquidity agreement;
- exceptional depreciation relating to the retirement of equipment not fully depreciated.

#### • Information on related companies

The following income statement items include sums in connection with related companies:

Other purchases and external expenses

506,888

### 3.2.2.6 FINANCIAL COMMITMENTS AND OTHER INFORMATION

#### • Financial commitments

#### Commitments given

Repayable advances totaling €14,507,309 have been received at the end of the fiscal year from the BPI, of which €1,450,732 obtained in June 2019 corresponding to the last tranche. The corresponding accrued interest amounts to €5,681,519 at the end of the financial year. This amount is repayable subject to achieving cumulative revenue of at least €38,000,000. The Bpifrance agreement provides for supplementary payments if certain conditions are met, so that the total amount repayable could exceed the amount of the advance initially granted, up to a ceiling of €50,000,000.

On June 24, 2008 the Company signed a royalties agreement with Professor Alain Carpentier and Matra Défense, who still held shares as at December 31, 2019. Under this agreement, the Company undertakes to pay Professor Alain Carpentier and Matra Défense 2% of the net proceeds from sales of the CARMAT artificial heart produced and distributed by CARMAT SA, with this sum being



shared between the two beneficiaries in proportion to their respective shares in the capital of the Company on the date it was established. These royalties will be payable every six months within 30 days of the end of each six-month period, commencing after the first marketing of the CARMAT artificial heart post CE marking in Europe and FDA marketing authorization in the United States, and ending upon expiration of the patents shown in the appendices to the agreement.

The Company is also authorized to repurchase at any time the right to benefit from these royalties for a sum of €30,000,000 less any royalties already paid under the agreement, with this total sum being shared between the two beneficiaries in proportion to their respective shares in the capital of the Company on the date it was established. This sum of €30,000,000 is index-linked to the Index of Prices for the Industrial Production of Services to Businesses – Medico-surgical and orthopedic equipment – for export within the Eurozone.

The rights allocated to Professor Alain Carpentier and to Matra Défense in this way are non-transferable.

As at December 31, 2019, since the marketing of the CAR-MAT artificial heart had not started, no royalties had been paid by the Company under the agreement.

In addition, the Company has signed a royalties agreement with the EIB providing for the payment of additional compensation to the EIB depending on the commercial performance of the Company. This agreement is valid for 13 years from the year during which the cumulative sales of CARMAT reach €500,000. The Company can decide to terminate the royalties agreement at any time by paying a lump sum (net of any royalties already paid), based on the amount borrowed and the year during which the decision is taken

Upon the occurrence of certain events (in particular should the EIB demand the early repayment of the loan or should a new shareholder reach 33% of the voting rights of CARMAT), the EIB could, if deemed necessary, demand from CARMAT an advance payment of royalties up to a certain percentage of the amount of the loan effectively used (this percentage would range from 100% of the borrowed amount if the event occurs during the first four years of the financial contract to 160% if the event occurs after the eleventh year).

#### Commitments received

None.

#### Pension and retirement obligations

The Company has not signed a specific agreement on retirement obligations. These are therefore limited to the agreed retirement lump-sum payment.

In application of the reference method (ANC 2018-01), the provision for retirement obligations has been booked as at December 31, 2019.

The calculation assumptions made were as follows:

- time-apportioned rights method in accordance with CNC Regulation 2003 R-01;
- retirement on the initiative of the member of staff, at 62 years (non-management) or 65 years (management);
- salary increases of 2% per annum;
- low staff turnover;
- discount rate of 0.77% per annum (versus the rate of 1.57% used at December 31, 2018 and 0.77% at June 30, 2019).

The overall amount of the provision was €413,906 at the end of the period, an increase of €110,938 on the previous period.

#### Other information

#### Information on executives

#### ADVANCES AND LOANS TO MANAGEMENT

No loans or advances were made to executives of the Company during the financial year, in accordance with the provisions of Article R.123-197 of the French Commercial Code.

#### MANAGEMENT COMPENSATION

Total directors' compensation recognized in respect of 2019 amounted to €69,839 (amounts entered under "Other expenses" in the income statement).

The total compensation paid to the Company's executives was €650,135 for the financial year and breaks down as follows:

Туре	2019	2018
Gross salaries	465,396	471,295
Benefits in kind	7,793	5,270
Bonuses	176,946	160,912
Total compensation	650,135	637,477



Increases and decreases in future tax liabilities

Type of temporary differences	Value
Tax loss carryforwards	268,500,634

This amount comprises:

- the tax loss carried forward made during previous periods and available as at January 1, 2019, in the sum of €221,385,242;
- the tax loss made in the 2019 financial year in the sum

of €47,115,392.

Headcount at year end

Salaried staff	2019	2018
Managers	80	66
Supervisors and technicians	18*	15***
Administrative employees	9**	9*
Total	107	90

- \* Including one temporary employee.
- \*\* Including three temporary employees.
- \*\*\* Including two temporary employees.

# 3 STATUTORY AUDITORS' REPORT ON THE 2019 FINANCIAL STATEMENTS

This is a free translation into English of the Statutory Auditors' report issued in French and is provided solely for the convenience of English speaking readers. This report includes information specifically required by European regulations or French law, such as information about the appointment of Statutory Auditors. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

#### CARMAT SA

36, Avenue de l'Europe Immeuble l'Etandard energy III 78140 Vélizy-Villacoublay, France

#### TO THE SHAREHOLDERS.

#### **OPINION**

In compliance with the engagement entrusted to us by your Shareholders' Meeting, we have audited the accompanying financial statements of CARMAT SA for the year ended December 31, 2019.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and of the financial position of the Company at December 31, 2019 and of the results of its operations for the year then ended in accordance with French accounting principles.

#### **BASIS FOR OPINION**

#### Audit framework

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under these standards are further described in the "Responsibilities of the Statutory Auditors relating to the audit of the financial statements" section of our report.

#### Independence

We conducted our audit engagement in compliance with the independence rules applicable to us, for the period from January 1, 2019 to the date of our report, and, in particular, we did not provide any non-audit services prohibited by the French Code of Ethics (Code de déontologie) for Statutory Auditors.

#### **JUSTIFICATION OF OUR ASSESSMENTS**

In accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code (Code de commerce) relating to the justification of our assessments, we inform you that the most significant assessments we made, in our professional judgment, concerned the appropriateness of the accounting policies applied, the reasonableness of the significant estimates used, and the overall presentation of the financial statements.

These matters were addressed as part of our audit of the financial statements as a whole, and therefore contributed to the opinion we formed as expressed above. We do not provide a separate opinion on specific items of the financial statements.

#### **SPECIFIC VERIFICATIONS**

In accordance with professional standards applicable in France, we have also performed the specific verifications required by French legal and regulatory provisions.

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#### FINANCIAL INFORMATION

Information given in the management report and in the other documents provided to the shareholders with respect to the Company's financial position and the financial statements

We have no matters to report as to the fair presentation and the consistency with the financial statements of the information given in Board of Directors' management report and in the other documents provided to the shareholders with respect to the Company's financial position and the financial statements.

We attest to the fair presentation and the consistency with the financial statements of the information about payment terms referred to in Article D.441-4 of the French Commercial Code.

#### Information on corporate governance

We attest that the Board of Directors' report on corporate governance sets out the information required by Article L.225-37-4 of the French Commercial Code.

#### Other information

In accordance with French law, we have verified that the required information concerning the acquisition of investments and controlling interests and the identity of shareholders and holders of the voting rights has been properly disclosed in the management report.

# RESPONSIBILITIES OF MANAGEMENT AND THOSE CHARGED WITH GOVERNANCE FOR THE FINANCIAL STATEMENTS

Management is responsible for preparing financial statements giving a true and fair view in accordance with French accounting principles, and for implementing the internal control procedures it deems necessary for the preparation of financial statements that are free of material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern, and using the going concern basis of accounting, unless it expects to liquidate the Company or to cease operations.

These financial statements have been approved by the Board of Directors.

# RESPONSIBILITIES OF THE STATUTORY AUDITORS RELATING TO THE AUDIT OF THE FINANCIAL STATEMENTS

Our role is to issue a report on the financial statements. Our objective is to obtain reasonable assurance about whether the financial statements as a whole are free of material misstatement. Reasonable assurance is a high

level of assurance, but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions taken by users on the basis of these financial statements.

As specified in Article L.823-10-1 of the French Commercial Code, our audit does not include assurance on the viability or quality of the Company's management.

As part of an audit conducted in accordance with professional standards applicable in France, the Statutory Auditors exercise professional judgment throughout the audit.

#### They also:

- identify and assess the risks of material misstatement
  of the financial statements, whether due to fraud or
  error, design and perform audit procedures responsive
  to those risks, and obtain audit evidence considered to
  be sufficient and appropriate to provide a basis for their
  opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery,
  intentional omissions, misrepresentations, or the override of internal control;
- obtain an understanding of the internal control procedures relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control;
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management and the related disclosures in the notes to the financial statements;
- assess the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of the audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the Statutory Auditors conclude that a material uncertainty exists, they are required to draw attention in the audit report to the related disclosures in the financial statements or, if such disclosures are not provided or are inadequate, to issue a qualified opinion or a disclaimer of opinion;
- evaluate the overall presentation of the financial statements and assess whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.



Signed in Neuilly-sur-Seine and Paris, March 12, 2020

The Statutory Auditors

PricewaterhouseCoopers Lison Chouraki

Audit Aud

Thierry Charron Lison Chouraki

# 3 4 INTERNAL CONTROL AND RISK MANAGEMENT PROCEDURES RELATING TO THE PREPARATION AND PROCESSING OF ACCOUNTING AND FINANCIAL INFORMATION

One of the objectives of internal control is to prevent and control the risks of error and fraud in the accounting and financial fields. In this context, CARMAT set up a system to provide reasonable assurance of the reliability of its produced and published accounting and financial information.

The accounting and financial processes correspond to all the activities enabling the economic operations of the Company to be translated into accounting and financial information.

The two key processes that affect the reliability of CAR-MAT's accounting and financial information are:

- the process of producing accounting and financial information (including the accounting closing process);
- the process of publishing accounting and financial information.

The Company's objectives in this area are:

- the production of reliable information that complies with legal and regulatory requirements;
- the prevention and detection of accounting and financial fraud or irregularities;
- the preservation of the assets of the Company;
- the application of the guidelines given by the Board of Directors;
- the reliability of the information used internally for monitoring and control purposes;
- the reliability of the financial statements and other financial information communicated to the financial markets.

#### PRODUCTION OF ACCOUNTING INFORMATION

Accounting is carried out by CARMAT's accounting team, assisted by an accounting firm that has been supporting the Company for many years.

Payroll is provided by an external firm. CARMAT is also assisted as needed by renowned specialist firms, particularly for legal and tax matters.

For the production of its financial statements, CARMAT relies mainly in terms of information systems on its ERP (Enterprise Resource Planning), and on more specific software used by its accounting firm; as well as a set of policies, operating procedures and calendar of operations, which are updated regularly.

The organization set up aims in particular to ensure segregation of duties, thereby limiting the risk of error and fraud, and to allow an appropriate level of control, especially on the most sensitive points. It is specified that CARMAT draws up its financial statements according to French accounting standards and does not draw up any consolidated financial statements.

The financial statements are prepared and reviewed monthly by the Finance Department, with the accounting firm. A summary of the net financial income (expense), including a comparison with the budget approved annually by the Board of Directors, is presented monthly to the Company's management team. The operational departments also receive a monthly statement of their expenses, in comparison with the budget, which is prepared by management control. A financial update is presented by the Chief Financial Officer at each Board of Directors' meeting.

CARMAT is still in the clinical phase and does not yet generate revenue, so a particular attention is paid to the financing plan of the Company, its cash flow forecasts and



the liquidity risk. In this context, the Company's business plan is updated and presented to the Board of Directors, at least once a year (and more frequently if necessary), and the financing strategy and options are regularly shared and discussed with the Board of Directors.

### PUBLICATION OF ACCOUNTING AND FINANCIAL INFORMATION

The Company publishes its financial calendar for the current year in January.

The Company publishes its results semi-annually and annually. The annual financial report is integrated into the Universal Registration Document (formerly Registration Document) which is made available to shareholders and the public, within the legal deadlines.

The accounting and financial information published semi-annually and annually is prepared by CARMAT's Administration and Finance Department, under the supervision of the Chief Executive Officer and is then reviewed by the Audit Committee, followed by the Board of Directors.

In addition, CARMAT's Statutory Auditors certify the Company's annual financial statements and review the interim financial statements.

All press releases published by the Company, whether or not they are of an accounting or financial nature, are validated beforehand by the Company's Chief Executive Officer.

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# 4 1 COMPOSITION OF THE COMPANY'S ADMINISTRATIVE AND MANAGEMENT BODIES

### 4.1.1 COMPOSITION OF THE BOARD OF DIRECTORS

The Board of Directors now consists of nine members, including five independent directors. Jean-Pierre Garnier is Chairman.

As a reminder, CARMAT had announced on December 3, 2018 the cooptation of Jean-Pierre Garnier to the Board of Directors of the Company to replace Jean-Claude Cadudal, Chairman of the Board of Directors who had resigned, for the remainder of his term of office, and his appointment as new Chairman of the Board. The appointment of Jean-Pierre Garnier as director of the Company was ratified by the Shareholders' Meeting of March 28, 2019.

At the end of this same meeting, Alain Carpentier left his position as director of CARMAT and was appointed Honorary President of the Company. As such, he remains invited to all Board meetings, without however taking part in the

votes.

On June 6, 2019, Karl Hennessee succeeded Anne-Pascale Guédon as permanent representative of Matra-Défense on the Board of Directors of the Company.

As a reminder, the Shareholders' Meeting of April 5, 2018 appointed Pierre Bastid as director, for a term of six years expiring at the end of the Ordinary Shareholders' Meeting held to approve the financial statements for the year ending December 31, 2023.

The table below details the information concerning each of the members of the Board of Directors (it being specified that the information on the other offices of the directors are those of which the Company is aware and that the companies marked with a \* are listed companies):

Full name or reg- istered name of the member and business address	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Previous other positions and functions in other companies over the last five years
Jean-Pierre Garnier (French & US citizenship)	First appointed: Dec. 3, 2018  Term of office: Until SM held to approve the financial statements for year ending Dec. 31, 2021	Chairman of the Board of Directors	- Chairman of Idorsia* - Director at Radius Health* - Director at United Technology* - Director at Fondation Paul Newman	- Chairman of Actelion* (till its acquisition by Johnson and Johnson in 2017)
Stéphane Piat (French citizenship) CARMAT 36, avenue de l'Europe 78 941 Velizy Villacou- blay, France	First appointed: April 27, 2017  Term of office: Until SM held to approve the financial statements for year ending Dec. 31, 2022	Chief Executive Officer** Member of the Board of Directors	Board member of Triflo Cardiovascular Inc.	Division Vice-President, Global Market Development, at Struc- tural Heart Division - Abbott Vascular - San Francisco
Matra Défense  Represented by Karl Hennessee (US citizenship)  Airbus Group 42, avenue Raymond Poincaré	First appointed: March 20, 2015 Term of office: Until SM held to approve the financial state- ments for year end- ing Dec. 31, 2021	Director	- Senior Vice President of Projic 9  - Senior Vice President of Matra Défense  - Managing Director of Matra Holding GmbH  - Board member of Shiny T BV, Sunny T BV, Perpetual Ltd, Fast Express Investment Ltd and Aeropart	- Member of the Executive Com- mittee of Projic 9

<sup>\*\*</sup> In accordance with the articles of association, the Board of Directors appoints the Chief Executive Officer, fixes the term of his office, determines his compensation and fixes the limits of his powers if necessary.

75016 Paris, France

Full name or reg- istered name of the member and business address	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Previous other positions and functions in other companies over the last five years
Henri Lachmann (French citizenship) Association Marie Lannelongue 133, avenue de la Résistance 92 350 Le Plessis Rob- inson, France	First appointed: Dec. 23, 2010  Term of office: Until SM held to approve the financial statements for year ending Dec. 31, 2021	Independent director	- Member of the supervisory board of Norbert Dentressangle SA*  - Chairman of the Board of Directors of the Centre chirurgical Marie Lannelongue (Marie Lannelongue Surgical Center) (nonprofit organization)  - Chairman of the Institut Télémaque (nonprofit organization)  - Director of the Fondation Entreprendre  - Chairman of the campaign committee of the Strasbourg University Foundation	- Director of various companies in the Schneider Electric Group* - Honorary Vice-Chairman of the supervisory board at Vivendi SA* - Vice-Chairman and treasurer of the Institut Montaigne (non-profit organization)
Truffle Capital  Represented by Dr. Philippe Pouletty (French citizenship)  Truffle Capital 5, rue de la Baume 75 008 Paris, France	First appointed: May 7, 2010  Term of office: Until SM held to approve the financial state- ments for year end- ing Dec. 31, 2021	Director	In a personal capacity:  - Chairman of the Board of Directors of Abivax SA*  - Manager at Nakostech SARL  - Chief Executive and director of Truffle Capital  - Honorary Chairman and director of France Biotech (non-profit organization)  As representative of Truffle Capital:  - Director at Biokinesis SAS  - Director at Pharnext SA*  - Director at Deinove SA*  - Director at Carbios SA*  - Director at Affluent Medical SA  - Chairman of the Board of Directors of Skinosive SASU  - Director at Artedrone SASU  - Chairman of the Board of Directors of Diaccurate SASU	- Director at Vexim SA* until 2017 - Director of Neovacs SA* until 2014 - Director at Plasmaprime SAS until 2015 - Director at Immune Targeting Systems Ltd (UK) until 2015 - Director at Altimmune, Inc. (United States) until December 2016
Pierre Bastid (French citizenship) Hougou 480, avenue Louise 1050 Bruxelles Belgium Santé Holdings SRL	First appointed: April 5, 2018  Term of office: Until SM held to approve the financial statements for year ending Dec. 31, 2023	Independent director	<ul><li>Chairman of Babalia</li><li>Director at Hougou SA</li><li>Director at Cellectis*</li><li>Director at Pharnext*</li></ul>	None
Represented by Antonino Ligresti (Italian citizenship)  NCTM Via Agnello 12 20121 Milan Italy	First appointed: April 12, 2016  Term of office: Until SM held to approve the financial state- ments for year end- ing Dec. 31, 2021	Independent director	- Sole shareholder of Immobiliare Cosio SRL, Iniziative Immobiliari Due SRL and Iniziative Immobiliari Tre SRL	None



Full name or reg- istered name of the member and business address	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Previous other positions and functions in other companies over the last five years
Jean-Luc Lemercier (French citizenship)	First appointed: Jan. 2, 2017			
Edwards Lifesciences Chemin du Clusel 1 1261 Le Vaud Switzerland	Term of office: Until SM held to approve the financial state- ments for year end- ing Dec. 31, 2021	Independent director	Corporate officer Edwards Lifesciences	None
Dr. Michael Mack (US citizenship)	First appointed: Jan. 2, 2017			
The Heart Hospital Baylor Plano 1100 Allied Drive 4708 Alliance - S. 500 TX 75093 Plano USA	Term of office: Until SM held to approve the financial state- ments for year end- ing Dec. 31, 2021	Independent director	None	None

As far as the Company is aware:

- there is no family link between the Company's directors;
- no director has been convicted of fraud in the last five years;
- no director has been associated with any bankruptcy, sequestration of assets or liquidation in the last five
- no director has been found guilty of any offense or any official public sanction pronounced by the statutory or

- regulatory authorities (including designated professional bodies) in the last five years; and
- no director has been prevented by a court from acting as a member of an administrative, management or supervisory board of an issuer or from taking part in the management or conduct of the affairs of an issuer over the past five years.

It should be noted that no strategic and/or historical investors acts together with others in relation to CARMAT.

#### **BIOGRAPHIES OF THE MEMBERS OF THE BOARD OF DIRECTORS**

#### **KARL HENNESSEE**

Karl Hennessee, Senior Vice-President of Airbus, has 25 years of experience in law, economics and regulation. He worked, in Europe and in the United States, as a business

lawyer on some of the most important files for a very large company in the energy sector, then as Secretary General of this same company. In addition to his management functions at Airbus, Karl

Hennessee is the Chairman of the Board of Directors of the International Arbitration Tribunal within the International Chamber of Commerce. He also sits on the Board of Directors of many other non-profit organizations. He also lectures and regularly publishes articles on law and regulations.

#### **DR. JEAN-PIERRE GARNIER**



A scientist and business leader, Jean-Pierre Garnier graduated from Louis Pasteur University (PhD in Pharmacology) and Stanford University (Master in Business Administration). He started his career in 1975 at the pharmaceutical company Schering-Plough where he held a number of management positions in Europe before becoming President of their American division. In 1990, he joined Smithkline Beecham Laboratories as President of the Pharmaceuticals Division and became President and CEO in 1999.

In 2000, Jean-Pierre Garnier achieved the merger of two of the largest pharmaceutical groups (Smithkline Beecham and Glaxo Wellcome), to create GlaxoSmithKline (GSK), which he chaired until 2008. He was also Chairman of Actelion from 2011 to 2017.

The Best Practice Institute has nominated Jean-Pierre Garnier as one of the world's top 20 CEOs. He is a French Officier de la Légion d'Honneur (Officer of the Legion of

#### **CORPORATE GOVERNANCE**

Honor) and Knight Commander of the Order of the British Empire.

#### **DR. PHILIPPE POULETTY**

Dr. Philippe Pouletty is a pioneer in biotechnology and medical devices. He founded SangStat in 1988, a company specializing in organ transplant therapy, listed on the NAS-DAQ, then Conjuchem in 1993, a biotech firm specialized in developing next-gen medicines from therapeutic peptides, listed on the Toronto Stock Exchange. He is the co-founder and CEO of Truffle Capital, founder and Chairman of Deinove, a biotech company that develops compounds for industry from rare microorganisms, and Abivax, an innovative biotech firm that targets the immune system to eliminate viral and inflammatory diseases. Dr. Pouletty is also founder of Carbios, a green chemical company developing innovative enzyme processes to reshape the lifecycle of plastics, co-founder and Board member of Pharnext, a leading biopharma company in combinatorial medicine, and Vexim, an innovative medical devices company, Chairman of Diaccurate, a biotech company specializing in immunomodulation, and Board member at Myopowers, Biokinesis, Kephalios and all other companies in the Truffle Capital portfolio.

Dr. Pouletty graduated as a doctor of medicine from the University of Paris VI and holds master's degrees in immunology and virology from Institut Pasteur. He is also a post-doctoral research fellow at Stanford University, the 1999 laureate of the American Liver Foundation and Chevalier de la Légion d'Honneur. Dr. Pouletty is the former Chairman and Honorary Chairman of France Biotech, the French biotech industry association, former Vice Chairman of Europabio and the author of 29 patents.

#### **HENRI LACHMANN**

Henri Lachmann began his career in 1963 as an auditor at Arthur Andersen. Seven years later, he joined French metal company Strafor-Facom and became the company's CEO in 1981. He has been a member of the Board at Schneider Electric since 1996 and became the company's CEO in 1999. He also held the position of Chairman of the Supervisory Board from 2006.

Mr. Lachmann graduated from HEC business school and is a qualified chartered accountant.

He is director and Vice-President of the Saint Joseph hospital/Marie Lannelongue hospital foundation.

#### **PIERRE BASTID**

Former manager at Schneider Electric then Valeo, Pierre Bastid became Vice President of Thomson Television Components France (Thomson Multimedia Group) in 1998. In 2004, via the Magenta Participations structure, he successfully participated in the acquisition of Alstom Power

Conversion, a group that later became Converteam Group, sold to General Electric in 2011.

Since that date, Pierre Bastid has managed his assets resulting from the sale of his shares of Converteam.

#### **DR. ANTONINO LIGRESTI**



Dr. Antonino Ligresti began his career in the Medical Clinic at Milan University and at the city's Fatebenefratelli Hospital. In 1979, following the gradual acquisition of several high-profile establishments in Lombardy, he created Italy's first private hospital group, acknowledged for the quality of its services and patient-centric care, as well as its ties with teaching and academic research. Dr. Ligresti joined the Générale de Santé Board of Directors in 2003 and became its Chairman a year later. He was also instrumental in creating the European Oncology Institute.

Dr. Ligresti is a qualified physician and surgeon, specializing in cardiology and internal medicine.

#### **JEAN-LUC LEMERCIER**



Jean-Luc Lemercier draws on more than 30 years' experience and acknowledged leadership in medical devices. During his career, he has held a number of key positions in the field of cardiology, notably at Johnson & Johnson Cordis from 1996 to 2008, where he created and headed the Structural Heart Disease division. Since 2017, he has been Corporate Vice President EMEA, Canada & Latin America at Edwards Lifescience.

Mr. Lemercier graduated in pharmacy from Claude Bernard Lyon 1 University.

#### **DR. MICHAEL MACK**



Michael Mack is an internationally renowned heart surgeon with extensive experience in the introduction of medical devices and innovative procedures for cardiovascular disease. He has authored more than 650 scientific publications and has received the Presidential Citation from the American College of Cardiology (ACC) and the Transcatheter Cardiovascular Therapeutics (TCT) Lifetime Achievement Award.

Dr. Mack is a graduate of Boston College, St Louis University and the University of Texas Southwestern Medical School. He is also the Director of the Cardiovascular Department for pharmaceutical firm Baylor Scott & White Health, a director on the American Board of Thoracic Surgery and a member of the FDA Medical Device Epidemiology Network Initiative (MDEpiNet) Advisory Committee.

#### **CORPORATE GOVERNANCE**

#### STEPHANE PIAT



Stéphane Piat is an acknowledged specialist in the medical device business, particularly in the field of cardiology. He joined CARMAT as Chief Executive Officer in September 2016.

Mr. Piat started his career at Becton Dickinson European Headquarters as a Market Researcher in 1995. He was appointed European Platform Leader for Locoregional Anaesthesia five years later. In 2002, he joined Cordis, a Johnson & Johnson company, where he spent five years in several management positions ranging from Business Director France to European Marketing Director for

Cardiology. In 2007, he moved to Abbott Vascular as General Manager for mid-size countries, EMEA, and two years later oversaw the integration of Evalve as the company's General Manager EMEA, heading clinical and commercial development of a new interventional cardiology product, Mitraclip. In 2014, he led Global Market Development of the Abbott Vascular Structural Heart Division in San Francisco as Division Vice President.

Mr. Piat holds a master's degree in Management Science from IAE Dijon School of Management, and a post-graduate degree in Quantitative Marketing from ESA business school in Grenoble.

### 4.1.3 MEMBERS OF THE MANAGEMENT TEAM

#### **STEPHANE PIAT**

See above.

#### **DR. PIET JANSEN**



Dr. Petrus "Piet" Jansen has 20 years' management experience in the circulatory support device industry. He began his career in 1997 as Director of Clinical Research for the Novacor Division of Edwards Lifesciences, a US company specializing in patient-focused medical innovations for structural heart disease.

In 2001, he was appointed Vice President at Jarvik Heart Inc in New York, where he was responsible for the clinical programs. From 2004 to 2009, he was Chief Medical Officer with World Heart Corporation.

Dr. Jansen holds a PhD in medicine from the University of Amsterdam and graduated as medical doctor from Radboud University Nijmegen, both in the Netherlands.

#### ÉRIC RICHEZ



Eric Richez joined CARMAT in September 2014 after a career in the European medical device industry.

He has over 13 years' experience in sales & marketing with Thoratec, a global leader in ventricular assistance devices, where he served as Sales & Marketing Director from 2002 to 2011 and Sales Director EMEA from 2011 to 2013. He then joined CircuLite, a company developing a circulatory support system to treat chronic heart failure, as Sales Director for Southern Europe.

Mr. Richez holds a degree in Mathematics and training in Business & Management and Sales Force Management.

#### **PASCALE D'ARBONNEAU**



A graduate of the ESCP business school and holder of a DEA in Management Control and a Postgraduate Diploma in Finance and Accounting, Pascale d'Arbonneau is also a lecturer at Paris Diderot University.

She began her career in 1989 as an auditor at Coopers & Lybrand (now PwC) before entering the pharmaceutical industry as Head of Finance & IT France at Johnson & Johnson – MSD (1995-1999). She spent most of her career (1999-2016) at GlaxoSmithKline (GSK). She joined as Director, Head of Controlling & Finance Partnering, and then held a number of senior positions within the Group (Vice President & Finance Controller, Pharma Europe from 2006 to 2010, Vice President & Area Finance Director, Western Europe from 2010 to 2014) before becoming Vice President Compliance and Control Integration for all business units worldwide. Before joining CARMAT at the end of 2018, Pascale d'Arbonneau was Executive Director of the Econocom International B.V. family office.

#### **MARC GRIMME**



Since 1996, Marc Grimmé has been the technical lead on the program to develop the CARMAT bioprosthetic heart. He began his career in 1991 at MBDA France, where he worked on a range of issues linked to the development of mission-critical electronics, from upstream studies and the design phase to production commissioning.

Marc Grimmé is a graduate of the Institute Supérieur d'Electronique et du Numérique (ISEN).

#### **THIERRY DUPOUX**



Thierry Dupoux is a seasoned medical device professional with a strong and large expertise in Quality Assurance/ Regulatory Affairs and R&D. An engineering graduate from

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Ecole Centrale de Lyon (France), he has worked most of his career in Life Sciences companies such as General Electric, where he became Supply Chain Quality & Compliance Manager for the plant in Buc (France) in his last position. In 2006, he joined Sorin Group, now LivaNova, a world leader in Heart Surgery and Neuromodulation. In 12 years at LivaNova, he held several senior positions in Quality Assurance, Regulatory Affairs and R&D. Prior to joining CARMAT, he was Vice President of Quality Assurance at LivaNova where he led the integration of the Quality Systems following the merger between Sorin Group and Cyberonics. He joined CARMAT in July 2018 as Director of Quality.

#### **ALEXANDRE ELEONORE**



Alexandre Eleonore is a confirmed industry expert with a strong background in operational management. He graduated from the Sevenans Polytechnic Institute, now UTBM (Université de Technologie Belfort-Montbéliard), and spent the first part of his career in leading automotive equipment manufacturers such as Faurecia and Plastic Omnium. After ten years in this sector, he joined the Sorin group in 2009, which became Microport CRM, one of the world's leading players in the treatment of cardiac rhythm disorders. He became Vice President Operations & Customer Service and implemented cost improvement plans, thanks to his knowledge of lean manufacturing and industrial process automation. He joined CARMAT as Director of Manufacturing in November 2019.

#### **FRANCESCO ARECCHI**



A marketing professional with strong experience in leading global companies within the healthcare industry, Francesco Arecchi joined CARMAT in September 2017. Francesco Arecchi spent most of his career in Life Sciences companies such as Johnson & Johnson and Abbott, where he held a number of positions from sales to marketing in cardiology breakthrough technology products such as Cypher and MitraClip.

Prior to joining CARMAT, he served as Product Manager EMEA Structural Heart at Abbott. Francesco Arecchi is a biomedical engineer and a graduate of Politecnico di Milano (Italy) with an MBA from Rotterdam School of Management (Netherlands).

#### **RAOUIA BOUYANZER**



Raouia has almost 16 years of experience in payroll and human resources management. She began her career in an accounting firm in 1998. In 2001, Raouia joined Morgan Stanley, where she served for more than nine years in several positions in social management control, payroll and human resources. Raouia joined CARMAT at the 'development' stage of the Company in February 2011 as an Administrative and Financial Manager, and implemented a human resources policy in 2012.

Raouia holds a master's degree in HR from ESSEC Business School and holds a degree in accounting and finance (2001).

# CONFLICTS OF INTEREST IN THE GOVERNING, MANAGEMENT AND SUPERVISORY BODIES AND EXECUTIVE MANAGEMENT

### 4.2.1 POTENTIAL CONFLICTS OF INTEREST

At the date of this Universal Registration Document and as far as the Company is aware, there are no current or potential conflicts of interest between the private interests of the Company's Board of Directors and the interests of the Company.

Similarly, as at the same date, the Company has no knowledge of any current or potential conflicts of interest between the private interests of the members of the Audit Committee, the Compensation Committee or the Scientific Committee and the interests of the Company.

As far as the Company is aware, there are no current or potential conflicts of interest between the duties of the members of the Board of Directors toward the Company and their private interests and/or other duties.

As at the date of this Universal Registration Document, there were no service contracts linking the members of the Board of Directors and Executive Management of the Company, nor any business relationship binding the independent directors and the Company. All related-party agreements are disclosed in section 5.6.1.



# 4.2.2 COMMITMENTS OF THE DIRECTORS AND EXECUTIVE MANAGEMENT TO PRESERVE SHAREHOLDINGS

No commitment to preserve shareholdings by directors or Executive Management was in force on December 31,

2019, with the exception of the obligation for the CEO, Stéphane Piat, to hold, in registered form, a certain percentage of ordinary shares which have resulted or which will result, where applicable, from the conversion of the preference shares granted without consideration in 2017, 2018 and 2019 (see section 4.5.1 of this document).

## 4.3 BOARD COMMITTEES

As at the date of this Universal Registration Document, the Company had set up the committees presented below.

### 4.3.1 AUDIT COMMITTEE

By decision of the Board of Directors of July 8, 2009 the Company set up an Audit Committee for an unlimited duration.

Under the exclusive and collective responsibility of the members of the Board of Directors of the Company and in order to ensure the quality of internal control and the reliability of the information provided to shareholders and financial markets, the Committee oversees matters relating to the preparation and control of accounting and financial information and, to this end, shall in particular:

- follow-up on the process of developing information and financial communication;
- monitor the effectiveness of the internal control and risk management systems and in particular:
  - evaluate the internal control procedures and any measures taken to remedy any significant internal control dysfunctions;
  - review the annual work programs of the auditors;
  - evaluate the adequacy of the risk monitoring procedure;
- monitor the statutory audit of the annual and consolidated financial statements by the auditors and in particular:
  - review the assumptions used for the preparation of the annual financial statements of the Company and the half-yearly and, where applicable, quarterly financial statements before their examination by the Board of Directors, after reviewing the financial position, cash position and commitments of the Company;

- evaluate, in consultation with the auditors, the appropriateness of the choice of accounting principles and methods;
- consult the members of the Board responsible for the financial aspects as well as the administrative and financial director if he is not a member of the Board, between the end of any financial year and the date on which the Committee decides on the draft annual financial statements, with regard to the adequacy of the accounting principles and methods used, the effectiveness of the accounting control procedures and any other appropriate matters;
- issue a recommendation on the auditors proposed for appointment by the Shareholders' Meeting and review their fees;
- monitor the independence of the auditors and in particular:
  - propose the establishment of rules for recourse to auditors for work other than auditing in order to guarantee the independence of the audit services provided by auditors in accordance with the laws, regulations and recommendations applicable to the Company, and verify proper application;
  - authorize the use of auditors for work other than auditing;
  - examine the conditions of use of derivatives;
  - execute periodic reviews of the status of significant litigation;
- · review the Company's procedures for the receipt,

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retention and treatment of claims relating to accounting matters and accounting internal controls, audit matters and documents transmitted by employees on a anonymous and confidential basis and which would call into question accounting or auditing practices; and

 generally, provide advice and make any appropriate recommendations in the above areas.

During the 2019 financial year, the Audit Committee met

twice, in particular to review the 2018 financial statements, to analyze CARMAT's cash needs and financing options, and to review the financial statements relating to the first half of 2019.

As at the date of this Universal Registration Document, the Audit Committee comprises Henri Lachmann, independent director and Chairman of the Audit Committee.

### 4.3.2 APPOINTMENTS & COMPENSATION COMMITTEE

The Company has also established an Appointments & Compensation Committee which as at the date of this Universal Registration Document is comprised of four members, including two independent members, appointed by the Board of Directors for an unlimited term:

- Truffle Capital, represented by Dr. Philippe Pouletty, director and Chairman of the Appointments & Compensation Committee;
- Matra Defense, represented by Karl Hennessee, director and member of the Appointments & Compensation Committee;
- Jean-Luc Lemercier, independent director;
- Santé Holdings SRL, represented by Antonino Ligresti, independant director.

The main objectives of the Appointments & Compensation Committee are to:

- recommend to the Board of Directors the persons who should be appointed to Executive Management, the Board of Directors and the main functions of the Company, as the case may be;
- review the compensation policies for executives and high-potential staff within CARMAT, propose the compensation of executives and, where applicable, the members of the Board of Directors and prepare any report that the Company must present on these subjects.

It reports to the Board of Directors on its activities at regular intervals.

### 4.3.3 BOARD OBSERVERS

Article 17-VI of the Articles of Association gives the Ordinary Shareholders' Meeting the power to appoint, at its discretion, up to three persons or legal entities, who may or may not be shareholders, for a term of office of one year expiring at the Shareholders' Meeting called to decide on the financial statements for the year just ended and held during the year in which their terms of office expire. This term of office may be renewed an unlimited number of times. The duty of the observers (censeurs) is to ensure the strict application of the Articles of Association and to present their observations at the meetings of the Board of

Directors. The observers perform a general and permanent role of advice and monitoring within the Company. In connection with their role they may make observations to the Board of Directors.

Observers must be invited to each meeting of the Board of Directors in the same way as directors. Observers have only consultative powers on an individual or joint basis and have no voting rights on the Board.

As at the date of this Universal Registration Document, no observer has been appointed.

# 4.4 STATEMENT ON CORPORATE GOVERNANCE

### 4.4.1 CORPORATE GOVERNANCI

The Company refers to the recommendations of the AFEP-MEDEF Corporate Governance Code for listed companies, to the extent that these principles are compatible with the organization, the size, the resources and the ownership structure of the Company.

To this end, the Company regularly proceeds with a review of its corporate governance in respect of the

recommendations of the AFEP-MEDEF Code, updated in June 2018\*. The principal recommendations not applied are presented below.

\* The Company has not yet taken into account the modifications made to the AFEP-MEDEF Code in January 2020.

Exclusions	Reasons
Assessment of the Board	There is no formal system to measure the individual contribution of each director.
of Directors	Reason: All Board members gave positive feedback on the Board's operation as a collective body, which is only possible if individual contributions are satisfactory.
- ( (C) ( ) ( )	The Company's Articles of Association provide for terms of office of the directors of six years, whereas the AFEP-MEDEF recommends a limit of four years.
Term of office of directors	Reason: When the Company was established, it was deemed that a longer term would ensure the stability of the Company's governance.
	The Appointments & Compensation Committee does not comprise two-thirds independent directors.
Composition of the Appointments & Compensation Committee	Reason: In each of the 2018 and 2019 financial years, an independent director was added to the committee, so that independent directors now represent 50% of the committee. The Company intends to continue increasing this proportion in the future.
Evaluation of the work of the Board of Directors and	Within the Board of Directors, a debate on its functioning and that of the committees is not systematically carried out every year.
committees	Reason: Special attention will be given to this point in the coming years.
Desirable balance in Board composition in terms of diversity (representation of women and men, nationalities, etc.)	The Company, which is not bound by the diversity obligations provided for by the French Commercial Code as its shares are not listed on a regulated market, intends in the long term to further diversify the composition of its Board, particularly in terms of female representation.
Conclusion of a non-compete agreement with executive corporate officers	To the extent that the contracts concluded between the Company and its employees do not include non-compete clauses, the Company wished to align the condition of executive corporate officers with that of its employees. The Company therefore does not benefit from the protection of this type of clause, even if it also intends to maintain and develop a retention policy by allocating securities giving access to capital to its executive corporate officers.

#### **CORPORATE GOVERNANCE**

In addition to setting up the Audit Committee and the Appointments & Compensation Committee, and in order to meet the standards of corporate governance that the Company has set itself, the elements described below have been put in place.

### 4.4.2 INTERNAL RULES OF THE BOARD OF DIRECTORS

In 2011, the Board of Directors adopted internal rules, the purpose of which is to define the ways in which it is organized and operates over and above the legal and statutory provisions in force. These internal rules were reviewed in 2016. They are available on request from the registered office of the Company.

In addition to respecting the legal, regulatory and statutory provisions applicable to the Board, the Board of Directors:

 determines the Company's business strategy and ensures its implementation. Subject to the powers expressly granted by Shareholders' Meetings and within the scope of the Company's purpose, the Board shall consider any matter affecting the proper functioning of the Company and shall, by its deliberations, resolve matters affecting it;

- appoints the Chairman of the Board, the Chief Executive Officer and the Deputy Chief Executive Officers, determines their duties and compensation;
- authorizes the agreements and commitments referred to in Articles L.225-38 et seq. of the French Commercial Code;
- authorizes the decisions and commitments listed in the Appendix to the internal rules. The Board ensures the quality of information provided to shareholders and the markets.

### 4.4.3 WORK OF THE BOARD OF DIRECTORS

During the 2019 financial year, the Board of Directors met six times.

In addition to its traditional governance missions, including the approval of the 2018 financial statements and those of the first half of 2019, the Board focused in particular on:

- steering and monitoring of the artificial heart development project;
- · the Company's strategic plan;

- the financial forecasts and the financing strategy of the Company;
- the commercial launch plan for the artificial heart;
- the long-term-incentives policy for the management of the Company and its employees.

Board meetings are subject to an annual provisional calendar defined at the latest in January of each year. Each meeting is prepared in advance by the Chairman and the Chief Executive Officer.

The table below summarizes the effective presence of the directors at the various Board meetings.

Effective presence at Board meetings (2019)	Number of meet- ings applicable	Effective pres- ence at meetings
Jean-Pierre Garnier - Chairman of the Board	6	6
Stéphane Piat - Chef Executive Officer and Director	6	6
Professor Alain Carpentier - Director	1	1
Truffle Capital - Director	6	6
Airbus Group - Director	6	3
Henri Lachmann - Director	6	6
Pierre Bastid - Director	6	6
Santé Holdings SRL - Director	6	5
Jean-Luc Lemercier - Director	6	6
Michael Mack - Director	6	5

# 4.4.4 SEPARATION OF THE OFFICES OF CHAIRMAN OF THE BOARD OF DIRECTOIRS AND CHIEF EXECUTIVE OFFICER

When the Company converted to a société anonyme, the Board of Directors opted for a separation of the offices of Chairman of the Board of Directors and of Chief Executive Officer.

The Board of Directors must approve in advance the following decisions and commitments, it being specified that the thresholds mentioned below in these decisions will be assessed (i) individually for each operation and (ii) annually:

- A. Corporate life of the Company:
- (a) any amendment to the articles or other documents constituting the Company or its subsidiaries;
- (b) liquidation, amicable dissolution or other similar proceedings relating to the Company and/or the companies or entities controlled by the Company (the "Subsidiaries") and withdrawal from the Company.
- B. Strategic decisions:
- (a) definition of strategic, economic, social, financial and scientific priorities for the Company;
- (b) operations outside the strategy announced by the Company;
- (c) significant development of related or derivative activities, directly within the Company, or through subsidiaries controlled or not;
- (d) the change in the normal business of the Company and its development strategy;
- (e) any significant agreement to use patents or production licenses granted to third parties outside the ordinary course of business;
- (f) any transfer, acquisition, contribution or exchange of assets of a unit amount exceeding three hundred thousand euros (€300,000);
- (g) any investment in excess of three hundred thousand euros (€300,000);
- (h) mergers, spin-offs, contributions, partnerships, joint ventures or similar significant transactions;
- (i) transfer and relocation of the Company's registered

office outside France, cross-border mergers or conversion of the Company into a European company;

- (j) additional indebtedness, modification, refinancing of a loan amounting to more than three hundred thousand euros (€300,000);
- (k) significant change in the accounting rules and principles applied by the Company;
- (I) hiring, dismissal and alteration of employment contracts (including the compensation) of any employee who has an executive function (i.e., medical director, director of operations, sales manager and administrative director and financial director);
- (m) selection of advisers and intermediaries in strategic decision-making and compensation.
- C. Related-party agreements (approval and annual review of contracts in progress).
- D. Securities:
- (a) issue of any securities giving access, immediately or in the future, to 5% or more of the share capital of the Company;
- (b) transfer of securities of subsidiaries to third parties or subscription or acquisition of securities issued by an entity other than a subsidiary.
- E. Any proposal to the Shareholders' Meeting relating to the policy of dividend distribution, redemption of shares or other payments or distribution to shareholders.
- F. Adoption and modification of the annual budget, approval and modification of the business plan.
- G. Any commitment exceeding three hundred thousand euros (€300,000).
- H. Compensation and profit-sharing of executives in respect of their office or employment contract (including any stock option plans, performance shares or other similar arrangements) on the proposal of the Appointments & Compensation Committee.
- I. Appointment and dismissal of executive corporate officers, the administrative and financial director, the scientific director and the medical director.
- J. Decision regarding commitments or transactions relating to a dispute of more than two hundred and fifty thousand euros (€250,000).

#### CORPORATE GOVERNANCE

- K. Site closure; adoption of a plan to safeguard employment.
- L. Appointment of Statutory Auditors and alternates.
- M. Subscription of any loan or advance to acquire securities of any subsidiary company except in the event that such subsidiary is wholly or partly owned by the Company.
- N. Granting of guarantees, deposits of endorsements for the benefit of third parties (including a subsidiary) or granting of security rights to guarantee debts of the Company.

It is specified that:

- one of the aforementioned decisions foreseen within the annual budget in a precise manner shall not have to be approved again when implemented; and
- decisions A to E shall be adopted by a majority of (i) half of the directors on first call and (ii) half of the directors present or represented on second call.

For a detailed description of the provisions governing the functioning of the Board of Directors and Executive Management, see section 5.4.2 "Provisions of the Articles of Association, charter or bylaws of the Company concerning the members of the Board of Directors and Executive Management".

### 4.4.5 INDEPENDENT DIRECTORS

The Company has five independent directors: Henri Lachmann, Jean-Luc Lemercier, Michael Mack and Pierre Bastid, and the company Santé Holdings SRL; the Company believes that since their appointment they have met the criteria of the AFEP-MEDEF Code of December 2008 (as amended in June 2018), that is:

- not be or have been in the past five years:
  - employee or corporate officer of the Company (the Chairman of the Board may be considered as independent if the Company justifies it) or of a group company;
  - corporate officer of another company in which the Company directly or indirectly holds an office or in which an employee or a corporate officer of the Company (currently or for less than five years) holds an office;

- not be (directly or indirectly) a significant customer, supplier or banker of the Company or its group or for which the Company or its group represents a significant part of the business;
- have no close family ties with a corporate officer;
- have not been an auditor of the Company during the last five years;
- have not been a member of the Board of the Company for more than 12 years;
- not to be a lead shareholder of the Company or of its parent company exercising control or having a controlling interest in the Company (beyond a 10% holding, the Board must consider the independence with regard to the composition of the capital and the existence of potential conflicts of interest).

### 4.4.6 INTERNAL CONTROL

At the date of this Universal Registration Document, the Company had internal control procedures, in particular in the administrative, accounting, and financial areas, so as to meet its strategic objectives.

In accordance with Regulation No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (the so-called MAR Regulation), CARMAT must also, like companies listed on a regulated market, establish and maintain the list of persons who have access to inside information concerning it.

CARMAT has put in place a Code of Ethics in order to raise awareness of this topic among all the Company's executives and employees, third parties with access to inside information and persons with whom they are in relation, and to prevent any improper use or disclosure of inside information.

The Board of Directors of 12 December 2016 adopted this Code of Ethics, which had been reviewed by the Audit Committee.

# 4.5 COMPENSATION AND BENEFITS OF EXECU-

# 4.5.1 COMPENSATION AND BENEFITS IN KIND OF EXECUTIVES AND DIRECTORS

Table 1: Summary table of compensation and options, warrants and free shares awarded to each executive corporate officer (in euros)

As a reminder, CARMAT announced on December 3, 2018 the cooptation of Jean-Pierre Garnier to the Board of Directors of the Company to replace Jean-Claude Cadudal, Chairman of the Board of Directors who had resigned, for the remainder of his term of office, and his appointment as new Chairman of the Board. The appointment of Jean-Pierre Garnier was ratified by the Shareholders' Meeting of March 28, 2019.

Jean-Claude Cadudal - Chairman of the Board of Directors (until December 3, 2018)	2018	2019
Compensation payable for the year (detailed in table 2)	62,551	-
Value of long-term variable compensation awarded during the year	-	-
Value of options and warrants awarded during the year (detailed in table 4)	-	-
Value of free shares awarded for the year (detailed in table 6)	-	-
TOTAL	62,551	-

Jean-Pierre Garnier - Chairman of the Board of Directors (since December 3, 2018)	2018	2019
Compensation payable for the year (detailed in table 2)	8,333	100,000
Value of long-term variable compensation awarded during the year	-	-
Value of options and warrants awarded during the year (detailed in table 4)	144,900*	0**
Value of free shares awarded for the year (detailed in table 6)	-	-
TOTAL	153,233	100,000

<sup>\* 46,000</sup> stock options awarded in December 2018, subject to conditions, with an exercise price of €20.35. Taking into account the price of the CARMAT share at December 31, 2018, i.e., €23.50, the potential capital gain relating to these stock options was €144,900 at December 31, 2018.

<sup>\*\* 46,000</sup> stock options awarded in April 2019, subject to conditions, with an exercise price of €22.70. Taking into account the price of the CARMAT share at December 31, 2019, i.e., €19.28, the potential capital gain relating to these stock options was zero at December 31, 2019.

Stéphane Piat - Chief Executive Officer	2018	2019
Compensation payable for the year (detailed in table 2)*	599,298	621,805
Value of long-term variable compensation awarded during the year	-	-
Value of options and warrants awarded during the year (detailed in table 4)	-	-
Value of free shares awarded for the year (detailed in table 6)**	3,598,438	1,083,343
TOTAL	4,197,736	1,705,148

<sup>\*</sup> Benefits in kind included. Stéphane Piat did not benefit from any increase in his fixed compensation in 2019. He benefits from variable compensation (based on objectives approved by the Board of Directors), the maximum % of which was increased in 2019 from 45% to 50%. The % achievement rate of objectives for 2019 has been set at 98% by the Compensation Committee.

Table 2: Summary table of the compensation of each executive corporate officer (in euros)

Jean-Claude Cadudal - Chairman of the Board of Directors (until December 3, 2018)	2018		2019	
	Amounts due*	Amounts paid**	Amounts due*	Amounts paid**
Fixed compensation	-	-	-	-
Variable compensation	-	-	-	-
Special compensation	-	-	-	-
Directors' fees	62,551***	62,551***	-	-
Benefits in kind	-	-	-	-
TOTAL	62,551	62,551	-	-

<sup>\*\*\*</sup> At the meeting of December 19, 2013, the Board decided that, to comply with the applicable regulations, the compensation of its Chairman would be treated for tax and social security purposes as a salary. This amount was raised to €62,551 in 2018.

land Diama Camaian Chairman af the Daniel of	2018		2019	
Jean-Pierre Garnier - Chairman of the Board of Directors (since December 3, 2018)	Amounts due*	Amounts paid**	Amounts due*	Amounts paid**
Fixed compensation***	8,333	0	100,000	53,653
Variable compensation***	-	-	-	-
Special compensation	-	-	-	-
Directors' fees	-	-	-	-
Benefits in kind	-	-	-	-
TOTAL	8,333	0	100,000	53,653

<sup>\*\*</sup> The free shares awarded in 2018 and 2019 are subject to performance conditions. Their values at December 31, 2018 and December 31, 2019 correspond to the estimate made by the Company of the probability of achievement of the criteria. At least 10% of the number of ordinary shares resulting from the conversion of the preference shares granted without consideration to Stéphane Piat must be held in registered form until the termination of his office as a corporate officer of the Company. To the best of the Company's knowledge, no hedging instrument has been put in place.

<sup>\*\*\*</sup> Under an employment contract as US Business Development Manager. Jean-Pierre Garnier receives fixed compensation but no variable compensation or any other benefits. He did not benefit from any increase in his compensation in 2019.



	2018		2019	
Stéphane Piat - Chief Executive Officer	Amounts due*	Amounts paid**	Amounts due*	Amounts paid**
Fixed compensation***	408,744	408,744	411,743	411,743
Variable compensation***	185,284	160,912	202,269	176,946
Special compensation	-	-	-	-
Directors' fees	-	-	-	-
Benefits in kind	5,270	5,270	7,793	7,793
TOTAL	599,298	574,926	621,805	596,482

<u>Table 3: Directors' fees and other compensation allocated to non-executive corporate officers</u>

	2018	2019
Professor Alain Carpentier - Director until March 28, 2019		
Directors' fees	6,000	1,500
Other compensation	-	-
Truffle Capital - Director		
Directors' fees	7,500	7,500
Other compensation	-	-
Airbus Group - Director*		
Directors' fees	7,500	4,500
Other compensation	-	-
Henri Lachmann - Director		
Directors' fees	7,500	7,500
Other compensation	-	-
Pierre Bastid - Director		
Directors' fees	6,000	7,500
Other compensation	-	-
Santé Holdings SRL - Director		
Directors' fees	7,500	6,000
Other compensation	-	-

<sup>\*</sup> Karl Hennessee replaced Anne-Pascale Guédon as permanent representative of Airbus Group on the CARMAT Board of Directors on June 6, 2019.

<sup>\*\*\*</sup> Stéphane Piat did not benefit from any increase in his fixed compensation in 2019. He benefits from variable compensation (based on objectives approved by the Board of Directors), the maximum % of which was increased in 2019 from 45% to 50%. The % achievement rate of objectives for 2019 has been set at 98% by the Compensation Committee.



Table 3 (cont.)	2018	2019
Jean-Luc Lemercier - Director		
Directors' fees	10,000	12,500
Other compensation	-	-
Michael Mack - Director		
Directors' fees	28,390	22,839
Other compensation	-	-

Table 4: Stock options awarded to each executive corporate officer during the year ended December 31, 2019

Below is a summary of the option plans awarded to Jean-Pierre Garnier during the 2019 financial year.

Plan # and date	Type of options	Value of options	Number of options awarded during the year	Exercise price	Exercise period	Exercise conditions
2019 Stock Option Plan April 1, 2019	Stock subscrip- tion options	Note 1	46,000	€22.70	Until March 31, 2029	Note 2

Note 1: 46,000 stock options awarded in April 2019, with an exercise price of €22.70. Taking into account the price of the CARMAT share at December 31, 2019, i.e., €19.28, the potential capital gain relating to these stock options was zero at December 31, 2019. Note 2: The options can be exercised in tranches of 1/36 each month as from January 1, 2019, and in any event no later than ten years after their date of award to the beneficiary.

<u>Table 5: Stock options exercised by each executive corporate officer during 2019</u>

Below is a summary of the options exercised by Jean-Claude Cadudal during the 2019 fiscal year, it being recalled that he was Chairman of the Board and Director of CARMAT until December 3, 2018.

Plan # and date	Exercise year of the options	Number of options exercised*	Exercise price**
BSA 2009-1 July 8, 2009	2019	904	€8.00

<sup>\*</sup> Each BSA share warrant gives right to 25 new CARMAT shares.

<sup>\*\*</sup> Price per new share subscribed.

#### **CORPORATE GOVERNANCE**

<u>Table 6: Free shares awarded to each corporate officer during 2019</u>

Free shares awarded to each corporate officer by the issuer	Plan # and date	Class and number of AGAP free preference shares awarded	num- Pfree shares d	Maximum num- ber of ordi- nary shares to which the AGAP awarded give right	Value of shares*	Date of award	Vesting date	Exercise	Perfor- mance condi- tions
Stéphane Piat Chief Executive Officer	2019 AGAP plan								
	5	of which AGAP 2019-01	2,640	26,400	€254,496				
		of which AGAP 2019-02	2,640	26,400	€305,395	April 1, 2019	April 1, 2020	From April 1, 2022 to June	See section 5.2.5
		of which AGAP 2019-03	1,320	13,200	£127,248			30, 2021	
Stéphane Piat	2019 AGAP Plan								
Chief Executive Officer	Sept. 23, 2019								
		of which AGAP 2019-01	1,800	18,000	£173,520				
		of which AGAP 2019-02	1,800	18,000	€208,224	Sept. 23, 2019	Sept. 23, 2020	23, 2022 to	See section 5.2.5
		of which AGAP 2019-03	150	1,500	€14,460			001. 31, 2027	
TOTAL			10,350	103,500	€1,083,343				

£19.28) and to the estimate made by the Company of the probability of achievement of the criteria. At least 10% of the number of ordinary shares resulting from the conversion of the probability of achievement of the criteria. At least 10% of the termination of his office as a corporate officer of the Company. To the best preference shares granted without consideration to Stéphane Piat must be held in registered form until the termination of his office as a corporate officer of the Company. To the best \* The free shares awarded during the financial year are subject to performance conditions. Their values at December 31, 2019 correspond to the CARMAT share price on this date (i.e., of the Company's knowledge, no hedging instrument has been put in place.



<u>Table 7: Free shares awarded to each corporate officer</u> that vested during the year ended December 31, 2019

Corporate officer name	Plan # and date	Class and numb free preferenc vested	e shares	Maximum number of ordinary shares to which the AGAP vested give right**	Exercise conditions
Stéphane Piat Chief Executive Officer	2018 AGAP plan				
	April 16, 2018				
		AGAP 2018-01	500	50,000	See sections 5.2.5
		AGAP 2018-02	7,500	150,000	and 5.4.3
TOTAL			8,000	200,000	

<sup>\*</sup> AGAP preference shares that vested during the 2019 financial year. These AGAP will be convertible into ordinary shares during the exercise period depending on the achievement of performance criteria (see sections 5.2.5 and 5.4.3).

<u>Table 8: History of stock option awards (for executive and non-executive directors)</u>

Table 8 - Part 1	BCE-2009-1	BCE-2009-2	BCE-2012-1	BCE-2012-2	BSA-2009-1
Date of the Board meeting	Sept. 9, 2009	July 8, 2009	June 27, 2012	Nov. 8, 2012	July 8, 2009
Number of shares that can be subscribed or acquired	77,700	189,150	56,500	6,700	77,400
Number of which can be subscribed or					
acquired by corporate officers (executive and non-executive)	77,700	0	4,000	0	64,750
Jean-Luc Lemercier*					
Michael Mack*					
Jean-Pierre Garnier*					
Marcello Conviti**	77,700		4,000		
Jean-Claude Cadudal**					38,850
Michel Finance**					12,950
André Ballester**					12,950
Starting point for exercising options	Sept. 9, 2009	July 8, 2009	June 27, 2012	Nov. 8, 2012	July 8, 2009
Expiration date	Sept. 9, 2019	July 8, 2019	June 27, 2022	Nov. 8, 2022	July 8, 2019
Subscription or purchase price	€8.00	€8.00	€108.483	€122.003	€8.00
Exercise conditions (when the plan includes several tranches)	See note 3, on the next page	See section 5.2.5	See section 5.2.5	See section 5.2.5	See section 5.2.5
Number of shares subscribed as at Dec. 31, 2019	77,700	111,875	0	0	63,500
Cumulative number of options canceled or expired	0	3,091***	45,000	0	556***
Number of options outstanding at year-end	0	0	11,500	6,700	0

<sup>\*</sup> Corporate officer on the date of publication of this document. \*\* Former corporate officer of the Company.

<sup>\*\*</sup> Assuming 100% achievement of the performance criteria.

<sup>\*\*\*</sup> I.e., 77,275 ordinary shares after adjustment resulting from the capital increase with pre-emptive subscription rights performed in August 2011.

<sup>\*\*\*\*</sup> I.e., 13,900 ordinary shares after adjustment resulting from the capital increase with pre-emptive subscription rights performed in August 2011.



Table 8 - Part 2	BSA-2017 - Board Members	Stock options - 2018	Stock options - 2019
Date of the Board meeting	May 15, 2017	Dec. 3, 2018	April 1, 2019
Number of shares that can be subscribed or acquired	12,000	46,000	46,000
Number of which can be subscribed or acquired by corporate officers (executive and non-executive)	12,000	46,000	46,000
Jean-Luc Lemercier*	6,000		
Michael Mack*	6,000		
Jean-Pierre Garnier*		46,000	46,000
Marcello Conviti**			
Jean-Claude Cadudal**			
Michel Finance**			
André Ballester**			
Starting point for exercising options	May 15, 2017	Jan. 1, 2019	Jan. 1, 2019
Expiration date	May 15, 2027	Dec. 2, 2028	March 31, 2029
Subscription or purchase price	€30.10 (1)	€20.35 (2)	€22.70 (2)
Exercise conditions (when the plan includes	See section	See section	See section
several tranches)	5.2.5	5.2.5	5.2.5
Number of shares subscribed as at Dec. 31, 2019	0	0	0
Cumulative number of options canceled or expired	0	0	0
Number of options outstanding at year-end	12,000	46,000	46,000

<sup>\*</sup> Corporate officer on the date of publication of this document. \*\* Former corporate officer of the Company.

Note 1: Price corresponding to the average weighted volume of the share prices quoted over the 20 trading days preceding the date of the Board of Director's decision.

Note 2: Share price (closing price) on Euronext Growth on the day preceding the Board of Director's decision.

Note 3: Information relating to BCE-2009-1.

5% of the BCE-2009-1 warrants may be exercised on the date of the first anniversary of the beneficiary ning the Company, subject to his/her actual and continued presence in the Company at that date;
5% of BCE-2009-1 warrants may be exercised on the basis of monthly periods in tranches of 1/36 from e date of the first anniversary of the beneficiary joining the Company over a period of three years, bject to his/her actual and continued presence in the Company at that date.
rly exercise in the event of a share transfer agreement being entered into, with or without conditions ecedent, resulting in a change in control of the Company to the benefit of the transferee on the basis a valuation in excess of €100 million.
a result of the success of the initial listing of the Company on the Alternext market of Euronext Paris, cording to the assessment of the meeting of the Board of Directors of September 8, 2010, 20% of CE-2009-1 warrants that were not exercisable as at the date of the initial listing may be exercised early.
r E e k



<u>Table 9: Stock options granted to the top ten employees</u> who are not corporate officers, and options exercised by these grantees

Options granted to the top ten employ- ees who are not corporate officers, and options exercised by these beneficia- ries, including BSA, BSAR, BSPCE, etc.	Total number of options awarded/ shares subscribed or purchased	Weighted average subscription price for 1 new share	Of which BCE-2009-02
Options granted during the year by the issuer to the top ten employees having been granted the highest number of options (comprehensive information)	N/A	N/A	N/A
Options held on the issuer exercised during the year by the top ten employees having purchased or subscribed to the highest number of options (comprehensive information)	1,245*	€8.00	1,245*

<sup>\*</sup> One option gives right to 25 new shares, parity after adjustment following the capital increase with pre-emptive subscription right performed in August 2011.

<u>Table 10: History of free share awards (comprehensive information)</u>

2017 AGAP plans

2017 AGAP plans						
Class of AGAP	AGAP 2017-01	AGAP 2017-02	AGAP 2017-03	AGAP 2017-01	AGAP 2017-02	AGAP 2017-03
Date of the Board meeting		May 15, 2017			Sept. 25, 2017	
Total number of AGAP awarded without consideration	270	1,800	3,180	50	200	310
Of which number of AGAP awarded to corporate officer beneficiaries	180	1,000	1,720	0	0	0
Stéphane Piat - Chief Executive Officer and director	180	1,000	1,720	0	0	0
AGAP vesting date		May 15, 2018			Sept. 25, 2018	
Exercise period to convert into ordinary shares*	From May 15, 2020 to May 15, 2025 From Sept. 25, 2020 to Sept. 25				ot. 25, 2025	
End date of lock-up period		May 15, 2020			Sept. 25, 2020	
Number of shares (AGAP) vested as at Dec. 81, 2019	270	1,800	3,180	50	200	310
Cumulative number of shares (AGAP) expired or canceled (total)	0	0	0	0	0	0
Cumulative number of shares (AGAP) expired or canceled (corporate officers)	0	0	0	0	0	0
Number of shares (AGAP) outstanding as at Dec. 31, 2019	0	0	0	0	0	0

<sup>\*</sup> See section 5.2.5 for the conversion ratios into ordinary shares, and the associated performance conditions.



2018 AGAP plans

2018 AGAP plans									
Class of AGAP	AGAP 2018-01	AGAP 2018-02	AGAP 2018-03	AGAP 2018-01	AGAP 2018-02	AGAP 2018-03	AGAP 2018-01	AGAP 2018-02	AGAP 2018-03
Date of the Board meeting		April 16, 2018			Sept. 27, 2018			Feb. 11, 2019	
Total number of AGAP awarded without consideration	580	11,500	0	0	0	370	0	0	370
Of which number of AGAP awarded to corporate officer beneficiaries	580	7,500	0	0	0	0	0	0	0
Stéphane Piat - Chief Executive Officer and director	200	7,500	0	0	0	0	0	0	0
AGAP vesting date		April 16, 2019			Sept. 27, 2019			Feb. 11, 2020	
Exercise period to convert into ordinary shares*	From Apri	From April 16, 2021 to April 16, 2026	116, 2026	From Sept.	From Sept. 27, 2021 to Sept. 27, 2026	27, 2026	From Feb	From Feb. 11, 2022 to May 11, 2027	, 11, 2027
End date of lock-up period		April 16, 2021			Sept. 27, 2021			Feb. 11, 2022	
Number of shares (AGAP) vested as at Dec. 31, 2019	580	10,350	0	0	0	370	0	0	0
Cumulative number of shares (AGAP) expired or canceled (total)	0	200	0	0	0	0	0	0	0
Cumulative number of shares (AGAP) expired or canceled (corporate officers)	0	0	0	0	0	0	0	0	0
Number of shares (AGAP) outstanding as at Dec. 31, 2019	0	950	0	0	0	0	0	0	370

\* See section 5.2.5 for the conversion ratios into ordinary shares, and the associated performance conditions.



2019 AGAP plans

2019 AGAP plans									
Class of AGAP	AGAP 2019-01	AGAP 2019-02	AGAP 2019-03	AGAP 2019-01	AGAP 2019-02	AGAP 2019-03	AGAP 2019-01	AGAP 2019-02	AGAP 2019-03
Date of the Board meeting		April 1, 2019			Sept. 23, 2019			Dec. 2, 2019	
Total number of AGAP awarded without consideration	4,760	4,760	2,380	2,240	2,240	220	1,000	1,000	1,000
Of which number of AGAP awarded to corporate officer beneficiaries	2,640	2,640	1,320	1,800	1,800	150	0	0	0
Stéphane Piat - Chief Executive Officer and director	2,640	2,640	1,320	1,800	1,800	150	0	0	0
AGAP vesting date		April 1, 2020			Sept. 23, 2020			Dec. 2, 2020	
Exercise period to convert into ordinary shares*	From Apri	From April 1, 2022 to June 30, 2027	30, 2027	From Sept	From Sept. 23, 2022 to Oct. 31, 2027	. 31, 2027	From Dec	From Dec. 2, 2022 to Jan. 1, 2028	1, 2028
End date of lock-up period		April 1, 2022			Sept. 23, 2022			Dec. 2, 2022	
Number of shares (AGAP) vested as at Dec. 31, 2019	0	0	0	0	0	0	0	0	0
Cumulative number of shares (AGAP) expired or canceled (total)	120	120	09	0	0	0	0	0	0
Cumulative number of shares (AGAP) expired or canceled (corporate officers)	0	0	0	0	0	0	0	0	0
Number of shares (AGAP) outstanding as at Dec. 31, 2019	4,640	4,640	2,320	2,240	2,240	220	1,000	1,000	1,000

\* See section 5.2.5 for the conversion ratios into ordinary shares, and the associated performance conditions.



<u>Table 10 bis: Free share awards to the top ten employees</u> who are not corporate officers, and shares that vested to these beneficiaries

Free shares awarded to the top ten employees who are not corporate officers, and shares that vested to these beneficiaries	Total number of shares (AGAP) awarded/shares (AGAP) vested	of which AGAP 2019-01	of which AGAP- 2019-02	of which AGAP- 2019-03	of which AGAP- 2018-01	of which AGAP- 2018-02	of which AGAP- 2018-03
Free shares (AGAP)* awarded during the year by the issuer to the top ten employees having been granted the highest number of shares (compre- hensive information)	9,420	3,480	3,480	2,090			370
Free shares (AGAP)** on the issuer that vested during the year, for the top ten employees with the highest number of shares vested (comprehensive information)	3,975				80	3,525	370

<sup>\*</sup> See to sections 5.2.5 and 5.4.3 for the characteristics and performance conditions attached to the AGAP shares.

<u>Table 11: Clarifications regarding the terms of compensa-</u> <u>tion and other benefits awarded to executive corporate</u> <u>officers</u>

The directors and the Chief Executive Officer do not enjoy any particular retirement benefits, compensation for loss of office, or non-compete indemnities.

Executive corporate officer	<u>-</u>	yment :ract		ntary pen- plan	Allowance efits due o be due up office or o	or likely to on loss of change in		ompete nnities
	Yes	No	Yes	No	Yes	No	Yes	No
Jean-Pierre Garnier, Chairman of the Board	X*			Х		Х		Х
Start date of office								Dec. 3, 2018
End date of office			At the close	of the Annual S		Meeting held to a		
Stéphane Piat, Chief Executive Officer		Х		Х		Х		Х
Start date of office								Aug. 29, 2016
End date of office							In	definite period

<sup>\*</sup> Employment contract as US Business Development Manager since December 3, 2018. Jean-Pierre Garnier receives fixed compensation but no variable compensation or any other benefits. He did not benefit from any increase in his compensation in 2019.

<sup>\*\*</sup> AGAP preference shares that vested during the financial year. These AGAP will be convertible into ordinary shares during the exercise period depending on the achievement of performance criteria (see sections 5.2.5 and 5.4.3).

# 4.5.2 AMOUNTS PROVISIONED OR RECOGNIZED BY THE COMPANY FOR THE PAYMENT OF PENSIONS, RETIREMENT OR OTHER BENEFITS FOR EXECUTIVES AND DIRECTORS

The Company has not signed a specific agreement on retirement obligations. These are therefore limited to the agreed retirement lump-sum payment.

In application of the reference method (ANC 2018-01), a provision for retirement obligations has been booked as at December 31, 2019.

See note 3.2.2.6 to the financial statements.

The total amount of the provision for executives stood at €23,531 at the end of the 2019 reporting period.

# 4.5.3 SHARE WARRANTS (BSA), COMPANY FOUNDER SHARE WARRANTS (BCE) AND STOCK OPTIONS AWARDED TO DIRECTORS AND EXECUTIVES

The table below shows all share warrants (BSA), company founder share warrants (BCE) and stock options issued by the Company to its corporate officers and executives, subscribed to by the beneficiaries, and not expired or exercised as at December 31, 2019.

Holder/Number of shares*	BSA-2017 - Board members	Stock options - 2018	Stock options - 2019
Jean-Pierre Garnier Chairman of the Board of Directors since December 3, 2018	-	46,000	46,000
Jean-Luc Lemercier Director	6,000	-	-
Michael Mack Director	6,000	-	-

<sup>\*</sup> See section 5.2.5 for details of the conditions attached to these BSA share warrants and stock options.

### 4.5.4 STATEMENT ON SERVICE CONTRACTS

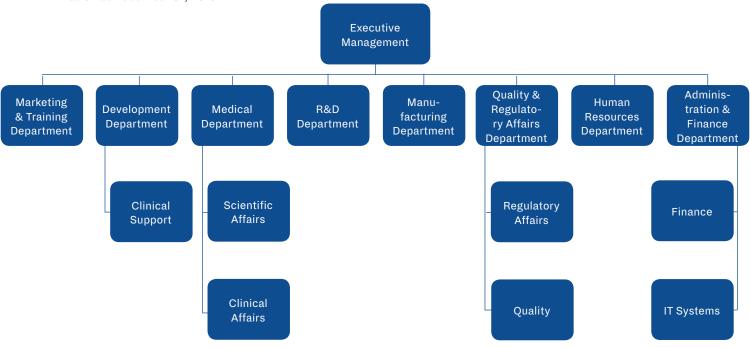
There are no service contracts binding the members of the Board of Directors or management of the Company and providing for the granting of benefits under such contracts, with the exception of those mentioned in section 5.6 "Related-party agreements and commitments".

### 4.6 EMPLOYEES AND ORGANIZATION

4.6.1 HUMAN RESOURCES

#### **FUNCTIONAL ORGANIZATIONAL CHART**

The chart below presents the Company's functional organization at December 31, 2019.



### NUMBER AND BREAKDOWN OF EMPLOYEES

At December 31, 2019, the Company's workforce amounted to 107 people, including four temporary workers; most members of staff are employed under permanent employment contracts.

The Company's workforce increased by 17 employees in 2019, including the hiring of a new Director of Manufacturing (Alexandre Eléonore).

For specific services within the framework of certain stages of the development of the bioprosthetic artificial heart project, the Company uses various external suppliers.

At December 31, 2019, there were 60 such suppliers, including approximately 20 in R&D and 15 in Production.

Headcount	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017
Managers	80	66	48
Non-management	23	21	15
Temporary	4	3	7
TOTAL	107	90	70

### **HUMAN RESOURCES POLICY**

Human resource management is of major importance to the Company. This is because the Company needs qualified employees with strong skill sets, as CARMAT's business relies in part on the expertise and effectiveness of its members of staff.

#### **CORPORATE GOVERNANCE**

The headcount at December 31, 2019 was made up of 39 women and 68 men. The average age of salaried employees was 40. In 2019, the Company financed approximately 1,100 hours of training.

The Company applies the following French National Collective Agreements: "Metallurgical Industries: workers, administrative employees, technicians and supervisors" and "Metallurgical Industries: engineers and managers". It also applies the French Regional Collective Agreement "Metallurgical Industries: workers, administrative employees, technicians and supervisors in the Paris Region". There are no company agreements other than the internal rules.

Standard employment contracts do not contain clauses relating to contract termination or to non-compete and non-solicitation (staff and/or customers) requirements.

All Company employees benefit, in addition to their basic salary, from a potential annual bonus subject to achieving quantitative and qualitative targets set in advance by their line managers. The amount of this bonus is limited to a percentage of the gross annual salary.

Working times at the Company are 35 hours per week for non-managers and 218 days per year for managers.

# 4.6.2 INTERESTS AND STOCK OPTIONS HELD BY MEMBERS OF THE MANAGEMENT AND SUPERVISORY BODIES AND BY EMPLOYEES

The history of stock option and share warrant awards to the various corporate officers of the Company, as well as the options and warrants that they exercised in 2019, are detailed in section 4.5.1.

The history of free share (preference shares subject to performance conditions) awards to the various corporate officers, as well as the free shares that vested in 2019, are detailed in section 4.5.1.

At December 31, 2019, to the knowledge of the Company, Stéphane Piat (Chief Executive Officer and director) held 10,900 Company shares (i.e., 0.09% of the share capital). The other current executive directors of CARMAT do not

hold any shares in the Company.

Certain employees of the Company are beneficiaries of stock options, share warrants (BSA and BSPCE) and free shares (preference shares subject to performance conditions), detailed in section 5.5.1.

Table 9 in section 4.5.1 specifies the number of stock options granted to the top ten employees who are not corporate officers, and the options exercised by these beneficiaries during the 2019 financial year.

Table 10bis in section 4.5.1 specifies the number of free shares (subject to performance conditions) awarded to the top ten employees who are not corporate officers, and the free shares that vested to them during the 2019 financial year.

### 4.6.3 STATUTORY AND DISCRETIONARY PROFIT SHARING

As at the date of this Universal Registration Document, the Company had not set up any statutory or discretionary profit-sharing plans.

### **CORPORATE GOVERNANCE**

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# THE COMPANY AND THE SHARE CAPITAL



## 5.1 LEGAL STRUCTURE

5.1.1

**REGISTERED NAME** 

The Company's registered name is: "CARMAT".

**5.1.2** PLACE AND NUMBER OF REGISTRATION

The Company is registered in the Versailles Trade and

Companies Register under number 504 937 905.

Its LEI (Legal Entity Identifier) number is 96 95 0 0 ARXAC MOPO KH333.

5.1.3 DATE OF INCORPORATION AND TERM

The Company was incorporated on June 25, 2008 and

registered on June 30, 2008 for a term of 99 years, unless said term is extended or the Company is wound up in advance.

**5.1.4** REGISTERED OFFICE, LEGAL FORM AND APPLICABLE LAW

The Company's registered office is located at 36, avenue

de l'Europe – Immeuble l'Etendard-Energy III – 78140 Vélizy-Villacoublay (phone number: +33 1 39 45 64 50). The Company is a French joint-stock corporation (société anonyme) with a Board of Directors. It is governed by French law, especially the provisions of Book II of the French Commercial Code (Code de commerce).

**5.1.5** ORGANIZATION OF THE GROUP

The Company is not part of a group.

5.1.6 SUBSIDIARIES AND INVESTMENTS

The Company has no subsidiaries or investments.

### 5.2 SHARE CAPITAL

5 9 1 VALUE OF THE SHARE CAPITAL

As at December 31, 2019, the fully paid-up share capital amounted to €504,385.96, divided into 12,609,649 shares with a par value of €0.04 each, including:

- 12,592,539 ordinary shares,
- 320 preference shares of class 2017-01,

- 2,000 preference shares of class 2017-02,
- 3,490 preference shares of class 2017-03,
- 580 preference shares of class 2018-01,
- 10,350 preference shares of class 2018-02,
- 370 preference shares of class 2018-03.

The Shareholders' Meeting of April 27, 2017 decided to add three classes of preference shares convertible into ordinary shares and governed by Articles L.228-11 et seq. of

### INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

the French Commercial Code to Article 12.2 of the Company's Articles of Association, respectively named "AGAP 2017-01", "AGAP 2017-02" and "AGAP 2017-03" (hereinafter together referred to as the "2017 Preference Shares").

The 2017 Preference Shares will be convertible into Ordinary Shares subject to vesting and lock-up periods and to performance criteria, as described in section 5.2.6 of the Universal Registration Document.

Likewise, the Shareholders' Meeting of April 5, 2018 decided to add three new classes of preference shares convertible into ordinary shares to Article 12.2 of the Company's Articles of Association, respectively named "AGAP 2018-01", "AGAP 2018-02" and "AGAP 2018-03" (hereinafter together referred to as the "2018 Preference Shares").

The 2018 Preference Shares will also be convertible into Ordinary Shares subject to vesting and lock-up periods and to performance criteria, as described in section 5.2.6 of the Universal Registration Document.

Lastly, the Shareholders' Meeting of March 28, 2019

decided to add three new classes of preference shares to Article 12.2 of the Company's Articles of Association, respectively called "AGAP 2019-01", "AGAP 2019-02" and "AGAP 2019-03" (hereinafter together referred to as the "2019 Preference Shares").

The 2019 Preference Shares will also be convertible into Ordinary Shares subject to vesting and lock-up periods and to performance criteria, as described in section 5.2.6 of this document.

The awards of the 2017, 2018 and 2019 Preference Shares are detailed in section 4.5 of this document. As at December 31, 2019, taking into account the required vesting periods, the following shares had vested:

- 320 preference shares of class 2017-01,
- 2,000 preference shares of class 2017-02,
- 3,490 preference shares of class 2017-03,
- 580 preference shares of class 2018-01,
- 10,350 preference shares of class 2018-02,
- 370 preference shares of class 2018-03.

### 5.2.2 SECURITIES NOT REPRESENTING CAPITAL

As at the date of this Universal Registration Document, there were no securities not representing capital.

### **5.2.3** PLEDGES, GUARANTEES AND COLLATERAL

As at the date of this Universal Registration Document, and to the best of the Company's knowledge, no shares have been pledged or used as guarantee or collateral.

### 5.2.4 ACQUISITION BY THE COMPANY OF ITS OWN SHARES

As at December 31, 2019, the Company held 4,170 treasury shares, representing 0.03% of its share capital.

The Combined Shareholders' Meeting of March 28, 2019 authorized the the Board of Directors to implement a share buyback program for a period of 18 months from the date of the meeting, pursuant to the provisions of Article L.225-209 of the French Commercial Code and in compliance with the General Regulation of the French Financial Markets Authority (Autorité des marchés financiers – AMF). The main terms of this authorization are the following:

Number of shares that may be purchased: 10% of the share capital at the date of the buyback. When shares are acquired in order to promote trading in and the liquidity of the shares, the number of shares taken into account to determine the above-mentioned 10% limit corresponds to the number of shares purchased, less the number of

shares sold during the period of the authorization.

#### Objectives of the share buyback program

- To ensure the liquidity of the shares of the Company under a liquidity agreement with an investment services provider that complies with a code of ethics recognized by the AMF.
- To honor obligations under stock purchase option programs, bonus share allocations, employee savings plans or other share allocations to employees and executives of the Company or related companies.
- To deliver shares upon exercise of the rights attached to securities giving access to the share capital.
- To hold shares in treasury for subsequent delivery as payment or exchange for external growth transactions.
- To cancel all or some of the shares bought back.



Or more generally, to carry out transactions for any purposes subsequently authorized by law or to implement any market practices subsequently authorized by the market authorities. In such event, the Company will inform the shareholders in a press release.

<u>Maximum purchase price</u>: €240, excluding fees and commissions and any adjustments made in order to account for corporate actions.

It is specified that the number of shares acquired by the Company for the purpose of being held in treasury for subsequent delivery as payment or exchange as part of a merger, demerger or contribution may not exceed 5% of the share capital.

Maximum amount of funds that may be allocated to the share buyback program: €5,000,000.

The shares bought back may be canceled up to a limit of 10% of the share capital per 24-month period.

### 5.2.5 OTHER SECURITIES GIVING ACCESS TO THE SHARE CAPITAL

As at December 31, 2019, the exercise or conversion of all the securities giving access to the share capital would result in the subscription of 1,314,700 new ordinary shares representing 10.44% of the current issued share capital and 9.45% of the share capital after issue of thee new ordinary shares.

Thus, a shareholder holding 1% of the current share capital would subsequently hold 0.91% if all the securities were exercised.

Type of instrument

Number of new ordinary shares that may be created (as at December 31, 2019)

Incentive instruments for Management, Consultants and Board members

- BCE-2009-2	0
- BCE-2012-1	11,500
- BCE-2012-2	6,700
- BSA-2009-1	0
- BSA-2017 - Board members	12,000
- BSA-2018 - Consultant	10,000
- BSA-2019 - Consultant	6,000
- Stock options - 2018	46,000
- Stock options - 2019	46,000
- Preference shares - 2017	421,000
- Preference shares - 2018	301,500
- Preference shares - 2019	193,000
Total incentive instruments	1,053,700
Financing tool	
- BSA Kepler Cheuvreux Tranches 1 & 2	261,000
Total financing instruments	261,000



The tables below present all the securities giving access to the issued share capital of the Company that have been granted and remain in effect as at December 31, 2019 and would result in the subscription of 1,314,700 new ordinary shares.

### **COMPANY FOUNDER SHARE WARRANTS (BCE)**

Security	BCE-2009-2	
Number of BCE warrants issued and allocated	7,566*	
Number of BCE warrants expired	3,091*	
Number of BCE warrants exercised	4,475*	
Balance of BCE warrants to be exercised	0	
Date of the Shareholders' Meeting	July 8, 2009	
Date of the Board meeting	July 8, 2009	
Exercise price per new share subscribed	€8	
BCE warrant expiration date	Ten years from the date of the allocation of the BCE warrants	
Ratio	1 BCE-2009-2 warrant for 25 new CARMAT shares	
	- 20% of the BCE-2009-2 warrants may be exercised on the date of the first anniversary of the beneficiary joining the Company, subject to his/he actual and continued presence within the Company at that date;	
Exercise conditions	<ul> <li>40% of the BCE-2009-2 warrants may be exercised per completed monthly period in tranches of 1/48<sup>th</sup> from the date of the first anniversar of the beneficiary joining the Company;</li> </ul>	
	- 10% of the BCE-2009-2 warrants may be exercised from the completion and successful outcome of the initial clinical trials of the CARMAT total artificial heart before the end of the second quarter of 2012 (medical report of completion of the trial covering the safety and end point aspects), subject to his/her actual and continued presence within the Company at that date	
	<ul> <li>- 10% of the BCE-2009-2 warrants may be exercised after the successful outcome of the first clinical implantation of the CARMAT total artificial heart before the end of November 2012 (report from a third party), subject to the actual and continued presence of the beneficiary within the Company at that date;</li> </ul>	
	<ul> <li>6.5% of the BCE-2009-2 warrants may be exercised after the successful outcome of the pivotal clinical trials of the CARMAT total artificial hear (report from the scientific advisory committee), subject to his/her actual and continued presence within the Company at that date;</li> </ul>	
	<ul> <li>6.5% of the BCE-2009-2 warrants may be exercised from the date o which the CE marking is obtained for the CARMAT total artificial heart subject to actual and continued presence of the beneficiary within th Company at that date;</li> </ul>	
	- 7% of the BCE-2009-2 warrants may be exercised after completion a December 31 of the first year of marketing of the CARMAT total artificial heart, confirmed by the Board of Directors, in accordance with the expectations in terms of revenue and gross profit margin set out in the busines plan drawn up by Executive Management and approved by the Board of Directors, subject to the actual and continued presence of the beneficiar within the Company at that date.	

CARMAT

Number of new shares that may be subscribed

\* After adjustments resulting from the increase in capital with pre-emptive subscription rights performed in August 2011.



Security	BCE-2012-1
Number of BCE warrants issued and allocated	56,500
Number of BCE warrants expired	45,000
Number of BCE warrants exercised	0
Balance of BCE warrants to be exercised	11,500
Date of the Shareholders' Meeting	April 26, 2012
Date of the Board meeting	June 27, 2012
Exercise price per new share subscribed	€108.483
BCE warrant expiration date	Ten years from the date of the allocation of the BCE warrants
Ratio	One BCE-2012-1 warrant for 1 new CARMAT share
	- 50% of BCE-2012-1 warrants may be exercised on the basis of monthly periods in tranches of 1/48 <sup>th</sup> from the date on which the BCE-2012-1 options are awarded to the beneficiary, subject to his/her actual and continued presence within the Company at that date;
Exercise conditions	<ul> <li>- 16.25% of the BCE-2012-1 warrants may be exercised after the successful outcome of the pivotal clinical trials of the CARMAT total artificial heart (report from the scientific advisory committee), subject to his/her actual and continued presence within the Company at that date;</li> </ul>
	- 16.25% of the BCE-2012-1 warrants may be exercised from the date on which the CE marking is obtained for the CARMAT total artificial heart, subject to actual and continued presence of the beneficiary within the Company at that date;
	- 17.5% of the BCE-2012-1 warrants may be exercised after completion at December 31 of the first year of marketing of the CARMAT total artificial heart, confirmed by the Board of Directors, in accordance with the expectations in terms of revenue and gross profit margin set out in the business plan drawn up by Executive Management and approved by the Board of Directors, subject to the actual and continued presence of the beneficiary within the Company at that date.
Number of new shares that may be subscribed	11,500
Security	BCE-2012-2
Number of BCE warrants issued and allocated	6,700
Number of BCE warrants expired	0
Number of BCE warrants exercised	0
Balance of BCE warrants to be exercised	6,700
Date of the Shareholders' Meeting	April 26, 2012
Date of the Board meeting	November 8, 2012
Exercise price per new share subscribed	€122.003
BCE warrant expiration date	Ten years from the date of the allocation of the BCE warrants
Ratio	One BCE-2012-2 warrant for 1 new CARMAT share
	<ul> <li>50% of BCE-2012-2 warrants may be exercised on the basis of monthly periods in tranches of 1/48<sup>th</sup> from the date on which the BCE-2012-2 options are awarded to the beneficiary, subject to his/her actual and continued presence within the Company at that date;</li> </ul>
	<ul> <li>- 16.25% of the BCE-2012-2 warrants may be exercised after the successful outcome of the pivotal clinical trials of the CARMAT total artificial heart (report from the scientific advisory committee), subject to his/her actual and continued presence within the Company at that date;</li> </ul>
Eventing and History	- 16.25% of the BCE-2012-2 warrants may be exercised from the date on which the
Exercise conditions	CE marking is obtained for the CARMAT total artificial heart, subject to actual and continued presence of the beneficiary within the Company at that date;

Number of new shares that may be subscribed

continued presence of the beneficiary within the Company at that date.

6,700



### **SHARE WARRANTS (BSA)**

Security	BSA-2009-1	
Number of BSA warrants issued and allocated	3,096*	
Number of BSA warrants expired	556*	
Number of BSA warrants exercised	2,540*	
Balance of BSA warrants to be exercised	0	
Date of the Shareholders' Meeting	July 8, 2009	
Date of the Board meeting	July 8, 2009	
Exercise price per new share subscribed	€8	
BSA warrant expiration date	Ten years from the date of allocation of the BSA warrants	
Ratio	1 BSA-2009-1 warrant for 25 new CARMAT shares	
	<ul> <li>- 25% of the BSA-2009-1 warrants may be exercised on the date of the first anniversary of the beneficiary joining the Company, subject to his/her actual and continued presence within the Company at that date;</li> <li>- 75% of BSA-2009-1 warrants may be exercised on the basis of monthly</li> </ul>	
	periods in tranches of 1/36 <sup>th</sup> from the date of the first anniversary of the beneficiary joining the Company, subject to his/her actual and continued presence within the Company at that date.	
Exercise conditions	Early exercise at the end of a period expiring 18 months after the establishment of the Company if the beneficiary has occupied the position of chairman of the Company for a period expiring 18 months after the establishment of the Company.	
	As a result of the success of the initial listing of the Company on the Euronext Paris Alternext market, according to the assessment of the meeting of the Company's Board of Directors on September 8, 2010, 20% of the BSA-2009-1 warrants that were not exercisable as at the date of the initial listing may be exercised early.	
Number of new shares that may be subscribed	0	

The Board of Directors meeting of December 3, 2018, acting on the departure of Jean Claude Cadudal, modified the conditions of exercise of the BSA-2009-1, which remained exercisable until July 8, 2019, even after the departure of its holder.

Security	BSA Kepler Cheuvreux - Tranches 1 & 2 (all exercisable by Kepler Cheuvreux)	
Number of BSA warrants issued and allocated	400,000	
Number of BSA warrants expired	0	
Number of BSA warrants exercised	139,000	
Balance of BSA warrants to be exercised	261,000	
Date of the Shareholders' Meeting	April 5, 2018	
Date of CEO's decision	Sept. 27, 2018	
Exercise price per new share subscribed	94% of the average volume-weighted trading price	
BSA warrant expiration date	September 26, 2020, at the latest	
Ratio	One Kepler BSA warrant for one new CARMAT share	
Number of new shares that may be subscribed	261,000	

The Company has put in place a new flexible equity financing arrangement with Kepler Cheuvreux, as the previous one expired in July 2018. Signed in September 2018, this new framework agreement comprises up to two consecutive 12-month tranches, namely a first €12 million tranche beginning on the date the agreement is signed followed by a second tranche making the total amount (Tranche 1 + Tranche 2) €25 million.

Under this framework, Kepler Cheuvreux has made a firm and definitive commitment to purchase new shares under Tranches 1 & 2 for €25 million at times and intervals of its own choosing during the 24 months following the signature of said framework agreement, subject to compliance with the terms agreed upon by the two parties. The Company may terminate the agreement at any time. Kepler Cheuvreux does not intend to retain the shares subscribed under these arrangements, and will subsequently sell them to investors or on the open market.



Security	BSA-2017 - Board members		
Number of BSA warrants issued and allocated for free	12,000		
Number of BSA warrants expired	0		
Number of BSA warrants exercised	0		
Balance of BSA warrants to be exercised	12,000		
Date of the Shareholders' Meeting	April 27, 2017		
Date of the Board meeting	May 15, 2017		
Exercise price per new share subscribed	€30.10		
BSA warrant expiration date	May 15, 2027		
Ratio	One BSA - Board members warrant for one new CARMAT share		
	- up to 1,500 warrants will be exercisable as from January 2, 2018;		
Exercise conditions	- up to 94 additional warrants will be exercisable from each month starting on January 2, 2018, i.e., from February 2, 2018 for the first tranche, it being specified that the last tranche will be limited to 82 warrants.		
Number of new shares that may be subscribed	12,000		

Security	BSA-2018 - Consultant
Number of BSA issued and subscribed at €3.14/BSA	10,000
Number of BSA warrants expired	0
Number of BSA warrants exercised	0
Balance of BSA warrants to be exercised	10,000
Date of the Shareholders' Meeting	April 5, 2018
Date of the Board meeting	June 11, 2018
Exercise price per new share subscribed	€20.93
BSA warrant expiration date	June 11, 2028
Ratio	One BSA - Consultant warrant for one new CARMAT share
Exercise conditions	- up to 2,500 warrants will be exercisable after each 12-month period, taking into account that the consulting agreement with the Company would have to be maintained during that period;
	- June 11, 2028, at the latest.
Number of new shares that may be subscribed	10,000

Security	BSA-2019 - Consultant
Number of BSA issued and subscribed at €3.03/BSA	6,000
Number of BSA warrants expired	0
Number of BSA warrants exercised	0
Balance of BSA warrants to be exercised	6,000
Date of the Shareholders' Meeting	March 28, 2019
Date of the Board meeting	June 24, 2019
Exercise price per new share subscribed	€20.21
BSA warrant expiration date	June 24, 2029
Ratio	One BSA - Consultant warrant for one new CARMAT share
Exercise conditions	- up to 166 warrants per full calendar month that has elapsed from the first day of the calendar month following the decision of the Board of Directors;
	- June 24, 2029, at the latest.
Number of new shares that may be subscribed	6,000



### STOCK OPTIONS

Security	Stock options - 2018		
Number of options issued and allocated	46,000		
Number of options expired	-		
Number of options exercised	-		
Balance of options to be exercised	46,000		
Date of the Shareholders' Meeting	April 5, 2018		
Date of the Board meeting	Dec. 3, 2018		
Exercise price per new share subscribed	€20.35		
Option expiration date	Ten years from the date of allocation of the options		
Ratio	One stock option for one new CARMAT share		
	- 50% of the options may be exercised in increments of 1/36 <sup>th</sup> each month elapsed from 1 January 2019, and in any event no later than 10 years after their date of allocation to the beneficiary;		
Exercise conditions	- 50% of the options are exercisable when the Company succeeds in successfully raising additional financing (excluding Equity Line financing and EIB type loans) for an amount of at least €100 million between the date of allocation and December 31, 2020, and in any event no later than 10 years after their date of allocation to the beneficiary.		
Number of new shares that may be subscribed	46,000		

Security	Stock options - 2019		
Number of options issued and allocated	46,000		
Number of options expired	-		
Number of options exercised	-		
Balance of options to be exercised	46,000		
Date of the Shareholders' Meeting	March 28, 2019		
Date of the Board meeting	April 1, 2019		
Exercise price per new share subscribed	€22.70		
Option expiration date	Ten years from the date of allocation of the options		
Ratio	One stock option for one new CARMAT share		
Exercise conditions	- the options can be exercised in increments of 1/36 <sup>th</sup> each month elapsed from 1 January 2019;		
	- March 31, 2029, at the latest.		
Number of new shares that may be subscribed	46,000		



### PREFERENCE SHARES (FREE PREFERENCE SHARES SUBJECT TO PERFORMANCE CRITERIA OVER A 3-YEAR PERIOD)

specifying the characteristics of Preference Shares and conversion ratios into Ordinary Shares).

(see section 5.4.3 "Rights, privileges and restrictions attached to shares (Articles 9 to 14 of the Articles of Association)" of the Universal Registration Document,

AGAP 2017 Preference share tranches	Performance criteria	Number of prefer- ence shares issued (as at Decem- ber 31, 2019)	Maximum conversion ratio appli- cable for each per- formance criteria	Number of ordinary shares that may be issued
Tranche 1	Definition of the Company's industrial development plan	320	100	32,000
Tranche 2	Successful implantation of the bioprosthesis evaluated on 10 patients in total worldwide	2,000	20	40,000
Tranche 3	Filing of the clinical module of the bioprosthesis' CE marking		15	52,350
	Bioprosthesis CE marking		20	69,800
	Obtaining additional financing for the Company for an aggregate amount, between the allocation date and the convertibility date, of €100 million		25	87,250
	Implementation of a production process meeting certain criteria	3,490	15	52,350
	Effective commercialization of bioprostheses at 15 European implantation centers		10	34,900
	Successful implantation of the bioprosthesis evaluated on 10 patients in the United States		10	34,900
	Successful implantation of the bioprosthesis evaluated on 100 patients in total worldwide		10	34,900
	Increase in the ordinary share price according to specific criteria		10	34,900
	Maximum number of ordinary shares that may be created, regardless ber of performance criteria achieved for Tranche 3		100	349,000
	TOTAL	5,810		421,000



AGAP 2018 Preference share tranches	Performance criteria	Number of prefer- ence shares issued  (as at Decem- ber 31, 2019)	Maximum conversion ratio appli- cable for each per- formance criteria	Number of ordinary shares that may be issued
Tranche 1	Successful completion of "prosthesis" test benches for CE marking	580	100	58,000
Tranche 2	Recruitment of 10 patients for the pivotal study for CE marking		10	113,000
	Recruitment of the 20 <sup>th</sup> patient for the pivotal study to obtain the CE marking or finalization of the pivotal study for submis- sion of the dossier to Dekra	11,300*	5	56,500
	Obtaining authorization to conduct an Early Feasibility Study in the United States by December 31, 2018		5	0**
	Maximum number of ordinary shares that may be created, regar ber of performance criteria achieved for Tranche		20	169,500
Tranche 3 Filing of the o	Filing of the clinical module of the bioprosthesis' CE marking		15	11,000
	Bioprosthesis CE marking		20	14,800
	Obtaining additional financing for the Company for an aggregate amount, between the allocation date and the convertibility date, of €38.5 million  Implementation of a production process meeting certain criteria		25	18,500
		740	15	11,000
	Effective commercialization of bioprostheses at 15 European implantation centers		10	7,400
	Successful implantation of the bioprosthesis evaluated on 10 patients in the United States		10	7,400
	Successful implantation of the bioprosthesis evaluated on 100 patients in total worldwide		10	7,400
	Increase in the ordinary share price according to specific criteria		10	7,400
	Maximum number of ordinary shares that may be created, regar ber of performance criteria achieved for Tranche		100	74,000
	TOTAL	12,820		301,500

<sup>\* 11,500</sup> AGAP-2018-02 had been awarded by the Board of Directors, reduced to 11,300 because of the departure of a beneficiary.

<sup>\*\*</sup> The corresponding performance criterion has not been achieved.



AGAP 2019 Preference share tranches	Performance criteria	Number of prefer- ence shares issued  (as at Decem- ber 31, 2019)	Maximum conversion ratio appli- cable for each per- formance criteria	Number of ordinary shares that may be issued
Tranche 1	Success of the first patient treated in the United States under the US pivotal study following the positive conclusion of the Early Feasibility Study	7,880*	10	78,800
Tranche 2	Obtaining CE marking with sufficient inventory to support the commercial launch	7,880**	10	78,800
Tranche 3	Billing and implantation of 5 prostheses within 4 months of CE marking	3,540***	10	35,400
	TOTAL	19,600		193,000

<sup>\* 8,000</sup> AGAP-2019-01 had been awarded by the Board of Directors, reduced to 7,880 because of the departure of a beneficiary.

### 5.2.6 AUTHORIZED BUT UNISSUED SHARE CAPITAL

Shareholders' Meeting of March 28, 2019

Table of delegations of authority applicable following the Shareholders' Meeting of March 28, 2019:

Resolution	Purpose of the resolution	Maximum nominal amount in euros	Terms and conditions for determining the issue price	Period of authorization and expiration
11 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to increase capital immediately or in the future by issuing ordinary shares or any other securities giving access to the capital or giving right to the allocation of debt securities, with pre-emptive subscription rights	Nominal value of increases in capital: €200,000 <sup>(1)</sup> Nominal value of bonds and other debt securities giving access to the share capital: €120,000,000 <sup>(1)</sup>	N/A	May 28, 2021 (26 months)
12 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to decide on the issue of shares and/or transferable securities giving immediate or future access to the share capital or giving right to the allocation of debt securities, with removal of the pre-emptive subscription right by way of a public offer (Article L.225-136)	nard of Directors to decide on the issue shares and/or transferable securities ving immediate or future access to the are capital or giving right to the allocan of debt securities, with removal of the e-emptive subscription right by way of a		May 28, 2021 (26 months)

(1) These amounts are not cumulative. The overall maximum nominal amount of capital increases that can be carried out under the delegations granted under resolutions 11 to 18 is set at €200,000. The maximum nominal amount of debt securities which can be issued under the above delegations is set at €120,000,000.

<sup>\*\* 8,000</sup> AGAP-2019-02 had been awarded by the Board of Directors, reduced to 7,880 because of the departure of a beneficiary.

<sup>\*\*\* 3,600</sup> AGAP-2019-03 had been awarded by the Board of Directors, reduced to 3,540 because of the departure of a beneficiary.



Resolution	Purpose of the resolution	Maximum nominal amount in euros	Terms and conditions for determining the issue price	Period of authorization and expiration
13 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to decide on the issue of shares and/or transferable securities giving immediate or future access to the share capital or giving right to the allocation of debt securities, with removal of the pre-emptive subscription rights, by offering to qualified investors or to a limited circle of investors within the meaning of paragraph II of Article L.411-2 of the French Monetary and Financial Code (Article L.225-136 3°)	Nominal value of increases in capital: €200,000 <sup>(1)</sup> Nominal value of bonds and other debt securities giving access to the share capital: €120,000,000 <sup>(1)</sup>	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price less any discount (maximum 30%)	May 28, 2021 (26 months)
14 <sup>th</sup> resolution	Subject to the listing of the Company's shares on a regulated market, the authorization allowing the Board of Directors, in the event of the issue of shares or of any security giving access to capital with removal of the pre-emptive subscription right, to set the issue price at a maximum of 10% of the share capital and within the limits determined by Shareholders' Meeting	Limited to 10% of the Company's share capital (as existing on the date of the transaction) per 12-month period	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price, less any discount (maximum 30%)	May 28, 2021 (26 months)
15 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to increase the amount of each of the issues with or without pre-emptive subscription right which would be decided under resolutions 11 to 13.	Limited to 15% of the initial issue	Price identical to that of the initial issue	May 28, 2021 (26 months)
16 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to increase capital immediately or in the future by issuing ordinary shares or any other securities giving access to the capital, with removal of the pre-emptive subscription right to a category of beneficiaries (Biotech/Medtech investors)	Nominal value of increases in capital: €200,000 <sup>(1)</sup> Nominal value of bonds and other debt securities giving access to the share capital: €120,000,000 <sup>(1)</sup>	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price less any discount (maximum 30%)	September 28, 2020 (18 months)
17 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to increase capital immediately or in the future by issuing ordinary shares or any other securities giving access to the capital, with removal of the pre-emptive subscription right to a category of beneficiaries (Strategic partners)	Nominal value of increases in capital: €200,000 <sup>(1)</sup> Nominal value of bonds and other debt securities giving access to the share capital: €120,000,000 <sup>(1)</sup>	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price less any discount (maximum 30%)	September 28, 2020 (18 months)
18 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to decide on the issue of shares and/or securities giving immediate or future access to the capital or providing a right to a debt instrument, with removal of the pre-emptive subscription right of shareholders for the benefit of a category of beneficiaries (equity line financing plan)	Nominal value of increases in capital: €200,000 <sup>(1)</sup> Nominal value of bonds and other debt securities giving access to the share capital: €120,000,000 <sup>(1)</sup>	At least equal to the average volume-weighted price of the last three stock market sessions prior to the defining of the issue price less any discount (maximum 30%)	September 28, 2020 (18 months)
20 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to increase capital by incorporation of premiums, reserves, profits or	Nominal value of increases in capital: €200,000 (2)	N/A	May 28, 2021 (26 months)



### Ordinary share subscription warrants:

Resolution	Purpose of the resolution	Maximum nom- inal amount in euros	Method of deter- mining the BSA issue price	Method of deter- mining the BSA exercise price	Period of autho- rization and expiration
21 <sup>st</sup> resolution	Delegation of authority allowing the Board of Directors to issue warrants dedicated to Board members (not employees or managers), persons bound by a service contract or members of Committees set up by the Board of Directors	€4,000 (corresponding to 100,000 shares) <sup>(i)</sup>	To be set by the Board of Directors  Issue price could be free	At least equal to the average of the prices weighted by the volumes of the last 20 trading sessions preceding the fixing of the issue price of the warrants	September 28, 2020 (18 months)

<sup>(1)</sup> These amounts are not cumulative. The overall maximum nominal amount of capital increases that can be carried out under the delegations granted under resolutions 21 and 22 is set at €4,000.

### Ordinary share subscription or purchase warrants:

Resolution	Purpose of the resolution	Maximum nominal amount in euros	Terms and conditions for determining the issue price	Period of authorization and expiration
22 <sup>nd</sup> resolution	Authorization granted to the Board of Directors to award options for the subscription or purchasing of shares.	€4,000 (corresponding to 100,000 shares) <sup>(1)</sup>	(2)	May 28, 2022 (38 months)

<sup>(1)</sup> These amounts are not cumulative. The overall maximum nominal amount of capital increases that can be carried out under the delegations granted under resolutions 21 and 22 is set at €4,000.

- (2) The purchase or subscription price per share will be set by the Board on the day the option is granted, based on the following:
- for as long as the shares are admitted for trading on the Euronext Growth market, the purchase or subscription price shall be determined in accordance with the provisions of Article L.225-177 of the French Commercial Code and must be at least equal to the sales price of one share at the close of the Euronext Growth market on the day prior to the decision of the Board of Directors to allocate the options, and for purchases, the price must be no less than 80% of the average price paid by the Company for all of the shares previously purchased;
- in the event that the Company's shares are admitted for trading on a regulated market, the Board may determine the purchase or subscription price per share with reference to the sales price of one share at the close of that regulated market on the day prior to the decision of the Board to allocate the options. However, the purchase or subscription price per share may under no circumstances be less than ninety-five percent (95%) of the average sales price of one share at the close of the said market during the twenty trading days prior to the decision of the Board of Directors to allocate the options rounded down to the nearest euro, or, for stock options, to 80% of the average sales price of the Company's treasury shares, rounded down to the nearest euro.



Free allocation of preference shares:

Resolution	Purpose of the resolution	Maximum nominal amount in euros	Acquisition period for the prefer- ence shares	Lock-up period appli- cable to the preference shares	Exercise period of the conversion option into ordinary shares	Period of authoriza- tion and expiration
25 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to allocate free preference shares convertible into ordinary shares "AGAP 2019-01" dedicated to employ- ees and/or corporate officers	€3,200 (corresponding to 80,000 ordinary shares)	1 year	2 years minimum	5 years and 3 months from the end of the lock-up period	May 28, 2022 (38 months)
26 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to allocate free preference shares convertible into ordinary shares "AGAP 2019-02" dedicated to employ- ees and/or corporate officers	€3,200 (corresponding to 80,000 ordinary shares)	1 year	2 years minimum	5 years and 3 months from the end of the lock-up period	May 28, 2022 (38 months)
27 <sup>th</sup> resolution	Delegation of authority allowing the Board of Directors to allocate free preference shares convertible into ordinary shares "AGAP 2019-03" dedicated to employ- ees and/or corporate officers	€1,600 (corresponding to 40,000 ordinary shares)	1 year	2 years minimum	5 years and 3 months from the end of the lock-up period	May 28, 2022 (38 months)

Performance criteria to be met in order to convert AGAP 2019-01, AGAP 2019-02 and AGAP 2019-03 preference shares into ordinary shares

### • For AGAP 2019-01:

- success of the first patient treated in the United States under the US pivotal study following the positive conclusion of the Early Feasibility Study.

### For AGAP 2019-02:

- obtaining the CE marking with sufficient inventory to support the commercial launch.

### • For AGAP 2019-03:

- billing and implantation of 5 prostheses in 4 months after obtaining CE marking.

On the date of filing this Universal Registration Document, the Board of Directors made use of the delegations of authority approved at the Shareholders' Meeting of April 5, 2018, and proceeded on February 11, 2019 to the free allocation of:

#### • 370 AGAP 2018-03.

In addition, the Board of Directors made use of the delegations of authority approved at the Shareholders' Meeting of March 28, 2019, as follows:

- the Board of Directors, making use of the delegations of authority approved at the Shareholders' Meeting of March 28, 2019, decided to freely allocate on April 1, 2019, September 23, 2019 and December 2, 2019 a total of:
- 8,000 AGAP 2019-01,
- 8,000 AGAP 2019-02,
- 3,600 AGAP 2019-03.

### INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

Following the departure of one of the beneficiaries, 7,880 AGAP 2019-01, 7,880 AGAP 2019-02 and 3,540 AGAP 2019-03 are currently in circulation.

- the Board of Directors, making use of the delegations of authority approved at the Shareholders' Meeting of March 28, 2019, decided to issue 6,000 BSA - 2019 to a consultant of the Company on June 24, 2019.
- the Board of Directors, making use of the delegations of authority approved at the Shareholders' Meeting of March 28, 2019, decided on April 1, 2019 to grant Jean-Pierre Garnier up to 46,000 stock options under a stock option program.
- the Board of Directors, making use of the delegations of authority approved at the Shareholders' Meeting of March 28, 2019, approved on September 18, 2019, the principle of two capital increases through the issue of ordinary shares with removal of shareholders' pre-emptive subscription rights for a total maximum nominal amount of €200,000:
- one reserved (16<sup>th</sup> resolution) for the benefit of a first category of beneficiaries,
- and the other (17<sup>th</sup> resolution) for the benefit of a second category of beneficiaries.

These capital increases resulted in the issue of 3,157,895 new ordinary shares.

# 5.2.7 INFORMATION ABOUT THE COMPANY'S SHARE CAPITAL SUBJECT TO AN OPTION OR A CONDITIONAL OR UNCONDITIONAL AGREEMENT MAKING THEM SUBJECT TO AN OPTION

None.

### 5.2.8 TABLE OF CHANGES IN THE COMPANY'S SHARE CAPITAL

The Company was registered with the Versailles Trade and Companies Registry on June 30, 2008 with an initial share capital of €40,000.

The table below shows a summary of the changes in share capital over the last 3 years:

Date of the operation	Transaction	Capital increase (in euros)	Share pre- mium or contribu- tion (in euros)	Number of shares created	Nominal value of shares (in euros)	Cumu- lative number of shares	Share capital following the trans- action (in euros)
February 10, 2017	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	380.00	245,975.00	9,500	0.04	6,035,444	241,417.76
May 15, 2017	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	1,520.00	971,430.00	38,000	0.04	6,073,444	242,937.76
June 12, 2017	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	2,644.00	1,760,686.00	66,100	0.04	6,139,544	245,581.76
Sept. 25, 2017	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	3,080.00	1,871,760.00	77,000	0.04	6,216,544	248,661.76
December 1, 2017	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	6,200.00	3,402,140.00	155,000	0.04	6,371,544	254,861.76

Note that Kepler Cheuvreux does not intend to retain the shares subscribed under the share issue agreements made in January 2015 and in September 2018, and will subsequently sell them to investors or on the open market.



Date of the operation	Transaction	Capital increase (in euros)	Share pre- mium or contribu- tion (in euros)	Number of shares created	Nominal value of shares (in euros)	Cumu- lative number of shares	Share capital following the trans- action (in euros)
December 12, 2017	Increase in capital by cash contribution	105,800.00	52,794,200.00	2,645,000	0.04	9,016,544	360,661.76
February 12, 2018	Increase in capital by cash contribution through the exercise of Kepler BSA warrants	1,840.00	957,800.00	46,000	0.04	9,062,544	362,501.76
April 16, 2018	Increase in capital by cash contribution through the exercise of Kepler BSA warrants	3,640.00	1,837,500.00	91,000	0.04	9,153,544	366,141.76
Dec. 3, 2018	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	3,445.00	1,785,240.00	86,125	0.04	9,239,669	369,586.76
February 11, 2019	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrant/ AGAP vesting	3,522.40	1,625,360.00	82,250 OS 5,810 PS	0.04	9,321,919 OS 5,810 PS	373,109.16
April 1, 2019	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	630.00	329,370.00	15,750 OS	0.04	9,337,669 OS 5,810 PS	373,739.16
June 24, 2019	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrant/ AGAP vesting	3,366.20	972,401.00	73,225 OS 10,930 PS	0.04	9,410,894 OS 16,740 PS	377,105.36
September 18, 2019	Increase in capital by cash contribution	126,315.80	59,873,689.20	3,157,895 OS	0.04	12,568,789 OS 16,740 PS	503,421.16
Sept. 23, 2019	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants	950.00	329,050.00	23,750 OS	0.04	12,592,539 OS 16,740 PS	504,371.16
Dec. 2, 2019	AGAP vesting	14.80	-	370 PS	0.04	12,592,539 OS 17,110 PS	504,385.96
OS: Ordinary Sh	ares PS: Preference Shares						

Note that Kepler Cheuvreux does not intend to retain the shares subscribed under the share issue agreements made in January 2015 and in September 2018, and will subsequently sell them to investors or on the open market.

### 5.3 MAJOR SHAREHOLDERS

5.3.1 DISTRIBUTION OF SHARE CAPITAL AND VOTING RIGHTS

CURRENT DISTRIBUTION OF SHARE CAPITAL AND VOTING RIGHTS

The table below shows the distribution of the share capital and voting rights (see section 5.3.2 "Voting rights" of this Universal Registration Document, which indicates the conditions under which double voting rights may be obtained) of the Company at December 31, 2019.

### INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

Shareholders (December 31, 2019)	Number of shares	Number of vot- ing rights	% of capital	% of voting rights
Matra Défense (Airbus Group)	1,670,640	2,652,040	13.2%	18.4%
Professor Alain Carpentier	548,583	1,097,166	4.4%	7.6%
Research Association of the Alain Carpentier Foundation	115,000	230,000	0.9%	1.6%
Funds managed by Truffle Capital	356,024	470,103	2.8%	3.3%
Air Liquide	76,982	76,982	0.6%	0.5%
Cornovum	458,715	458,715	3.6%	3.2%
Lohas	1,449,603	1,449,603	11.5%	10.0%
Santé Holdings SRL	925,091	925,091	7.3%	6.4%
Thérabel Pharma	309,210	309,210	2.5%	2.1%
Corely Belgium	800,000	800,000	6.3%	5.5%
Bratya SPRL	250,000	250,000	2.0%	1.7%
BAD 21	652,632	652,632	5.2%	4.5%
Treasury stock	4,170	-	0.0%	-
Free float	4,992,999	5,055,326	39.6%	35.0%
Total	12,609,649	14,426,868	100.0%	100.0%

To the best of the Company's knowledge, there is no other shareholder owning more than 5% of the share capital or voting rights.

### Funds managed by Truffle Capital

Founded in 2001 in Paris, Truffle Capital is an acknowledged European player in the area of capital investment, investing in and developing innovative SMEs and building technological leaders in the areas of Life Sciences, Information Technology and Energy.

### Airbus Group

Airbus Group (formerly EADS), born out of a merger in July 2000 between DaimlerChrysler Aerospace AG, Aérospatiale- Matra and Construcciones Aeronáuticas SA, is a world leader in the aeronautic, space and defense and associated services sectors. Airbus Group holds shares in CARMAT through its wholly-owned subsidiary, Matra Défense.

#### **Professor Carpentier**

Professor emeritus at the Pierre and Marie Curie University (University of Paris VI) and Professor at the Mount Sinai School of Medicine in New York, he is the founder and director of the Biosurgical Research Laboratory at the Scientific Research Association of the Alain Carpentier Foundation.

Winner of the 1998 Grand Prix from the Foundation for Medical Research, and Vice-President of the French Academy of Sciences, he also received the prestigious Albert Lasker Award for Clinical Medical Research in 2007 in recognition of his two main contributions to the field - the invention of valve bioprostheses (Carpentier-Edwards valves) and the development of techniques for plastic and reconstructive surgery of heart valves, which benefit several hundred thousand patients worldwide each year.

### Scientific Research Association of the Alain Carpentier Foundation (ARSFAC)

Set up in December 2007 by Professor Alain Carpentier, the purpose of the Scientific Research Association of the Alain Carpentier Foundation is to finance medical research projects, in particular in the surgical, cardiovascular and neurological areas.

#### Lohas

This entity is a family office of Pierre Bastid, having acquired the existing shares originally subscribed by ZAKA (another family office of Pierre Bastid) as part of the Company's private placement carried out in 2016, from Babalia (another family office of Pierre Bastid) in July 2018.

### Santé Holdings SRL

This entity is the family office of Dr. Antonino Ligresti, who was notably Chairman of Générale de Santé.

### CorNovum

This entity is an investment vehicle equally owned by the French State and by BPI France.

### INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

### Thérabel Group

The Thérabel group is a pharmaceutical group operating both in the fields of prescription drugs and over-the counter (OTC) drugs.

### Corely Belgium SPRL and Bratya SPRL

These two entities are investment holding companies of the Gaspard family, owner of the Lyreco group.

### **Bad 21 SPRL**

This entity is the investment holding company of Pierre-Edouard Stérin, founder of Smartbox.

### CHANGE IN THE DISTRIBUTION OF SHARE CAPITAL AND VOTING RIGHTS

The table below shows the distribution of share capital and voting rights in the Company as at December 31, 2018, December 31, 2017 and as at December 31, 2016, insofar as known to the Company.

It should be noted that on February 26, 2016 the Company announced a significant fundraising initiative, for €50 million, via a reserved capital increase operation after the Extraordinary Shareholders' Meeting held on April 12, 2016, and subscribed by a pool of strategic

investors, composed of Air Liquide via its investment holding company ALIAD, the joint investment vehicle of Bpifrance and the State (Programme des Investissements d'Avenir (future investments program - CorNovum), the family offices of Pierre Bastid (ZAKA) and of Dr. Ligresti (Santé Holdings SRL) and by the reference shareholders, Matra Défense (Airbus Group) and Truffle Capital.

In addition, in December 2017, the Company launched a capital increase operation through a public offering that benefited from the support of historic shareholders, in particular the family offices of Pierre Bastid (Babalia) and Dr. Ligresti (Santé Holdings SRL).

Finally, the Company announced on September 19, 2019 the success of a private placement of €60 million to investors specializing in the life sciences and medical technologies sectors, and to strategic partners. In particular, some historic shareholders (Matra Defense of the Airbus Group, Lohas, Santé Holdings SRL and Thérabel group) participated in this financing round, but also new family shareholders and entrepreneurs including Corely Belgium SPRL and Bratya SPRL (Gaspar family investment holdings, owner of the Lyreco Group), and Bad 21 SPRL (investment holding company of Pierre-Edouard Stérin, founder of Smartbox).

These operations explain the changes observed in the composition of CARMAT's ownership structure over the past years.

	As at Decen	As at December 31, 2018		nber 31, 2017	As at December 31, 2016	
Shareholders	% of share capital	% of voting rights	% of share capital	% of voting rights	% of share capital	% of voting rights
Matra Défense (Airbus Group)	14.4%	20.9%	14.8%	20.7%	22.1%	27.5%
Professor Alain Carpentier	5.9%	9.9%	6.1%	9.8%	9.1%	13.0%
ARSFAC	1.2%	2.1%	1.3%	2.1%	1.9%	2.7%
Funds managed by Truffle Capital	3.8%	4.2%	8.5%	11.5%	15.4%	19.6%
Air Liquide	0.8%	0.7%	0.9%	0.7%	0.5%	0.3%
Cornovum	5.0%	4.1%	5.1%	4.1%	7.6%	5.4%
Lohas	13.9%	11.6%	14.3%	11.5%	4.8%	3.5%
Santé Holdings SRL	7.4%	6.2%	7.6%	6.1%	3.1%	2.2%
Thérabel Pharma	1.4%	1.1%	-	-	-	-
Treasury stock	0.0%	-	0.0%	0.0%	0.1%	0.0%
Free float	46.1%	39.1%	41.4%	33.6%	35.4%	25.7%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

### 5.3.2 VOTING

The voting right attached to shares is proportional to the percentage of share capital that they represent. Each share entitles at least one vote.

However, in accordance with Article 14 of the Articles of

Association and the provisions of the French Commercial Code, all fully paid up shares which have been registered to the same shareholder for at least two years will benefit, with effect from the initial public offering of the Company on the Euronext Growth market, from double voting rights compared with those given to other shares with respect to the percentage of share capital that they represent.

### 5.3.3 STATEMENT CONCERNING THE CONTROL OF THE COMPANY

As at the date of this Universal Registration Document,

to the best of the Company's knowledge, no single share-holder was in control of the Company, directly or indirectly or with others, within the meaning of Article L.233-3 et seq. of the French Commercial Code.

### 5.3.4 AGREEMENTS THAT MAY BRING ABOUT A CHANGE IN CONTROL

As at the date of this Universal Registration Document, and to the best of the Company's knowledge, there are no agreements that may bring about a change in control of the Company.

# 5.4 MEMORANDUM AND ARTICLES OF ASSOCIATION

### 5.4.1 CORPORATE PURPOSE (ARTICLE 2 OF THE ARTICLES OF ASSOCIATION)

The purpose of the Company is, either directly or indirectly, both in France and abroad:

- the research and development of medical devices and equipment, specifically in the cardiovascular field, and in all scientific fields directly or indirectly related thereto:
- the production and marketing of (i) medical devices and equipment in the cardiovascular field and (ii) all

associated technologies;

- the acquisition or creation of technology products and licenses related to the cardiovascular field;
- the investment in French or foreign companies, which have activities that are similar to, or which complement those mentioned above;
- and, more generally, all operations of any kind economic, legal, financial, civil or commercial, industrial, securities or real estate that may be directly or indirectly connected with the above-mentioned purpose or likely to contribute to the development thereof.

5.4.2 PROVISIONS OF THE ARTICLES OF ASSOCIATION, CHARTER OR BYLAWS OF THE COMPANY CONCERNING THE MEMBERS OF THE BOARD OF DIRECTORS AND EXECUTIVE MANAGEMENT (ARTICLES 15 TO 21 OF THE ARTICLES OF ASSOCIATION)

#### **ARTICLE 15 - BOARD OF DIRECTORS**

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The Company is administered by a Board of Directors consisting of a minimum of five (5) and a maximum of eighteen (18) members subject to the derogation provided for by law in the case of a merger.

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### ARTICLE 16 - APPOINTMENT AND REMOVAL OF DIRECTORS

### I. Appointment/removal of directors

Over the life of the Company, the directors are appointed by the Ordinary Shareholders' Meeting. However, in the event of a merger or demerger, appointments may be made by an Extraordinary Shareholders' Meeting. Directors are appointed for a term of six (6) years, expiring at the end of the Ordinary Shareholders' Meeting held during the year in which their term of office expires to approve the financial statements for the previous year.

Any outgoing director may be re-appointed subject to fulfilling the conditions of this Article.

Directors may be removed from office and replaced at any time by the Ordinary Shareholders' Meeting.

Natural persons aged over eighty-five (85) years may not be directors; when a director reaches this age during their term of office they are deemed to have officially resigned at the next Shareholders' Meeting. Any appointment made in breach of the above provisions is null and void, with the exception of those which may be made on a temporary basis.

Any director who is a natural person must, at the time of their appointment and throughout their term of office, meet the legal requirements in terms of the total number of directorships that a single person may hold in French joint-stock corporations (sociétés anonymes) based in Metropolitan France, unless otherwise provided for by law.

A Company employee may only be appointed as a director if their contract of employment relates to an actual position within the Company. The number of directors who have a contract of employment with the Company may not exceed one third of the directors in office.

### II. Director in the form of a legal entity

Directors may be natural persons or legal entities. In the latter case, at the time of appointment, the legal entity is required to designate a permanent representative who will be subject to the same conditions and obligations and with the same civil and criminal liabilities as if they were a director in their own right, without prejudice to the joint and several liability of the legal entity that they represent. The permanent representative of a director in the form of a legal entity is subject to the age conditions that relate to directors who are natural persons.

The term of office of the permanent representative designated by the legal entity appointed as director is the same as the term of office of the latter.

If the legal entity removes its permanent representative

from office, it is required to notify the Company, without delay, by registered letter, of this removal and of the identity of its new representative. The same applies in the case of death or resignation of the permanent representative.

The designation of the permanent representative and the termination of their term of office are subject to the same publication formalities as if they were a director in their own right.

#### III. Vacancies, deaths, resignations

In the event of a vacancy due to death or resignation of one or more directors, the Board of Directors may proceed with interim appointments between two Shareholders' Meetings.

When the number of directors falls below the legal minimum, the remaining directors must immediately call an Ordinary Shareholders' Meeting in order to bring the Board up to strength.

Interim appointments made by the Board are subject to ratification by the next Ordinary Shareholders' Meeting. In the absence of ratification, decisions made and actions taken previously by the Board will remain valid.

### ARTICLE 17 - ORGANIZATION AND DELIBERATIONS OF THE BOARD

### <u>I. Chairman</u>

The Board of Directors elects a chairman from among its members, who must be a natural person, failing which the appointment will be null and void. The Board of Directors determines the Chairman's compensation.

The Chairman of the Board of Directors organizes and directs the work of the latter, and reports thereon to the Shareholders' Meeting. He ensures that the Company bodies are operating properly, and in particular that the directors are capable of performing their duties.

In order to perform his duties, the Chairman of the Board of Directors must be less than eighty-five (85) years of age. If the Chairman of the Board of Directors reaches this age during his term of office, he will be deemed to have officially resigned and the appointment of a new Chairman will take place subject to the conditions provided for in this Article.

The Chairman is appointed for a term that may not exceed that of his term of office as a director. The Chairman is eligible for re-appointment.

The Board of Directors may revoke the appointment at any time.

In the event of the Chairman being temporarily

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unavailable, or of his death, the Board of Directors may delegate the duties of Chairman to a director.

In the event of the Chairman being temporarily unavailable, this delegation is made for a limited, renewable period. In the event of death, it remains valid until the election of a new Chairman.

#### II. Board meetings

The Board of Directors meets as often as the interests of the Company require, at the invitation of the Chairman and at least every two (2) months.

When it has not met for more than two (2) months, a minimum of one third of the members of the Board of Directors may ask the Chairman to call a meeting with a specific agenda.

The Chief Executive Officer may also ask the Chairman to call a meeting of the Board of Directors with a specific agenda.

The Chairman is bound to act on requests made to him by virtue of the above two paragraphs.

Notices may be given by any means, including verbally.

The Board meets at the registered office or at any other location (in France or abroad) indicated in the notice, under the chairmanship of the Chairman or, if he is unavailable, the member designated by the Board to chair it.

The Chairman of the Board of Directors chairs the meetings. In the event of the Chairman being unavailable, the Board appoints a chairman for each meeting from among the members present.

At each meeting, the Board may appoint a secretary, who does not necessarily have to be a member.

A register is kept which is signed by the directors attending the Board meeting.

The directors and any person called upon to attend the meetings of the Board of Directors are bound by secrecy in respect of information of a confidential nature indicated as such by the Chairman.

### III. Quorum, majority

Deliberations of the Board will only be valid if at least half of the directors are present or deemed present under the arrangements laid down in the internal rules where videoconference and other means of telecommunication are used.

Unless otherwise stipulated by these Articles of Association and subject to the arrangements laid down in the

internal rules, where videoconferencing or other means of telecommunication are used, decisions are taken by a majority of votes of the members present or represented or deemed present.

Directors are deemed present for the purposes of calculating a quorum or majority where they take part via videoconference or telecommunication under the conditions defined by the internal rules of the Board of Directors. However, physical presence or representation will be necessary for all deliberations of the Board relating to approval of the annual financial statements and the consolidated financial statements, and also for drawing up the management report and the consolidated management report, as well as for decisions concerning the removal of the Chairman of the Board of Directors, the Chief Executive Officer and the Deputy Chief Executive.

Furthermore, half of the directors in office may oppose a meeting of the Board being held via videoconference or telecommunication. Such opposition must be notified in the forms and by the deadline required by the internal rules and/or in those that may be laid down in the legal or regulatory provisions.

#### IV. Representation

Any director may give another director written authority to represent him/her at a meeting of the Board.

Each director may hold only one proxy for the same meeting given by application of the above paragraph.

These provisions are applicable to the permanent representative of a director who is a legal entity.

### V. Minutes of meetings

The meetings of the Board of Directors are recorded in minutes drawn up in a special register, numbered and initialed, and kept at the registered office in accordance with the regulatory provisions.

#### VI. Observers

Throughout the lifetime of the Company, the Ordinary Shareholders' Meeting may proceed with the appointment of observers (censeurs) who may or may not be shareholders.

The number of observers may not exceed three (3).

Observers are appointed for a term of one (1) year. Their terms of office expire at the end of the Ordinary Shareholders' Meeting held during the year in which their term of office expires to approve the financial statements for the previous year.

Any outgoing observer may be re-elected subject to

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meeting the conditions of this Article.

Observers may be removed and replaced at any time by the Ordinary Shareholders' Meeting without any compensation being due to them. The duties of the observers also cease upon the death or incapacity of an observer who is a natural person, or in the event of winding up or receivership in the case of an observer who is a legal entity.

Observers may be natural persons or legal entities. In the latter case, at the time of appointment, the legal entity is required to designate a permanent representative who will be subject to the same conditions and obligations and with the same civil and criminal liabilities as if they were an observer in their own right, without prejudice to the joint and several liability of the legal entity that they represent.

The duty of the observers is to ensure the strict application of the Articles of Association and to present their observations at the meetings of the Board of Directors.

The observers perform a general and permanent role of advice and monitoring within the Company. In the context of their duties they may make observations to the Board of Directors and request access to information at the registered office of the Company.

Observers must be invited to each meeting of the Board of Directors in the same way as directors.

Observers have only consultative powers on an individual or joint basis and have no voting rights on the Board.

Failure to invite an observer or to send documents to an observer or observers prior to the meeting of the Board of Directors may in no case constitute grounds for nullity of the decisions taken by the Board of Directors.

### ARTICLE 18 - POWERS OF THE BOARD OF DIRECTORS

The Board of Directors sets the business strategy of the Company and ensures that this is implemented.

Save for the powers expressly reserved to the Shareholders' Meetings and within the scope of the corporate purpose, the Board of Directors considers any matter relating to the proper operation of the Company and through its deliberations, deals with matters affecting it.

In its relations with third parties, the Company assumes an obligation, even for actions of the Board of Directors that do not fall within the scope of the corporate purpose, unless it can prove that the third party was aware that the action exceeded that scope, or, under the circumstances, must have been aware, although the simple publication of the Articles of Association will not suffice as proof.

The Board of Directors will proceed with the controls and verification that it deems appropriate.

Each director must receive the information necessary to perform his duties and may obtain from Executive Management all documents he/she considers useful.

The Board of Directors may decide to set up working groups to look into any matters referred to them by the Board or its Chairman.

### ARTICLE 19 - EXECUTIVE MANAGEMENT - DELEGA-TION OF POWERS

#### I. Organizational principles

In accordance with the legal provisions, Executive Management of the Company is led, on behalf of the Company, either by the Chairman of the Board of Directors or by another natural person appointed by the Board of Directors and bearing the title of Chief Executive Officer.

The choice between the two methods of Executive Management is made by the Board of Directors, which must inform the shareholders and third parties subject to the regulatory requirements.

The decision of the Board concerning the choice of Executive Management method is taken by a majority vote of the directors present or represented, subject to the specific provisions of Article 17-III where directors attend the meeting by videoconference or other means of telecommunication.

A change in the Executive Management method does not result in a change to the Articles of Association.

Where Executive Management of the Company is led by the Chairman of the Board of Directors, the following provisions relating to the Chief Executive Officer are applicable to him.

#### II. Executive Management

### Chief Executive Officer

Depending on the choice made by the Board of Directors in accordance with the provisions of the above paragraph, Executive Management of the Company is led by the Chairman of the Board of Directors, or by a natural person, who may or may not be a director, appointed by the Board of Directors and bears the title of Chief Executive Officer.

Where the Board of Directors chooses to separate the functions of Chairman and Chief Executive Officer, it will proceed to appoint the Chief Executive Officer, define his term of office, determine his compensation and, as necessary, the limits to his powers.

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A person over the age of eighty-five (85) years may not be appointed as Chief Executive Officer. If a Chief Executive Officer in office reaches this age he is deemed to have officially resigned.

The Chief Executive Officer may be removed from office at any time by the Board of Directors. Where the Chief Executive Officer does not perform the role of Chairman of the Board of Directors, his removal may be subject to payment of compensation if this takes place without good cause.

The Chief Executive Officer is invested with the highest powers to act in all circumstances on behalf of the Company. He exercises these powers within the scope of the corporate purpose, save for those which the law expressly reserves to Shareholders' and Board of Directors' meetings.

He represents the Company in its relations with third parties. The Company assumes an obligation, even for actions of the Chief Executive Officer that do not fall within the scope of the corporate purpose, unless it can prove that the third party was aware that the action exceeded that scope, or, under the circumstances, must have been aware, although the simple publication of the Articles of Association will not suffice as proof.

In respect of the shareholders and without this restriction being binding upon third parties, the Chief Executive Officer may not take any decision on behalf of the Company in the following areas without the prior authorization of the Board of Directors:

- securing loans or advances in order to acquire shares or securities of any subsidiary company except where such subsidiary is wholly-owned;
- granting guarantees on behalf of a subsidiary or to guarantee bank accounts;
- all investments in excess of €250,000;
- all commitments in excess of €100,000 and not provided for in the annual budget;
- hiring, laying off and amending the contracts of employment of employees at management level;
- a change in the normal business of the Company and in its development strategy;
- disposing, transferring, licensing or pledging any industrial or intellectual property or any substantial asset;
- approving the budget and the strategic plan.

The Chief Executive Officer may not, without a prior decision of the Board of Directors by a qualified majority of three quarters of the directors making up the Board as at the date that the decision is taken:

- take any decision to proceed with the transfer of any substantial asset or any intellectual/industrial property belonging to the Company;
- take any decision to acquire a holding in a listed or unlisted company.

**Deputy Chief Executive Officers** 

At the proposal of the Chief Executive Officer, whether this function is assumed by the Chairman of the Board of Directors or by another person, the Board of Directors may appoint one or more natural persons, known as Deputy Chief Executives Officers, who may or may not be chosen from among the directors and shareholders, who are charged with assisting the Chief Executive Officer. The number of Deputy Chief Executive Officers may not exceed five. If the Deputy Chief Executive Officer is a director, his/her term of office may not exceed that of his/her term of office as a director.

A person over the age of eighty-five (85) years may not be appointed as Deputy Chief Executive Officer. If a Deputy Chief Executive Officer in office reaches this age he/she is deemed to have officially resigned.

Deputy Chief Executive Officers may be removed at any time by the Board of Directors at the proposal of the Chief Executive Officer. Removal without just cause may give rise to damages.

By agreement with the Chief Executive Officer, the Board of Directors decides on the scope and the duration of the powers granted to the Deputy Chief Executives. The Deputy Chief Executive Officers have the same powers in respect of third parties as the Chief Executive Officer.

Where the Chief Executive Officer ceases or is prevented from performing his duties, the Deputy Chief Executive Officers will retain their functions and powers until the new Chief Executive Officer is appointed, unless otherwise decided by the Board.

The Board of Directors decides on the compensation of the Deputy Chief Executive Officers.

#### III. Delegation of powers

The Board of Directors may entrust to its corporate officers, who may or may not be directors, the permanent or temporary duties it decides upon, delegate powers to them and set the compensation it considers appropriate.

### **ARTICLE 20 - DIRECTORS' COMPENSATION**

The Shareholders' Meeting may allocate to the directors, to compensate them for their work, by way of directors' fees, a fixed annual sum defined by the meeting, without being bound by previous decisions. The amount is posted to operating expenses.

The Board of Directors freely distributes among its members the total amounts allocated to the directors as directors' fees; it may in particular allocate a higher share to directors who are members of working groups than to other directors.

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The Board of Directors may award exceptional compensation for the duties or mandates entrusted to directors.

The Board of Directors may authorize the reimbursement of travel and subsistence costs and expenses incurred by the directors in the interests of the Company.

### ARTICLE 21 - AGREEMENTS BETWEEN THE COM-PANY AND A DIRECTOR, THE CHIEF EXECUTIVE OFFICER OR A DEPUTY CHIEF EXECUTIVE OFFICER

### I. Agreements submitted for authorization

Except for those relating to day to day operations and entered into under normal conditions, any agreement that is made, directly or through a nominee, between the Company and one of its directors, Chief Executive Officers or Deputy Chief Executive Officers, or a shareholder holding more than 10% of the voting rights in the Company, or in the case of a shareholding company, the Company controlling it pursuant to Article L.233-3 of the French Commercial Code, must be referred to the Board of Directors for prior authorization.

The same applies to agreements in which one of the persons referred to in the above paragraph has an indirect interest.

Agreements entered into by CARMAT and another company are also subject to prior authorization if they are with a company where the Chief Executive Officer, one of the Deputy Chief Executive Officers or one of the directors of CARMAT, is the owner, partner with unlimited liability, manager, director, member of the supervisory committee or, generally speaking, an executive of the other company.

Such agreements must be authorized and approved in accordance with the statutory provisions.

#### II. Prohibited agreements

It is prohibited, on pain of nullity of the contract, for directors other than those who are legal entities, to contract for loans of whatever kind with the Company, to have an overdraft granted by it, on a current or other account, or to have it act as guarantor or stand surety for undertakings by them to third parties.

The same prohibition applies to the Chief Executive Officer, Deputy Chief Executives and permanent representatives of directors in the form of legal entities. It also applies to the spouses, ascendants and descendants of the persons mentioned in this Article and to any nominee.

### III. Current agreements

Agreements relating to current and ordinary transactions and agreements concluded between two companies, one of which holds, directly or indirectly, the whole capital of the other, if any, less the minimum number of shares required to satisfy the requirements of Article 1832 of the French Civil Code or Articles L.225-1 and L.226-1 of the French Commercial Code are not subject to the legal authorization and approval procedure. However, these agreements, unless as a result of their subject-matter or their financial implications they are not significant for any of the parties, must be reported to the Chairman of the Board of Directors by the interested party. A list and subject-matter of such agreements are provided by the Chairman to the members of the Board of Directors and to the auditors at the latest on the day of the meeting of the Board to approve the financial statements for the year ended.

Shareholders may also be sent the list and subject-matter of these agreements.

# 5.4.3 RIGHTS, PRIVILEGES AND RESTRICTIONS ATTACHED TO SHARES (ARTICLES 9 - 14 OF THE ARTICLES OF ASSOCIATION)

#### ARTICLE 9 - DEPRECIATION OF THE SHARE CAPITAL

The share capital may be depreciated in accordance with the provisions of Articles L.225-198 et seq. of the French Commercial Code.

### **ARTICLE 10 - SETTLEMENT OF SHARES**

At the time of a capital increase, cash shares are settled, upon subscription, for at least a quarter of their face value and, as appropriate, the full share premium.

Settlement of the balance must take place on one or more occasions at the call of the Board of Directors and within five years of the date when the transaction becomes definitive in the case of an increase in capital.

Calls for funds are announced to the subscribers and shareholders at least two weeks prior to the date set for payment by individual registered letter with acknowledgment of receipt.

A shareholder who does not make the required payments for shares on the due dates will be liable to pay the Company, automatically and without prior warning, delay interest calculated on a daily basis from the due date at the legal rate for commercial court matters plus three points.

In order to obtain payment of these sums, the Company is entitled to take the enforcement action and apply the

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sanctions provided for by Articles L.228-27 et seq. of the French Commercial Code.

#### **ARTICLE 11 - FORM OF SHARES**

Ordinary shares are in registered or bearer form depending on the shareholder's choice. They can take the bearer form only after they are fully paid up. Fully paid-up preference shares are registered.

The Company is authorized to identify holders of bearer shares by simple request, to the body in charge of clearing securities, of the name or company name, nationality, year of birth or establishment, shareholders' addresses or number of shares held by each of them.

### ARTICLE 12 - TRANSFER OF SHARES - RIGHTS AND OBLIGATIONS ASSOCIATED WITH SHARES -THRESHOLD CROSSING

#### 12.1. Transfer of shares

The ordinary shares may be freely traded once issued in accordance with the procedures set out by law.

They remain tradable following the winding up of the Company and until liquidation is complete. Preference shares are transferable in accordance with paragraph 12.2.

Ordinary shares and the preference shares give rise to a book entry and are transferred by a movement between accounts under the conditions and according to the procedures set out in the law and the rules in force.

The provisions of this Article are generally applicable to all securities issued by the Company.

### 12.2. Rights and obligations attached to shares

The share capital of the Company is composed of Ordinary Shares and Preference Shares.

Shareholders are only liable for social liabilities up to the amount of their contributions.

#### I. Rights attached to ordinary shares

Without prejudice to the rights attached to the preferred shares, each ordinary share entitles the holder to a share in the profits and in the share capital in proportion to the portion of share capital it represents. It gives the right to participate, under the conditions set by the law and the present Articles of Association, in Shareholders' Meetings and to vote on resolutions.

The ownership of an ordinary share automatically entails unreserved compliance with the Articles of Association and decisions of the Shareholders' Meeting of the Company.

The rights and obligations attached to the ordinary shares remain the same regardless of the holder.

Whenever it is necessary to own more than one share to exercise a right, in case of exchange, consolidation, allocation of shares, capital increase or reduction, merger or any other operation, owners of individual securities or less than the required number can exercise these rights only if they make it their personal business to group and possibly purchase or sell the necessary number of securities.

#### II. Rights attached to preference shares

Preference shares and the rights of their holders are governed by the applicable provisions of the French Commercial Code, in particular Articles L.228-11 et seq.

The maximum number of preference shares that can be issued is:

- 7,600 for 2017 preference shares;
- 13,980 for 2018 preference shares; and
- 20,000 for 2019 preference shares.

Preference shares are classified into nine distinct classes according to the performance criteria attached to them:

- "AGAP 2017-01" for a maximum of 320;
- "AGAP 2017-02" for a maximum of 2,000;
- "AGAP 2017-03" for a maximum of 5,280;
- "AGAP 2018-01" for a maximum of 580;
- "AGAP 2018-02" for a maximum of 11,500;
- "AGAP 2018-03" for a maximum of 1,900;
- "AGAP 2019-01" for a maximum of 8,000;
- "AGAP 2019-02" for a maximum of 8,000; and
- "AGAP 2019-03" for a maximum of 4,000.

From the time of their vesting and until they become convertible, the preference shares have the right to vote at the Ordinary and Extraordinary meetings of ordinary shareholders, with one voting right per preference share. From the date on which they become convertible, the number of voting rights that each preference share entitles becomes equal to the number of ordinary shares to which the conversion of each preference share gives entitlement.

From the time of their vesting, preference shares shall have the right to vote at a special meeting of the holders of each class of preference shares. The holders of each class of preference shares shall meet in a special meeting for any proposed amendment to the rights attached to such class of preference shares. In addition, in accordance with the provisions of Article L.228-17 of the French Commercial Code, any proposed merger or demerger of the Company whereby preference shares could not be exchanged for shares with specific equivalent rights will be subject to the approval of the special meeting concerned.

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The quorum for special meetings will only be met if the shareholders present or represented possess at least one third of the preference shares with the right to vote on the first call and one fifth on the second call. In the event of a change or depreciation of the share capital, the rights of the holders of preference shares are adjusted in such a way as to preserve their rights pursuant to Article L.228-99 of the French Commercial Code. Other rights attached to preference shares are set out in the following paragraph.

From the time of their vesting and until they become convertible, the preference shares benefit from a dividend and give right to the reserves. The amount of the dividend (and, where applicable, the reserves) that each preference share entitles is equal to the amount due in respect of one ordinary share multiplied by the number of ordinary shares to which the conversion of each preference share gives right. For this purpose, the preference shares shall bear dividends from the first day of the financial year preceding the year in which they vest. From the date on which they become convertible, the amount of the dividend (and, where applicable, the reserves) that each preference share entitles becomes equal to the amount due in respect of one ordinary share multiplied by the number of ordinary shares to which the conversion of each preference share gives right.

From the time of their vesting, in the event of the liquidation of the Company, preference shares enjoy the same right to the liquidation bonus as ordinary shares, i.e., a right proportional to the share that their par value represents in the share capital.

From the time of their vesting, preference shares are entitled to pre-emptive subscription rights for any capital increase or any transaction with rights to the ordinary shares.

In the case of capital depreciation or reduction, changes in the distribution of profits, the allocation of free shares, capitalization of reserves, profits or share premiums, distribution of reserves or any issue of equity securities or securities giving right to the allocation of capital securities with a subscription right reserved for shareholders before the preference shares are convertible under the conditions set out in paragraph III below, the maximum number of ordinary shares that the preference shares may entitle by conversion shall be adjusted to take account of such transaction in accordance with the provisions of Article L.228-99 paragraph 2, 3° and paragraph 5 of the French Commercial Code.

For the purposes of this adjustment, the Board of Directors will calculate, at the time of fixing the final number of ordinary shares that each preference share entitles, the conversion ratio applicable according to the degree to which the performance criteria are met, such as provided for in paragraph III below, and adjust this ratio for all

transactions previously completed, in accordance with the above provisions.

Each beneficiary will be informed of the practical details of this adjustment and of its consequences on the allocation of ordinary shares on conversion of the preference shares he/she has been allocated.

After the preference shares have become convertible and the Board of Directors has calculated the conversion ratio as provided for in paragraph III below (as adjusted in accordance with this Article, if necessary), no adjustment shall be made to this conversion ratio, as the holders of preference shares may convert them freely thereafter. The preference shares will be fully paid up when they are issued by capitalizing the Company's reserves, premiums or profits.

# III. Conversion of preference shares into ordinary shares

The issue of preference shares may only be decided in the context of a free allocation of shares to employees and corporate officers of the Company in accordance with the provisions of Articles L.225-197-1 et seq. of the French Commercial Code.

The preference shares will vest (the "Vesting") to the beneficiaries at the end of a vesting period of one (1) year from their allocation by the Board of Directors (the "Provisional Allocation").

However, if the beneficiary has a disability classified under the second or third category provided for in Article L.341-4 of the French Social Security Code (or their equivalent in applicable foreign law), the preference shares will vest before the end of the remaining vesting period. In the event of the beneficiary's death, in accordance with the provisions of Article L.225-197-3 of the French Commercial Code, the beneficiary's heirs or successors may, if they wish, apply for the vesting of the preference shares within six months of the date of death. In the event of retirement, the beneficiaries will retain their right to the Vesting of preference shares even though they are no longer bound by a contract of employment.

Holders of preference shares may request conversion of their preference shares into new or existing ordinary shares (the Company's choice) of the Company as follows:

1. Preference shares become convertible by their holder into new or existing ordinary shares (Company's choice) at the end of a two year lock-up period beginning on the date of the Vesting (the "Lock-up Period") under the conditions set out in paragraphs 2 to 9 below. From the date they become convertible (the "Convertibility Date"), preference shares may be converted for five (5) years and three (3) months (the "Exercise Period").

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2. In accordance with the provisions of Article L.225-197-1 I, paragraph 7 of the French Commercial Code, preference shares will be freely transferable during the Lock-up Period if the beneficiary becomes disabled under the second or third category provided for in Article L.341-4 of the French Social Security Code (or their equivalent in applicable foreign law), regardless of whether the disability occurs before or after the Vesting Date.

In the event of the beneficiary's death, whether the beneficiary dies during the vesting period or the Lock-up Period, his/her heirs will no longer be required to comply with this non-transferability commitment, so the preference shares for which they requested vesting shall become freely transferable.

3. 2017 preference shares are classified into three distinct classes according to the performance criteria attached to them: "AGAP 2017-01", "AGAP 2017-02" and "AGAP 2017-03". The number of ordinary shares to which the conversion of a 2017 preference share will give entitlement will depend on whether one or more (or all) of the 2017 Performance Criteria have been met on the Convertibility Date (the "2017 Performance Criteria").

For the "AGAP 2017-01" 2017 preference shares, the 2017 Performance Criterion will be the definition of the Company's industrial development plan, which will give the right to convert each preference share into 100 ordinary shares.

For the "AGAP 2017-02" 2017 preference shares, the 2017 Performance Criterion will be the successful implantation of the bioprosthesis evaluated on a total of ten patients worldwide, which will give the right to convert each preference share into 20 ordinary shares.

For the "AGAP 2017-03" 2017 preference shares, the 2017 Performance Criteria will be as follows:

- i. the filing of the clinical module of the bioprosthesis'
   CE marking, which will give the right to convert each preference share into 15 ordinary shares;
- ii. bioprosthesis' CE marking, which will give the right to convert each preference share into 20 ordinary shares;
- iii. obtaining additional financing for the Company for a cumulative amount of €100 million between the Provisional Allocation Date and the Convertibility Date which will give the right to convert each preference share into 25 ordinary shares. Such financing may take the form of, in particular, capital increases, debt instruments, conditional advances, operating subsidies or revenues received from collaborative or licensing agreements;
- iv. the establishment of a production process that (i)
  meets the applicable regulatory and quality standards,
  and (ii) enables the production of a sufficient number
  of bioprosthesis' within a sufficient timeframe to carry
  out the necessary clinical trials and to respond to commercial orders in the contractual deadlines, without any
  major interruption of production or quality problems

leading to a recall of sold products, which will give the right to convert each preference share into 15 ordinary shares;

- v. the effective commercialization of the bioprosthesis at 15 European implantation centers, which will give the right to convert each preference share into ten ordinary shares;
- vi. the successful implantation of the bioprosthesis evaluated on ten patients in the United States, which will give the right to convert each preference share into ten ordinary shares;
- vii. the successful implantation of the bioprosthesis evaluated on 100 patients worldwide, which will give the right to convert each preference share into ten ordinary shares;
- viii. the change in the price of the ordinary share according to the following criteria, which will give the right to convert each preference share into a maximum of ten ordinary shares.

(a) If the Final Price is strictly lower than the Initial Price, the number of ordinary shares that each preference share will be converted into will be equal to zero;

(b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value below the Ceiling Price, the number of ordinary shares that each preference share will be converted into will be equal to:

[(Final Price / Initial Price) - 1] x 10

(c) If the Final Price is equal to or greater than the Ceiling Price, the number of ordinary shares that each preference share will be converted into will be equal to ten.

The "Final Price" is the highest average of the trading session closing prices of ordinary shares taken over a period of sixty consecutive days, calculated at any time during the three (3) years preceding the Convertibility Date.

The "Ceiling Price is equal to the Initial Price multiplied by three, and a maximum of €114.

The "Initial Price" is equal to the closing price of the ordinary share on the date of the Provisional Allocation, with a minimum of €30 and a maximum of €38 per ordinary share

The conversion ratio thus determined for each class of 2017 preference shares will be adjusted to take into account the shares to be issued to preserve the rights of holders of securities giving access to the share capital of the Company and holders of 2017 preference shares in accordance with the applicable legal and regulatory provisions and paragraph II above.

4. 2018 preference shares are classified into three distinct classes according to the performance criteria attached to them: "AGAP 2018-01", "AGAP 2018-02" and "AGAP

# INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

2018-03". The number of ordinary shares to which the conversion of a 2018 preference share will give entitlement will depend on whether one or more (or all) of the 2018 Performance Criteria have been met on the Convertibility Date (the "2018 Performance Critera"), with the 2017 Performance Criteria (together known as the "Performance Criteria").

For the "AGAP 2018-01" 2018 preference shares, the 2018 Performance Criterion will be will be the successful completion of the "prosthesis" test benches used to obtain the CE marking, which will give the right to convert each AGAP 2018-01 into 100 ordinary shares.

For the "AGAP 2018-02" 2018 preference shares, the 2018 Performance Criterion, which will give the right to convert each AGAP 2018-02 into 20 ordinary shares will be as follows:

- i. the recruitment of ten patients for the pivotal study to obtain the CE marking, which will give the right to convert each AGAP 2018-2 into ten ordinary shares;
- ii. the recruitment of the 20<sup>th</sup> patient for the pivotal study to obtain CE marking or the finalization of the pivotal study for submission of the dossier to Dekra, which will give the right to convert each AGAP 2018-2 into five ordinary shares;
- iii. obtaining authorization to complete the Early Feasibility Study in the US by December 31, 2018, which will entitle the holder to convert each AGAP 2018-2 into five ordinary shares.

For the "AGAP 2018-03" 2018 preference shares, the 2018 Performance Criteria will be as follows:

- i. the filing of the clinical module of the CE marking of the bioprosthesis, which will give the right to convert each AGAP 2018-03 share into 15 ordinary shares;
- ii. the CE marking of the bioprosthesis, which will give the right to convert each AGAP 2018-03 share into 20 ordinary shares;
- iii. obtaining additional financing for the Company for a cumulative amount of €38.5 million between the Provisional Allocation Date and the Convertibility Date which will give the right to convert each AGAP 2018-03 into 25 ordinary shares. Such financing may take the form of, in particular, capital increases, debt instruments, conditional advances, operating subsidies or revenues received from collaborative or licensing agreements;
- iv. the establishment of a production process that (i) meets the applicable regulatory and quality standards, and (ii) enables the production of a sufficient number of bioprosthesis' within a sufficient timeframe to carry out the necessary clinical trials and to respond to commercial orders in the contractual deadlines, without any major interruption of production or quality problems leading to a recall of sold products, which will give the right to convert each AGAP 2018-03 into 15 ordinary shares;

- v. the effective commercialization of the bioprosthesis at 15 European implantation centers, which will give the right to convert each AGAP 2018-03 into ten ordinary shares;
- vi. the successful implantation of the bioprosthesis evaluated on 10 patients in the United States, which will give the right to convert each AGAP 2018-03 into ten ordinary shares;
- vii. the successful implantation of the bioprosthesis evaluated on 100 patients worldwide, which will give the right to convert each AGAP 2018-03 into ten ordinary shares;
- viii. the change in the price of the common share according to the following criteria, which will give the right to convert each AGAP 2018-03 into a maximum of ten ordinary shares.
- (a) If the Final Price is strictly lower than the Initial Price, the number of ordinary shares in which each AGAP 2018-03 will be converted will be equal to zero;
- (b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value below the Ceiling Price, the number of ordinary shares that each AGAP 2018-03 will be converted into will be equal to:

[(Final Price / Initial Price) - 1] x 10

 c) If the Final Price is equal to or greater than the Ceiling Price, the number of ordinary shares that each AGAP 2018-03 will be converted into will be equal to ten.

The "Final Price" is the highest average of the trading session closing prices of ordinary shares taken over a period of sixty consecutive days, calculated at any time during the three (3) years preceding the Convertibility Date.

The "Ceiling Price is equal to the Initial Price multiplied by three, and a maximum of €114.

The "Initial Price" is equal to the closing price of the ordinary share on the date of the Provisional Allocation, with a minimum of €30 and a maximum of €38 per ordinary share.

The conversion ratio thus determined for each class of 2018 preference shares will be adjusted to take into account the shares to be issued to preserve the rights of holders of securities giving access to the share capital of the Company and holders of 2018 preference shares in accordance with the applicable legal and regulatory provisions and paragraph II above.

5. 2019 preference shares are classified into three distinct classes according to the performance criteria attached to them: "AGAP 2019-01" for a maximum number of 8,000, "AGAP 2019-02" for a maximum number of 8,000 and "AGAP 2019-03" for a maximum number of 4,000. The conversion of a 2019 preference share will give the right to ten

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ordinary shares if the performance criteria corresponding to the class in question have been achieved as at the Convertibility Date (together, the "Performance Criteria").

For the "AGAP 2019-01" 2019 preference shares, the Performance Criterion will be the success of the procedure on the first patient treated as part of the pivotal study in the United States following the positive conclusion of the Early Feasibility Study (EFS), which will give the right to convert each preference share into ten ordinary shares.

For the "AGAP 2019-02" 2019 preference shares, the 2019 Performance Criterion will be the obtaining of CE marking with sufficient inventory to support the commercial launch of the CARMAT prosthesis, which will give the right to convert each preference share into ten ordinary shares.

For the "AGAP 2019-03" 2019 preference shares, the Performance Criterion will be the invoicing and implantation of five prostheses within four months of the CE marking (excluding implantations as part of the innovation package in France), which will give the right to convert each preference share into ten ordinary shares.

The conversion ratio thus determined for each class of 2019 preference shares will be adjusted to take into account the shares to be issued to preserve the rights of holders of securities giving access to the share capital of the Company and holders of 2019 preference shares in accordance with the applicable legal and regulatory provisions and paragraph II above.

6. The achievement of each Performance Criterion shall be determined at a Board of Directors' Meeting held as soon as possible after completion of the Performance Criterion, which shall determine the number of ordinary shares entitled by each preference share at that date. As soon as possible after the Convertibility Date, the Board of Directors will meet to determine the final number of ordinary shares entitled by each preference share. The conversion ratio of AGAP 2017-03 and of AGAP 2018-03 may under no circumstances exceed 100, regardless of the number of Performance Criteria achieved.

However, in the event of a takeover bid or exchange on the ordinary shares:

- (i) taking place as of the Provisional Allocation Date,
- (ii) whose definitive results are announced no later than the day before the Convertibility Date, and
- (iii) being made at a price per share between the Initial Price and a ceiling equal to three times the Initial Price,

the Board of Directors will determine the number of ordinary shares entitled by the preference shares on the date of announcement of the final results of the offer exclusively under the following conditions:

- For each beneficiary, a number "p" equal to the ratio (i) of the aggregate number of ordinary shares entitling all

preference shares (all classes) which have been allocated to the beneficiary according to the achievement of the Performance Criteria at the date of the announcement of the final results of the bid, and (ii) the aggregate number of ordinary shares entitling all preference shares (all classes) if all Performance Criteria are achieved.

- If "p" is less than or equal to 0.35, the "N" number of ordinary shares entitling each of the preference shares (whichever class) allocated to the beneficiary will be calculated using the following formula:

$$N = [0.35 + 0.65*(R-1)/2]*n$$

N being capped at 100 for AGAP 2017-01, 20 for AGAP 2017-02, 100 for AGAP 2017-03, 100 for AGAP 2018-01, 20 for AGAP 2018-02, 100 for AGAP 2018-03 and 10 for AGAP 2019-01, 2019-02 and 2019-03.

n being equal to 100 for AGAP 2017-01, 20 for AGAP 2017-02, 100 for AGAP 2017-03, 100 for AGAP 2018-01, 20 for AGAP 2018-02, 100 for AGAP 2018-03 and 10 for AGAP 2019-01, 2019-02 and 2019-03.

With

R = (Acquisition Price) / (Initial Price)

The "Acquisition Price" is equal to the closing price of the ordinary share on the last day of the offering period, with a maximum of €114 per ordinary share.

The "Initial Price" is equal to the closing price of the ordinary share on the day of the allocation of preference shares, with a minimum of €30 for 2017 preference shares and 2018 preference shares and €22 for 2019 preference shares and a maximum of €38 per ordinary share for all preference shares.

- If "p" is greater than 0.35, N will be calculated according to the following formula:

$$N = [p + (1-p)*(R-1)/2]*n$$

knowing that, in any case, N can not be less than n\*0.35, i.e., 35 for AGAP 2014-01, 7 for AGAP 2017-02, 35 for AGAP 2017-03, 35 for AGAP 2018-01, 7 for AGAP 2018-02, 35 for AGAP 2018-03 and 10 for AGAP 2019-01, 2019-02 and 2019-03.

The preference shares concerned will vest to the beneficiaries on the Vesting Date, irrespective of whether or not a new attendance condition is provided for in the terms of the Preference Share Plan and of the Performance Criteria above. In any case, preference shares will only become convertible on the Convertibility Date.

7. If on the Convertibility Date none of the Performance Criteria has been achieved or if no takeover bid has been made under the conditions described above, the Company

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may (not an obligation) redeem the preference shares at any time at their par value.

Similarly, preference shares which may be converted but which have not been converted at the end of the Exercise Period, may (without this being an obligation for the Company) be bought at any time by the Company at their par value

- 8. At the end of the Exercise Period, the Company may, in accordance with the applicable legal and regulatory provisions, cancel preference shares not yet converted, including those which it has bought back. The share capital will then be correlatively reduced and creditors will have a right of opposition under the conditions provided for in Article L.225-205 of the French Commercial Code.
- 9. The new ordinary shares resulting from the conversion of the preference shares shall be assimilated to the ordinary shares in circulation and shall bear dividend from the first day of the financial year preceding the year in which the preference shares are converted and will confer on their holders, upon delivery, all rights attached to the ordinary shares. They will be the subject of a request for admission to trading on the Euronext Growth market on the same trading line as the ordinary shares.
- 10. The Board of Directors will recognize the conversion of the preference shares into ordinary shares for which the conversion is in accordance with the conditions set out above, take note of the number of ordinary shares resulting from the conversions of preference shares and amendments to the Articles of Association, in particular as regards the allocation of shares by class. This option may be delegated to the Chief Executive under the conditions laid down by law.
- 11. Shareholders will be informed of the conversions made through the reports of the Board of Directors and the Statutory Auditors provided for in Article R.228-18 of the French Commercial Code. These additional reports will be made available to the shareholders at the registered office as from the date each meeting is convened.
- 12. Capital increases resulting from the creation of preference shares and new ordinary shares will be carried out by special incorporation of all or part of available reserve accounts and, in particular, into the share premium account.

# 12.3. Threshold crossing

Any natural person or legal entity acting alone or together with others who comes to possess a number of shares representing a percentage of the share capital or the voting rights in excess of the thresholds set by law, will inform the Company within the statutory period, counting from when the holding threshold is crossed, of the total number of shares or voting rights held.

This information is also provided within the same time frames when the holding of share capital or voting rights drops below the thresholds mentioned in this paragraph.

A person required to provide this information will state the number of securities held giving access to the share capital and the voting rights attached to these.

If required by the rules of a securities market other than a regulated market on which the Company's securities are admitted for trading, this person will also inform the French Financial Markets Authority within a time frame and according to the arrangements set by the General Regulations of the latter, with effect from when the threshold to the holding is crossed. If necessary, this information is made public under the conditions laid down by the General Regulations of the French Financial Markets Authority.

Failure to make a due declaration under the above conditions will result in the shares exceeding the fraction that should have been declared by law having their voting right removed for any Shareholders' Meeting held within a period expiring two years after the date that the notification is dealt with.

Similarly, voting rights attached to these shares and which are not duly declared may not be exercised or delegated by the defaulting shareholder.

The commercial court having jurisdiction for the registered office, at the request of the Chairman of the Company, a shareholder or the French Financial Markets Authority, holds sole jurisdiction to pronounce a total or partial suspension, for a period not to exceed five years, of the voting rights of any shareholder who has not made the required declarations

# ARTICLE 13 - INDIVISIBILITY OF SHARES - BARE OWNERSHIP - USUFRUCT

1 - Shares are indivisible with respect to the Company.

Co-owners of undivided shares are represented at Share-holders' Meetings by one of these or by a single proxy. In the event of disagreement, the proxy is appointed by a court at the application of the most diligent co-owner.

2 - The voting right belongs to the usufructuary at Ordinary Shareholders' Meetings and to the bare owner at Extraordinary Shareholders' Meetings. However, shareholders may agree any other distribution of the voting right at Shareholders' Meetings. The agreement is notified by registered letter to the Company, which will be required to apply this agreement at any meeting that takes place following expiration of a period of one month after such letter is sent.

The voting right is exercised by the owner where securities are pledged.

# INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

# **ARTICLE 14 - DOUBLE VOTING RIGHT**

The voting right attached to capital or dividend shares is proportional to the percentage of the share capital that they represent. Each share gives entitlement to one vote.

However, a voting right that is double that conferred on other shares, having regard to the percentage of the capital that they represent, is attributed to all shares that are fully paid up, and which can be shown to have been registered to the same shareholder for at least two (2) years. This right is exercised subject to the provisions of No. 12.3 (5) of the Articles of Association.

This double voting right is also conferred from the time they are issued, in the event of an increase in capital through capitalization of reserves, profits or share premiums, upon registered shares in a scrip issue to a shareholder based on previous shares providing such an entitlement.

The transfer of a share as a result of succession, liquidation of community property between spouses or donation by living persons to a spouse or a parent entitled to inherit, does not result in the loss of the right acquired and does not interrupt the periods provided for above.

# **5.4.4** CONDITIONS FOR CHANGING SHAREHOLDERS' RIGHTS

The Articles of Association of the Company do not make

any special provision that derogates from general company law.

# 5.4.5 SHAREHOLDERS' MEETINGS (ARTICLES 24 TO 31 OF THE ARTICLES OF ASSOCIATION)

# **ARTICLE 24 - QUORUM AND MAJORITY**

Shareholders' Meetings deliberate under the conditions set by law.

The Ordinary Shareholders' Meeting takes all decisions other than those reserved to the Extraordinary Shareholders' Meeting by law and by these Articles of Association. The quorum will only be met at the first call if the shareholders present or represented hold at least one fifth of shares with voting rights. At the second call no quorum is required. It acts by a majority of the votes cast by the shareholders present or represented.

The Extraordinary Shareholders' Meeting alone has the power to modify any of the provisions of the Articles of Association. The quorum will only be met if the shareholders present or represented hold at least one quarter of shares with voting rights at the first call and one fifth of the shares at the second call. In the absence of the latter quorum, the second meeting may be postponed to a later date no more than two months after the date it was originally called. It acts by a two-thirds majority of the votes cast by the shareholders who are present or represented.

Where videoconferencing or other means of telecommunication permitted by law is used under the conditions set out in Article 25 below, shareholders are deemed present for the purposes of calculating a quorum or majority where they take part by such videoconferencing or other means of telecommunications.

# ARTICLE 25 - CALLING OF SHAREHOLDERS' MEETINGS

Shareholders' Meetings are called either by the Board of Directors, or by the Statutory Auditors, or by a proxy appointed by a court under the conditions and arrangements laid down by law.

They take place at the registered office or at any other location specified in the notice of the meeting.

Where shares in the Company are not traded on a regulated market or if all its shares are not registered shares, the Company is required to publish in the Bulletin des Annonces Légales Obligatoires (BALO - French Mandatory Legal Announcements Bulletin), at least thirty-five (35) days before the meeting, a notice of such meeting containing the information required by the current regulations in force.

Shareholders' Meetings are called by publication in a journal authorized to carry legal notices in the department where the registered office is based and also in the French Mandatory Legal Announcements Bulletin (BALO).

However, the publications referred to in the above paragraph may be replaced by a call made, at the cost of the Company, by normal or registered letter sent to each shareholder. Such a call may also be sent by electronic means of telecommunication employed under the regulatory conditions.

If this is decided by the Board at the time the meeting is called, any shareholder may also take part and vote in meetings by video-conference or by any other means of

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telecommunication allowing them to be identified, under the following conditions and according to the arrangements provided for by law and decree.

Any meeting not duly called may be canceled. However, it may not be canceled if all shareholders are present or represented.

# **ARTICLE 26 - MEETING AGENDA**

The agenda is set by whoever issues the notice of the meeting.

However, one or more shareholders representing at least 5% of the share capital (or an association of shareholders meeting the legal conditions) are empowered to request, under the conditions laid down by law, the inclusion in the agenda of draft resolutions. Such a request must be accompanied by the text of the draft resolutions which may be accompanied by a brief outline of the reasoning.

These draft resolutions, which must be brought to the attention of the shareholders, are included in the agenda and put to a vote of the meeting.

The meeting may not deliberate on a matter that is not included in the agenda.

However, it may under any circumstances remove one or more directors and proceed with their replacement.

The agenda may not be changed if the meeting has to be called a second time.

When the meeting is called upon to deliberate on changes to the economic or legal organization of the Company, in respect of which the works council has been consulted in accordance with Article L.2323-6 of the French Labor Code, the opinion of the council is made known to the meeting.

# **ARTICLE 27 - ADMISSION TO MEETINGS**

Any shareholder may participate personally, by proxy, or by postal vote in Shareholders' Meetings, of whatever kind.

A legal right of participation in Shareholders' Meetings exists:

- for registered shares, as a result of the entry of these in the books of registered shares kept by the Company at midnight at the start of the second working day prior to the meeting, Paris time;
- for bearer shares, as a result of the entry of these in the books of bearer shares kept by the authorized intermediary, at midnight at the start of the second working day prior to the meeting, Paris time.

The entry or registration of securities in the books of bearer shares kept by the authorized intermediary is acknowledged by a shareholding certificate issued by the latter.

However, the Board of Directors may reduce or remove these time frames, provided that it is in the interests of shareholders.

Shareholders who have not settled their shares by making the payments due are not admitted to meetings.

# ARTICLE 28 - REPRESENTATION OF SHAREHOLDERS AND POSTAL VOTING

# I. Representation of shareholders

A shareholder may be represented by another shareholder or by their spouse.

Any shareholder may be empowered by other shareholders to represent them at a meeting, without any restriction other than those resulting from the legal provisions setting the maximum number of votes that the same person may hold in their own name and as a proxy.

# II. Postal voting

Once the meeting has been called, a postal voting form and attachments will be sent, at the cost of the Company, to any shareholder who makes a written request for this.

The Company must comply with any request filed or received at the registered office at the latest six days prior to the date of the meeting.

# **ARTICLE 29 - OFFICERS FOR THE MEETING**

Shareholders' Meetings are chaired by the Chairman of the Board of Directors or, in his absence, by a director delegated for this purpose by the Board. Failing this, the meeting elects a chairman itself.

Where a meeting is called by the Statutory Auditors, a court-appointed proxy or by the liquidators, the meeting is chaired by whichever of these has called it.

The two attendees at such meeting holding the largest number of shares and accepting this function will act as vote tellers.

The officers for the meeting will appoint a secretary, who does not need to be a shareholder.

# **ARTICLE 30 - MINUTES OF MEETINGS**

The deliberations of Shareholders' Meetings are recorded in minutes drawn up by the meeting officers and signed

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by them.

These will state the date and place of the meeting, how it was called, the agenda, the composition of the group of meeting officials, the number of shares participating in the voting and the quorum achieved, the documents and reports submitted to the meeting, a summary of the proceedings, the text of the resolutions voted upon and the outcome of these votes.

The minutes are recorded in a special register kept at the registered office under the conditions laid down in the regulations.

If, in the absence of a quorum, a meeting is unable to deliberate properly, minutes to that effect are drawn up by the officers of said meeting.

# ARTICLE 31 - SHAREHOLDERS' RIGHT OF INFORMA-TION AND CONTROL

Before each meeting, the Board of Directors must provide shareholders with the documents necessary to allow them to speak in full knowledge of the facts and to come to an informed judgment on the functioning of the Company.

Upon receipt of the information referred to above, any shareholder will be entitled to submit written questions, to which the Board of Directors will be required to respond during the meeting.

At any time, any shareholder has an entitlement to receive the documents that the Board of Directors is required, as the case may be, to keep available at the registered office, or to send them, in accordance with the legislative and regulatory provisions in force.

5.4.6 PROVISIONS OF THE MEMORANDUM AND ARTICLES OF ASSOCIATION, CHARTER OR BYLAWS OF THE COMPANY THAT MAY DELAY, DEFER OR PREVENT A CHANGE IN ITS CONTROL

The Articles of Association of the Company do not make any special provision that derogates from general company law.

# 5.4.7 CHANGES TO THE SHARE CAPITAL (ARTICLE 8 OF THE ARTICLES OF ASSOCIATION)

1 - The share capital may be increased by any process and under any arrangements provided for by law.

Only an Extraordinary Shareholders' Meeting is competent to decide on an increase in capital based on a report from the Board of Directors.

Shareholders have a pre-emptive right, in proportion to the number of shares they hold, to subscribe to cash shares issued in order to increase the capital, and may waive this on an individual basis. The Extraordinary Shareholders' Meeting may decide to withdraw this pre-emptive subscription right in accordance with the statutory provisions.

2 - A reduction in capital is authorized or decided upon by the Extraordinary Shareholders' Meeting and may in no case adversely affect the equality of shareholders.

A reduction in capital to below the legal minimum may only be decided subject to the condition precedent of an increase in capital intended to bring this up to at least the legal minimum, unless the Company converts into another form of company that does not require capital in excess of the share capital after it has been reduced.

Failing this, any interested party may seek a legal order to wind up the Company. This may not be issued if, on the day on which the court rules on the merits of the case, the situation has been regularized.

# 5 5 INFORMATION ON THE LEGAL AFFAIRS OF THE COMPANY DURING THE FINANCIAL YEAR

# 5.5.1 INFORMATION ABOUT COMPANY CORPORATE OFFICERS AND CONTROL

## FREE SHARES AND STOCK OPTIONS

The historical allocation of stock options and share warrants to the various corporate officers of the Company, as well as the options and warrants they exercised during the 2019 financial year, are detailed in section 4.5.1.

The historical allocation of free shares (preference shares subject to performance conditions) to the various corporate officers, as well as the free shares that became available during the 2019 financial year, are detailed in section 4.5.1.

As at December 31, 2019, to the knowledge of the Company:

- Stéphane Piat (Chief Executive Officer and director) holds 10,900 shares in the Company (i.e., 0.09% of the share capital).
- The other current executive directors of CARMAT do not hold any shares in the Company.

## SHARE TRANSACTIONS BY EXECUTIVES

We indicate below the transactions made by executives and their relatives on the shares of the Company during the 2019 financial year, as declared by these executives and their relatives pursuant to the provisions of Articles 223-22 A and 223-26 of the AMF General Regulation.

We also indicate the transactions carried out by these same people of which we are aware.

Persons concerned	Transaction	Date of transaction	Number of shares	Value of transaction
Lohas (Pierre Bastid)	Pledge	June 12, 2019	1,291,709	€26,222k
Matra Défense (Airbus Group)	Subscription	September 18, 2019	336,842	€6,400k
Lohas (Pierre Bastid)	Subscription	September 18, 2019	157,894	€3,000k
Santé Holdings SRL (Antonino Ligresti)	Subscription	September 18, 2019	236,210	€4,488k

# 5.5.2 INFORMATION ON THE COMPANY'S SECURITIES

# **EMPLOYEE SHAREHOLDING**

In accordance with the provisions of Article L.225-102 of the French Commercial Code, we hereby indicate that the Company has not set up any company savings plan for the benefit of employees and that no agreement provides for employee participation in the share capital of the Company.

On the other hand, certain employees of the Company are beneficiaries of stock options, share warrants (BSA and BSPCE) and free shares (preference shares subject to performance conditions), detailed in section 4.5.1

Table 9 in section 4.5.1 specifies the number of stock options granted to the top ten employees who are not corporate officers, and the options exercised by these

beneficiaries during the 2019 financial year.

Table 10bis in section 4.5.1 specifies the number of free shares (subject to performance conditions) awarded to the top ten employees who are not corporate officers, and the free shares that vested to them during the 2019 financial year.

# **DEALINGS BY THE COMPANY IN ITS OWN SHARES**

We are also obliged to report to you on purchases and sales by the Company of its own shares for the purposes of regulating the price, in accordance with the provisions of Article L.225-209-1 of the French Commercial Code.

During the year ended December 31, 2019, the Company made the following transactions in its own shares under the liquidity agreement entered into for a period of one year with an independent financial services provider, as authorized by the Shareholders' Meetings of April 5, 2018

# INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

(9th resolution) and of March 28, 2019 (9th resolution):

- purchase of 112,881 shares at an average price of €20.39;
- sale of 110,972 shares at an average price of €20.34.

As at December 31, 2019, the Company held 4,170 treasury shares, i.e., 0.03% of the share capital.

## SECURITIES GIVING ACCESS TO CAPITAL

In total, these securities confer subscription rights to 1,314,700 new shares (10.44% of the existing capital as at

December 31, 2019).

For details on the securities giving access to the Company's share capital and currently valid, see section 5.2.5 "Other securities giving access to the share capital".

# PARTICIPATING AND CONTROLLING INTERESTS

In accordance with the provisions of Articles L.233-6 and L.247-1 of the French Commercial Code, we can report that the Company has not acquired any participating or controlling interests during the reporting period.

# 5.6 RELATED-PARTY AGREEMENTS

# 5.6.1 DESCRIPTION OF RELATED-PARTY AGREEMENTS

## **ROYALTIES AGREEMENT**

Under a royalties agreement signed on June 24, 2008 and amended by an addendum of February 5, 2010 between CARMAT, Professor Alain Carpentier and Matra Défense (a subsidiary of the Airbus Group) as a result of contributions made when the Company was established, it was agreed that CARMAT would pay Professor Alain Carpentier and Matra Défense a total sum equal to 2% of the direct net sales generated by the Total Artificial Heart in the countries covered by at least one of the patents initially contributed by them to the Company after obtaining CE marking and FDA authorization. These payments will be made on a half-yearly basis within thirty days of the end of each sixth-month period, according to a distribution between Professor Alain Carpentier and Matra Défense established in proportion to their holdings in the share capital of the Company on the date it was established.

However, CARMAT may repurchase this right to royalties by paying Professor Alain Carpentier and Matra Défense, in proportion to their holdings in the share capital of the Company on the date it was established, a total sum of €30 million less the amount of royalties already paid at the time this right to royalties is repurchased. This sum of €30 million is indexed-linked to the Production prices index for industry and services to companies – Medico-surgical and orthopedic material for export in the Eurozone PVIC Code 3310921007M with a base level of 100.3 in April 2008 as calculated and published by the French National Institute for Statistics and Economic Studies (INSEE).

# RELATIONS BETWEEN CARMAT AND THE SCIENTIFIC RESEARCH ASSOCIATION OF THE ALAIN CARPENTIER FOUNDATION

Owing to the specific competencies sought and historical relations, the Company maintains commercial relations with the Scientific Research Association of the Alain Carpentier Foundation (ARSFAC) in the normal conduct of its business and ordinary financial conditions for the type of services performed.

It thus signed a collaboration agreement for medical research with ARSFAC on April 30, 2013 which was since renewed and last renewed on July 24, 2019 for the period from January 1 to December 31, 2019. Under the terms of this agreement, the Company committed to repay ARSFAC all the costs mentioned in the appendices to said agreement. For the 2019 financial year, expenses of €20,460 excluding tax were recorded under this agreement.

# RELATIONS BETWEEN CARMAT AND THE MARIE LAN-NELONGUE SURGICAL CENTER (CCML)

Owing to the specific competencies sought, the Company maintains commercial relations with the Marie Lannelongue Surgical Center (CCML) in the normal conduct of its business and under ordinary financial conditions for the type of services performed.

It thus signed a collaboration agreement for medical research with CCML on June 12, 2014. Under the terms of this agreement, the Company undertook in particular to reimburse CCML for all the costs mentioned in the appendices to said agreement. For 2019, no expenses were recorded under this agreement.

As a reminder, Mr. Henri Lachmann, director of CARMAT, is

# INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

Chairman of the Board of Directors of CCML.

# 5.6.2 STATUTORY AUDITORS' SPECIAL REPORT ON RELATED-PARTY AGREEMENTS

This is a free translation into English of the Statutory Auditors' special report on related-party agreements and commitments issued in French and is provided solely for the convenience of English speaking readers. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

CARMAT SA 36, avenue de l'Europe 78941 Vélizy-Villacoublay cedex France

To the Shareholders,

In our capacity as Statutory Auditors of CARMAT, we hereby report to you on related-party agreements.

It is our responsibility to report to shareholders, based on the information provided to us, on the main terms and conditions of agreements that have been disclosed to us or that we may have identified as part of our engagement, as well as the reasons given as to why they are beneficial for the Company, without commenting on their relevance or substance or identifying any undisclosed agreements or commitments. Under the provisions of Article R.225-31 of the French Commercial Code (Code de commerce), it is the responsibility of the shareholders to determine whether the agreements are appropriate and should be approved.

Where applicable, it is also our responsibility to provide shareholders with the information required by Article R.225-31 of the French Commercial Code in relation to the implementation during the year of agreements already approved by the Shareholders' Meeting.

We performed the procedures that we deemed necessary in accordance with professional standards applicable in France to such engagements. These procedures consisted in verifying that the information given to us is consistent with the underlying documents.

# AGREEMENTS AND COMMITMENTS TO BE SUBMITTED FOR THE APPROVAL OF THE SHAREHOLDERS' MEETING

We were not informed of any agreement authorized and entered into during the year to be submitted for the approval of the Shareholders' Meeting pursuant to the provisions of Article L.225-38 of the French Commercial Code.

# AGREEMENTS ALREADY APPROVED BY THE SHARE-HOLDERS' MEETING

Agreements approved in previous years

a) that were implemented during the year

In accordance with Article R.225-30 of the French Commercial Code, we were informed of the following agreements, approved by the Shareholders' Meeting in previous years, which were implemented during the year.

RESEARCH COLLABORATION AGREEMENT WITH THE SCIENTIFIC RESEARCH ASSOCIATION OF THE ALAIN CARPENTIER FOUNDATION (ARSFAC)

A medical collaboration agreement was concluded with ARSFAC as of January 1, 2014. This agreement, renewed on July 24, 2019, covers animal training trials. Under the terms of this agreement, CARMAT undertakes to reimburse the costs incurred by ARSFAC as described in the appendix to the said agreement.

During the 2019 financial year, and under this agreement, CARMAT reimbursed ARSFAC an amount of €20,460 (taxes excluded).

Mr. Alain Carpentier, director of CARMAT until March 28, 2019, is a founding member and Chairman of the Board of Directors of ARSFAC.

b) that were not implemented during the year

In accordance with Article R.225-30 of the French Commercial Code, we were informed of the following agreements, approved by the Shareholders' Meeting in previous years, which were not implemented during the year.

RESEARCH COLLABORATION AGREEMENT WITH THE MARIE LANNELONGUE SURGICAL CENTER (CCML)

A collaboration agreement for the training of clinical teams was concluded with the CCML as of January 1, 2014. Under the terms of this agreement, CARMAT undertakes to reimburse the costs incurred by the CCML as described in the appendix to the said agreement.

No expenses were recorded under this agreement for the past financial year.

Mr. Henri Lachmann, director of CARMAT, is Chairman of the CCML Board of Directors.

# INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

ROYALTIES AGREEMMENT BETWEEN CARMAT (HEREIN-AFTER "THE COMPANY"), PROFESSOR ALAIN CARPEN-TIER AND MATRA DEFENSE

On June 24, 2008, the Company signed a royalty agreement (hereinafter the "Agreement") with Professor Alain Carpentier and Matra Défense, the founding shareholders of the Company. Under this Agreement, the Company undertakes to pay to Professor Alain Carpentier and Matra Défense 2% of the net sales proceeds of the CARMAT artificial heart manufactured and distributed by CARMAT SAS, this amount to be divided between the two beneficiaries in proportion to their respective share in the capital of the Company on the date of its creation. These royalties will be payable every 6 months within thirty days after the end of each six-month period, from the first marketing of the CARMAT Artificial Heart and until the expiration of the patents presented in Appendix 1 of the Agreement.

The Company is also authorized to repurchase at any time the right to benefit from these royalties for a sum of €30,000,000 less any royalties already paid under the agreement, with this total sum being shared between the two beneficiaries in proportion to their respective shares in the share capital of the Company on the date it was established. This amount of €30,000,000 is indexed to the Producer Price Index of the Business Services Industry-Euroarea orthopedic and orthopedic equipment.

The rights allocated to Professor Alain Carpentier and to Matra Défense in this way are non-transferable.

As at December 31, 2019, since CARMAT has not yet obtained the CE marking and the marketing authorization from the FDA, no royalty has been paid under the Agreement.

Signed in Neuilly-sur-Seine and Paris, March 12, 2020

The Statutory Auditors

PricewaterhouseCoopers Lison Chouraki

Audit Audit

Thierry Charron Lison Chouraki

# ADDITIONAL INFORMATION



# PERSON RESPONSIBLE FOR THE UNIVERSAL REGISTRATION DOCUMENT

6.1.1 NAME OF THE PERSON RESPONSIBLE FOR THE UNIVERSAL REGISTRATION DOCUMENT

Stéphane Piat, CARMAT's Chief Executive Officer, is the person responsible for the Universal Registration Document.

# 6.1.2 DECLARATION BY THE PERSON RESPONSIBLE FOR THE UNIVERSAL REGISTRATION DOCUMENT

"Having taken all reasonable steps to verify the content of this 2019 Universal Registration Document, I declare that the information contained therein is accurate to the best of my knowledge, and that no material information has been omitted.

I further declare that, to the best of my knowledge, the financial statements have been prepared in accordance with the applicable accounting standards and give a true and fair view of the Company's financial position and results, and that the management report, for which a cross-reference table appears in section 6.7.2 of this document, gives a true and fair view of changes to the business, results and financial position of the Company and that it describes the main risks and uncertainties it faces."

Vélizy-Villacoublay, March 12, 2020

Stéphane Piat Chief Executive Officer, CARMAT

# 6.2 STATUTORY AUDITORS

# 6.2.1 STATUTORY AUDITORS

<u>PricewaterhouseCoopers Audit</u>, registered member of the Compagnie régionale des Commissaires aux Comptes de Versailles

Represented by Thierry Charron

63, rue de Villiers - 92200 Neuilly-sur-Seine, France

Start of first term: the incorporation of the Company on June 25, 2008.

Duration of current term: six financial years, following renewal at the Shareholders' Meeting of June 24, 2015.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

<u>Lison Chouraki Audit</u>, registered member of the Compagnie des Commissaires aux Comptes de Paris

Represented by Lison Chouraki

3, rue Anatole de la Forge - 75017 Paris, France

Start of first term: June 24, 2015.

Duration of current term: six financial years.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

# 6.2.2 ALTERNATE STATUTORY AUDITORS

<u>Jean-Christophe Georghiou</u>, registered member of the Compagnie régionale des Commissaires aux Comptes de Versailles

63, rue de Villiers - 92200 Neuilly-sur-Seine, France

Start of first term: June 24, 2015.

Duration of current term: six financial years.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

<u>Soulika Benzaquen</u>, registered member of the Compagnie des Commissaires aux Comptes de Paris

5, rue de Prony - 75017 Paris, France

Start of first term: October 16, 2008.

Duration of current term: six financial years, following renewal at the Shareholders' Meeting of June 24, 2015.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

# **6.2.3** FORMER STATUTORY AUDITORS (RESIGNED, REMOVED OR NOT RE-APPOINTED)

Since appointment, the Statutory Auditors and their alternates have not been removed or resigned.

# **6.3**

# THIRD-PARTY INFORMATION, STATEMENTS BY EXPERTS AND DECLARATIONS OF ANY INTEREST

None.

# 6.4 AVAILABLE DOCUMENTS AND 2017-2018 HISTORICAL INFORMATION

Copies of this Universal Registration Document are available free of charge from the Company and from the Company's website (www.carmatsa.com) or the website of the French Financial Markets Authority – AMF (www.amffrance.org).

All documents that must be made available to shareholders (such as the Articles of Association, minutes of Shareholders' Meetings, historical financial information and the evaluations and opinions given by experts at the Company's request included or referred to in this Universal Registration Document) may be consulted at the Company's registered office at 36, avenue de l'Europe – 78140 Vélizy-Villacoublay, France.

All regulatory information, as defined in Article 221-1 of the AMF General Regulations, is available on the Company's website.

The historical financial information for the years ended December 31, 2017 and December 31, 2018 incorporated by reference into this document was previously presented in the 2017 Registration Document and the 2018 Registration Document, which were filed with the AMF on March 22, 2018 under number D.18-0169 and on March 12, 2019 under number D.19-0135, respectively, and was the subject of reports by the Statutory Auditors, which contained no observations.

# 6.5 INFORMATION ON HOLDINGS

At the date of this Universal Registration Document, the Company did not have any holdings in the share capital of other companies.

# 6.6 RECENT

Since the end of the 2019 financial year, the Company has published the following press releases:

- On February 5, 2020, a press release entitled: CARMAT announces FDA full approval to initiate US clinical feasibility study of its total artificial heart;
- On February 12, 2020, a press release entitled: CAR-MAT reports its 2019 annual results and confirms its 2020 objectives;
- On February 17, 2020, a press release entitled: CAR-MAT confirms the submission of a "Forfait Innovation" dossier in France and its eligibility with observations received from the French National Authority for Health (HAS);
- On March 10, 2020, a press release entitled: CARMAT announces that it has achieved record individual support of 2 years with its bioprosthesis.

The full text of these press releases may be viewed on the Company's website, https://www.carmatsa.com/en/documentation/?p\_thema=press-release.

CARMAT plans to communicate on the overall progress of the CE marking or on the completion of significant milestones in its clinical trials. In accordance with good clinical practice and subject to regulatory requirements or special circumstances, CARMAT will not communicate on patient implants and the health of said patients individually.

# ADDITIONAL INFORMATION

# 6.7 CROSS-REFERENCE TABLES

# 6.7.1 UNIVERSAL REGISTRATION DOCUMENT CROSS-REFERENCE TABLE

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 1.2. Declaration by the person responsible
 1.3. Experts' reports
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 Not applicable

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**SECTION 2** 

# STATUTORY AUDITORS

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	Mark and Parallala

14.1. Management and administration of the issuer
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<sup>\*</sup> To the best of the Company's knowledge, there is no litigation, arbitration, governmental or judicial procedure, or exceptional event, likely to have or having had in the last 12 months significant effects on the financial position or profitability of the Company.

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# 6.7.2 ANNUAL FINANCIAL REPORT CROSS-REFERENCE TABLE

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# 6.8 GLOSSARY

# Stroke

Sudden neurological damage due to blockage of blood flow or hemorrhage in the brain.

# Actuator

A device that controls the movement of a fluid or a solid.

# Clinical Trial Authorization (CTA)

Authorization issued by the French national agency that evaluates drug safety (Agence Nationale de sécurité du Médicament - ANSM). One of two authorizations required

to carry out biomedical research on humans in France, the other being that of the Patient Protection Committee (Comité de Protection des Personnes - CPP) (see corresponding entry).

# **AFSSAPS**

French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Aliments et Produits de Santé). This agency evaluates and monitors the safe use of health products, examines their quality in the laboratory and inspects production, distribution and testing sites. It also

# **ADDITIONAL INFORMATION**

produces information campaigns to ensure the correct use of health products. It was replaced by the ANSM (see corresponding entry) by French Law no. 2011-2012 of December 29, 2011.

# **Annuloplasty**

Procedure to tighten or reinforce the mitral valve.

## ANSM

French National Drug and Health Product Safety Agency (Agence nationale de sécurité du médicament et des produits de santé). This French public institution's objective is to evaluate the health risks of health products for humans. It has authority over the regulation of biomedical research.

# Platelet aggregation inhibitor

Drug preventing blood platelets, which are partly responsible for blood coagulation (see corresponding entry), from sticking together and forming the beginning of a clot. The best known is aspirin.

# <u>Anticoagulant</u>

Drug limiting blood-clotting to avoid the formation of clots by acting on coagulation factors other than platelets (see corresponding entry). Dosages are complex: too much risks hemorrhage, not enough risks thromboembolic events. Use at high dosage is required for all metal or plastic implanted devices that are not hemocompatible and are the source of numerous complications.

# Aorta

The aorta is the body's largest artery, supplying oxygenated blood from the left ventricle to all parts of the body.

# Pulmonary artery

Arteries that carry blood from the heart to the lungs.

# Beta blockers

Drugs which reduce the cardiac rhythm and output to decrease blood pressure.

# Bioprosthetic (valves) or bioprosthesis

An artificial valve made from animal tissue in order to replace a failing heart valve. By extension, a medical device containing animal tissue.

# **Bpifrance**

French public investment bank (Banque Publique d'Investissement française), which now includes the activities of Oseo Innovation (formerly ANVAR), aiming to promote innovation through financial guarantees and partnerships.

# Cardiogenic shock

Inability of the myocardial pump function to generate adequate blood flow to the peripheral organs.

# Coagulation (blood)

Blood clot formation. This is the body's normal reaction to stop blood loss. However, when clots form in the heart, a

blood vessel or in an implanted device, they may obstruct blood flow and cause a pulmonary embolism or cerebrovascular accident.

# Total orthotopic artificial heart

A total artificial heart (TAH) is a device that replaces the natural heart. It is different from a ventricular assistance device, which supports the function of a diseased heart.

# Critical Event Committee (CEC)

Committee made up of members who are completely independent from the sponsor and study investigators, established as part of the ISO 13485 standard and the Good Clinical Practice (GCP) guidelines. The Committee's role is to review all adverse events, serious or otherwise, and to determine their causal link with the device under investigation.

# <u>Patient Protection Committee (Comité de Protection des Personnes - CPP)</u>

The Patient Protection Committee's role is to ensure that all biomedical research projects on humans carried out in France comply with medical, ethical and legal considerations aimed at ensuring the protection of the persons participating in the research.

# Data Safety and Monitoring Board (DSMB)

Board made up of members who are completely independent from the sponsor and study investigators, established as part of the ISO 13485 standard and the Good Clinical Practice (GCP) guidelines. The Board's role is to review all study data and issue an opinion to the sponsor on whether to continue the inclusion of subjects in the clinical study.

# **Compliance**

In medical terms, the ability of a hollow organ to change volume under the influence of a variation in pressure.

# Research Tax Credit (RTC)

Financial aid created to encourage research and development efforts within companies.

# <u>Diastole</u>

The period of relaxation of the muscle tissue of the chambers of the heart that allow them to fill with blood.

# Diuretic

Drug that removes excess fluids, to decrease pressure on the heart and prevent pulmonary edema.

# <u>Pulmonary embolism</u>

Situation where a blood clot blocks a pulmonary artery.

# Ex vivo

Refers to tests which are performed on cadavers (see in vivo).

# ADDITIONAL INFORMATION

# **Etiology**

The study and analysis of the causes of diseases.

# US Food and Drug Administration (FDA)

Regulatory agency that authorizes the marketing of drugs and medical devices in the United States.

# Reduced ejection fraction

Terminal chronic heart failure in patients with an ejection fraction measurement under 40%.

# **Humanitarian Device Exemption (HDE)**

FDA approval process allowing a device to be marketed without evidence of effectiveness (only data relating to the safety of the device are required). The FDA calls a device approved in this way a Humanitarian Use Device (HUD). This approval limits the number of devices that can be released on the US market to 4,000 per year.

## Red blood corpuscles

Red blood cells.

# **Hemocompatibility**

A measure of the compatibility between non-living materials used in medical devices that are in contact with blood and other organs.

# **Hemolysis**

Destruction of red blood cells, releasing hemoglobin into the blood plasma and reducing oxygen-carrying capacity.

# **HUD**

See Humanitarian Device Exemption (HDE).

# **Hyperlipidemia**

Condition caused by abnormally high levels of fat in the blood.

# High blood pressure

Condition associated with cardiovascular disease characterized by arterial pressure greater than normal levels, causing an increase in the left ventricular volume.

# **Hypertrophy**

Excessive growth of an organ or body tissue.

# Investigational Device Exemption (IDE)

Approval process allowing a device to be used during a clinical study with the aim of generating the safety and efficacy data required to obtain PMA.

# <u>Immunosuppressant</u>

Drugs that limit the body's immune reactions in order to reduce rejection risk following a transplant. The most well known is cyclosporin.

# Incidence

The number of new cases of a disease observed during a given period and in a specific population. It differs from

the prevalence, which is a status measurement that counts all cases (new or not) at a given time.

# Myocardial infarction

Necrosis (death) of part of the cardiac muscle. In plain language, a heart attack. It occurs when one or more coronary arteries become blocked slowing the flow of blood, and therefore oxygen, to the cells of the myocardium (the muscular tissue of the heart), causing them to suffer (painful sensation) and potentially die.

Angiotensin-converting enzyme (ACE) inhibitors

Drugs reducing vascular resistance.

## Inotrope

Drug increasing the force of heart muscle contractions. Dependence on inotropes marks the terminal phase of heart failure.

## In silico

Refers to tests that are performed on computers and/or by digital simulation.

# Acute heart failure

Sudden inability of the heart to provide sufficient blood flow and supply oxygen to the organs. The symptoms are severe. It occurs either following a heart attack (see myocardial infarction) that caused lesions to an area of the heart, or following a sudden incapacity of the body to compensate for chronic cardiac insufficiency (see chronic heart failure).

# Chronic heart failure

The incapacity of the heart to provide sufficient blood flow to deal with the oxygen needs of the various organs. The main causes of chronic heart failure are angina and myocardial infarction, high blood pressure, valvular heart disease and myocardial degeneration. In each of these cases, the result is the progressive destruction of the cardiac muscle with loss of its ability to contract.

# In vitro

Refers to tests that take place outside the organism, in the laboratory or on a test bench. Originally, these tests were carried out in glass tubes.

# <u>In vivo</u>

Refers to tests which are performed in living organisms (see also ex vivo).

# <u>Ischemia</u>

Decrease of the arterial blood flow to an organ.

# Coronary disease

Decrease in the power of one or more arteries of the heart (coronary arteries), resulting in angina and myocardial infarction (heart attack).

# **ADDITIONAL INFORMATION**

# **CE** marking

A declaration by the manufacturer certifying that the product complies with the applicable legal requirements and European directives (meeting a number of conditions including safety, efficacy and traceability).

## Mitral valve

Valve in the heart that separates the left atrium from the left ventricle.

# New York Heart Association (NYHA) Classification

A scale based on symptoms that aims to quantify and monitor the functional impact (on activity) of cardiac insufficiency for an individual.

## ISO standards

Standards created by the International Organization for Standardization (ISO) in order to guarantee reliable and good quality products and services.

# Pulmonary edema

Pulmonary alveoli fill with blood plasma that has passed through the walls of capillaries (small blood vessels). Acute pulmonary edema (APE) is a medical emergency and typically results in cardiac decompression.

# **Medical Board**

Professional, administrative and legal body for the defense and regulation of the medical profession.

# Atrium

One of the two small upper chambers of the heart that receive blood before passing it into the corresponding ventricle. Each atrium communicates with the corresponding ventricle through an atrioventricular valve, the tricuspid valve on the right and the mitral valve on the left.

# **Orthotopic**

Refers to the transplantation of an organ to its normal anatomical location.

# Chemically treated animal pericardial tissue

A double-walled sack that contains the heart and the roots of the large blood vessels of animal origin (bovine, porcine or equine) treated with a sterilizing fixative, glutaral-dehyde. Known to be the least thrombogenic biomaterial and does not bring about transplant rejection.

# Fuel cell

Cell in which electricity is produced through the oxidation on an electrode of a reduction fuel (for example hydrogen) coupled with the reduction on the other electrode of an oxidant, such as oxygen from the air.

# Pre-Market Approval (PMA)

FDA approval process before the marketing of a device. It requires exhaustive safety and effectiveness data, notably by means of a clinical study (IDE).

# **Prevalence**

Measurement of the state of health of a population at a given time, which can be expressed as a percentage. For a given pathology, the prevalence is obtained by dividing the number of people affected at a given time by the size of the total population.

# Product Lifecycle Management (PLM)

Software used to create and maintain product definition throughout their life cycle, from initial offering to end of useful life. PLM covers the management of product definition, including configuration, development and project management.

# Polyetheretherketone (PEEK)

A high-performance plastic with a unique combination of properties used for its strength in the medical, aeronautical, automobile, electronics, food and industrial sectors.

## Polyurethane

A plastic material used in varnishes, paints and synthetic rubbers obtained through polymerization.

## Proteinio

Concerning proteins.

## Pulsatile

Rhythmic pulsations of the heart beat.

# Cleanroom

Room or suite of rooms where the concentration of particles is controlled in order to minimize the introduction, generation and retention of particles inside, generally with a specific industrial or research aim. Factors such as temperature, humidity and relative pressure are also maintained at a precise level.

# Human whole blood

Unprocessed blood containing plasma, red blood cells, white blood cells and platelets.

# Septicemia

Serious generalized infection when bacteria from a local infection enter the bloodstream of an organism.

# Hardware-in-the-Loop (HIL) simulation

Real-time simulation that makes computers believe they are navigating the actual system.

# <u>Stasis</u>

In medical terms, this refers to the abnormal stagnation of blood in an organ.

# Systole

Contraction phase of the chambers of the heart muscle to eject the blood it contains.

# <u>Telemetry</u>

Means of monitoring certain biological, particularly cardio-respiratory, or technical factors, remotely.

# **ADDITIONAL INFORMATION**

# **Thrombosis**

Obscuration, through the formation of a clot (thrombus), of an artery, vain or cardiac chamber (embolism). The blood no longer flows or supplies organs.

# **Thromboembolism**

Condition characterized by the formation of blood clots in veins (thrombus) which, upon detaching, may cause embolisms (sudden blockages of blood vessels).

<u>Thrombogenic, thrombogenicity</u>
Refers to causing a thrombus (blood clot).

# **Destination Therapy (DT)**

Definitive implantation, as opposed to bridge therapy.

# **Transplantation**

Surgical operation consisting in replacing a diseased organ with a healthy one.

# Vasodilator

Drug which relaxes blood vessels to increase the blood and oxygen flow to the heart without increasing its workload.

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