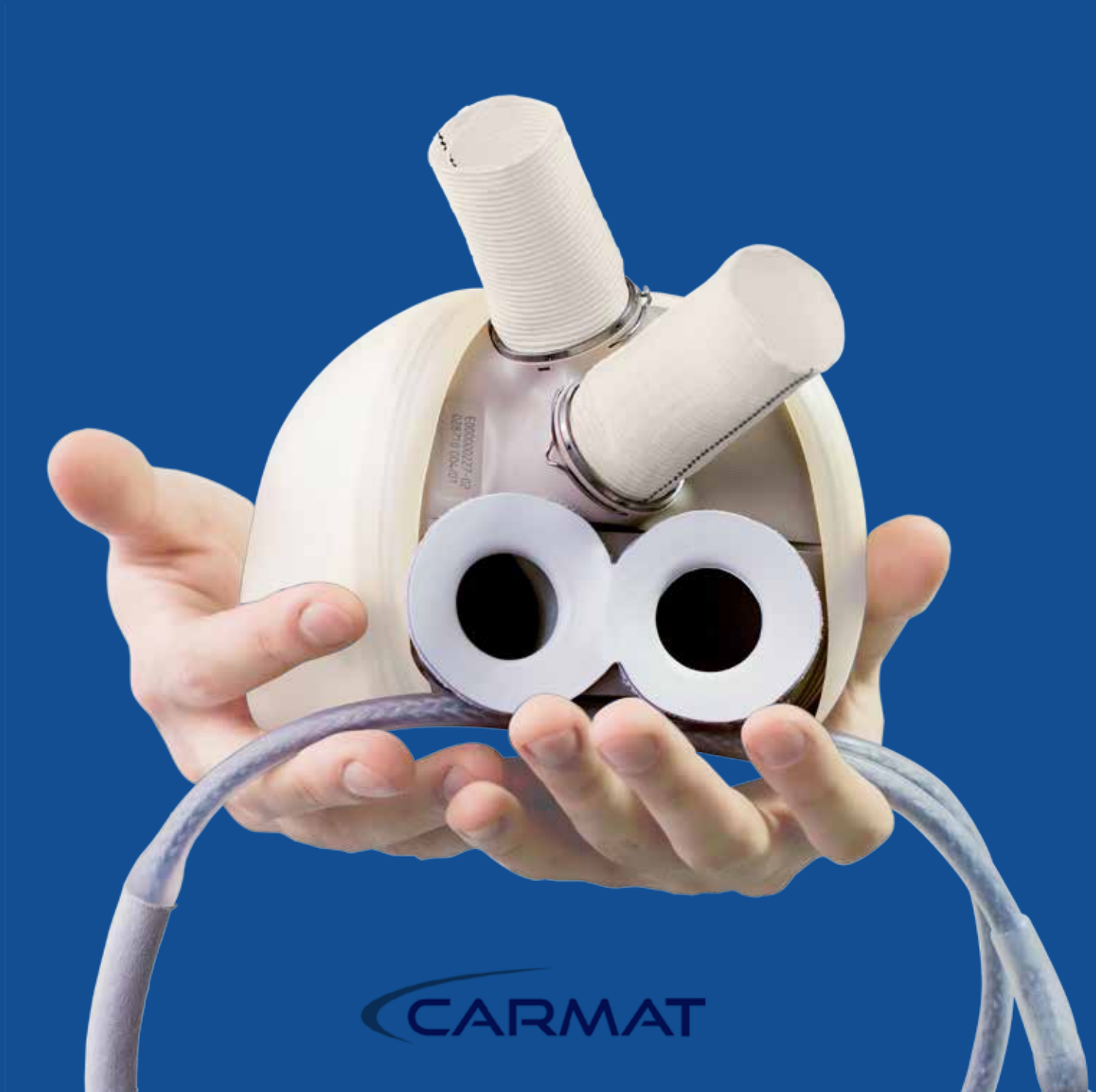
CARMAT

2017 Registration document

Including Annual Financial Report



GENERAL REMARKS

In this registration document, the terms “CARMAT” or the “Company” shall mean the company, CARMAT.

This registration document contains information on the Company’s objectives and its avenues for development. This information is sometimes identified by the use of the future or the conditional, and terms that refer to the future, such as “consider”, “envisage”, “think”, “have as an objective”, “expect”, “intend”, “must”, “aspire”, “estimate”, “believe”, “wish”, “can” or, where appropriate, the negative form of these verbs, or any other variation or similar terminology.

The reader’s attention is drawn to the fact that these objectives and avenues for development depend on circumstances or events which may or may not occur.

These objectives and avenues for development are not historical data and must not be interpreted as guarantees that the events and data set out will occur, that the hypotheses will be verified or that the objectives will be achieved.

By their very nature, the objectives and avenues for development in this 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 the factors set out in Chapter 2, “Risk Factors”, of this registration document. It is therefore possible that these objectives and avenues for development may not be achieved, and the statements or information in this registration document may turn out to 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 (AMF).

This registration document also contains information relating to the Company’s activity, 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, public bodies and corporations 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”, in this registration document. If some or all of the risks materialize, this could have a negative impact on the Company’s activity, its position, its financial performance or its objectives.

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

Drawings, images, graphics 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 registration document has a glossary attached. Words identified by an asterisk “*” when they first appear can be found in this glossary. A summary of references used in the document and their sources is provided at the end of the document.

This registration document (document de référence) was filed with the Financial Markets Authority (AMF) on March 22, 2018 in accordance with Article 212-13 of the General Regulations of the Authority. It may be used in connection with a financing operation if it is supplemented by a securities note signed by the Financial Markets Authority. This document has been drawn up by the issuer and liability is borne by its signatories.

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

Items forming part of the Corporate Governance Report are available within the 4.1, 5.6, 5.2.6 and 4.4.3 paragraphs

MESSAGE FROM THE CHAIRMAN

JEAN-CLAUDE CADUDAL

Could you give us your impression of 2017?

In 2017, the Company has clearly entered into the active strategic market access deployment aimed at providing end-stage heart failure patients with an alternative solution to heart transplantation.

The start of the pivotal international study, the creation of an integration center of the CARMAT device in Bois d'Arcy, in the Paris region, whose production capacity will eventually reach several hundred prostheses and the success of our latest capital increase open to the public, allow us to secure the next steps leading to CE marking.

I would like to remind you that our business plan has not changed since Company's IPO. On the medical side, in the continuity of the feasibility study executed in France, we are currently conducting, as we had always planned, an international pivotal study in order to demonstrate that the CARMAT system meets the requirements for which it has been designed.

Although not all risk factors are lifted, the accumulated patient experience with medical teams, supplemented by prostheses endurance data recorded on test benches, encourages us to engage in 2018 the movement transformation of CARMAT into an industrial and commercial company.

We have obtained authorizations to conduct the study in 3 new countries, Kazakhstan, the Czech Republic and Denmark, and we are aiming for 3 new countries in the coming months. The training cycle of the surgical teams of the principal investigative centers retained continued in 2017. At the same time, we have ongoing and promising relationships with the US authorities.

Finally, we act in complete transparency with the scientific community and learned societies. Thus, publications concerning the results obtained with the CARMAT artificial heart were published in 2017 by the Journal of Heart and Lung Transplantation, the European Heart Journal, the Journal of the American College of Cardiology and the Journal of Cardiothoracic and Vascular Anesthesia.

CARMAT reached a level of maturity in 2017 that allows it today to work with confidence and determination to its industrial and commercial development to become a leading company in its field.

What was the highlight of the year for you?

It is important to understand that CARMAT is here to help patients who find themselves in a therapeutic stalemate. I would not speak of a single milestone, but rather a succession of achievements that make us today closer to this medical goal.

Through work with health authorities in different countries, we have been allowed to significantly increase our patient recruitment capabilities as part of the pivotal study. Although the accumulated results do not at this stage of statistical value, they attest to the potential of the prosthesis to restore social life as close to normal as possible to patients.

Based on recent data, doctors are satisfied with the functioning of the prosthesis, the quality of post-implantation patient recovery, as well as the lack of heavy drug monitoring. These first elements are of course to be confirmed in the weeks and months to come and on a larger number of patients.

Can you give us a little more detail about the «industrial» transformation of CARMAT?

If we talk today about an industrial transformation and deployment, it is precisely thanks to the confidence in our product and in what it can offer to patients. We could not do it without this absolutely essential precondition.

This confidence is shared by individual shareholders and qualified investors as evidenced by the success of the € 53 million capital increase carried out in December 2017 with, for the first time, strong interest brands from Anglo-Saxon funds. Our cash position reached € 60 million at the end of 2017, which gives us the necessary means to accelerate the industrial transformation of the company. As such, we have a prostheses integration site in Bois d'Arcy that will be equipped with industrial robots for the assembly of sensitive parts. These highly innovative processes will further enhance the quality of our product, especially for the large-scale production phase.

The transformation is conducted in project mode with a dedicated team and aims to implement the best industrial practices in terms of organization, process and information system for maximum efficiency and quality.

I would like to emphasize, and the example of the robotic factory illustrates in part that the industrial deployment is done in strict compliance with the CARMAT DNA: innovation.

We are particularly attentive to the technological trends

of the future and the various partnerships that we develop prove it. Through the agreement with AddUp, the joint venture of the Michelin and Fives groups, we are considering a 2nd generation prosthesis which could be largely manufactured by the «additive» method or, in other words, 3D printing.

We also have joint projects with Air Liquide on energy and we are actively working on a remote monitoring project for patient data and prosthetic data with industry players.

We will not neglect our research and innovation capabilities.

The year 2018 promises to be crucial for the project, how do you approach it?

The year 2018 should be marked by the achievement of several key milestones of the project, with the finalization of the clinical study, the completion of the CE marking file and the initialization of the tests expected in the United States. From this point of view, we can consider that this is a crucial year, but, in view of our progress so far, we approach it with serenity.

During this year, we also want to develop patient services. In this spirit, the development of a remote monitoring solution will be a strong axis for remotely collecting patients' cardiac parameters. This solution will be all the more useful as we will have an increasing number of patients in different countries, involving the analysis of a large amount of information, both on the state of functioning of the prosthesis and on the state of the patient. patient's health. We hope to be able to limit patient stays in hospital to the current constraints on severe heart failure by allowing doctors to offer quality support to their patients.

Our ambition has not changed: building on our lead on competing projects, we want to become one of the key players, and potentially the world leader, in the treatment of terminal heart failure.

MESSAGE FROM THE CEO

STÉPHANE PIAT

About a year ago, I presented in this same editorial our objectives for the year 2017. Today, I am happy to be able to affirm that we have all achieved them. Thanks to the efforts of our technical and clinical teams, we were able to resume the pivotal study during the year and intensify our interactions with international hospitals to fully implement our clinical strategy. With three active centers now in Astana, Kazakhstan, Prague, Czech Republic and Copenhagen, Denmark, and advanced discussions with other European institutions, we continue to expand our network of highly specialized centers. This multi-center strategy not only allows us to maintain a patient recruitment rhythm in line with our goal of finalizing the pivotal study by the end of 2018, but also to ensure our future product recognition and buy-in of the international cardiological community.

These clinical developments were carried out in a context of CARMAT's active transition towards an industrial and commercial company. This technical objective has also been achieved, since we have succeeded in materializing all the constraints of large-scale industrial production in a state-of-the-art robot assembly plant, which will be opened very soon.

To bring this dynamic growth of our project to a successful conclusion, we have perfected our managerial organization by surrounding ourselves with experts from the industrial and marketing fields, with the arrival of Mr Wenzel Hurtak as Director of Manufacturing and Mr Francesco Arecchi as Director of Marketing.

In early 2018, we are ready and solidly structured in all areas - clinical, industrial and organizational - to meet the ultimate challenges of our project, that of the finalization of the pivotal study, but also that of the initiation of our clinical activities in the United States, the world's leading medical device market.

MISSION AND VISION

CARMAT, with its artificial heart, is dedicated to providing doctors 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 No. 1 alternative to heart transplantation. CARMAT relies on the commitment of its teams and the support of its shareholders

CARMAT aims to meet a major public health challenge related to cardiovascular diseases, 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, mainly cardiac transplantation.

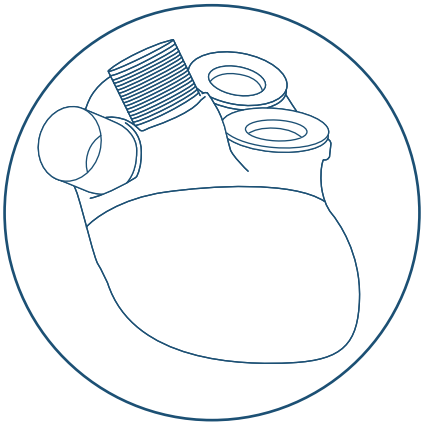
Heart failure is a progressive disease that affects 20 million patients in Europe and the United States. Of this population, tens of thousands of people are terminally ill. The number of human grafts available is only 4,000 to 5,000 per year. The artificial heart CARMAT is intended to offer a permanent solution to these patients who are facing a therapeutic impasse.

MARKET

A fast-growing, high-potential market with more than 100,000 patients suffering from terminal biventricular heart failure each year

ONLY 5,000 GRAFTS AVAILABLE PER YEAR

CARMAT PROSTHESIS



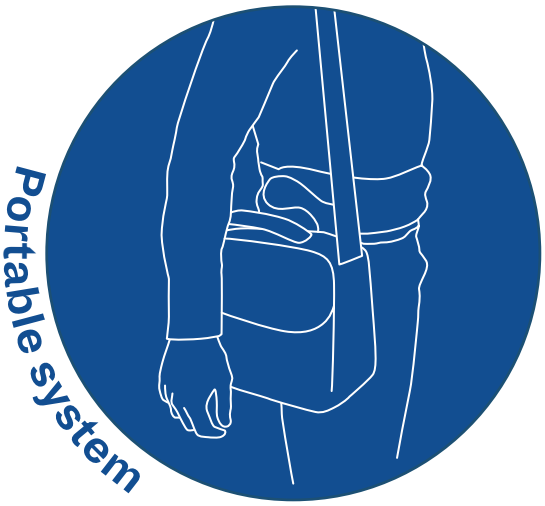
The first physiological cardiac bioprosthesis aimed at becoming a credible therapeutic and economic alternative to cardiac transplantation

An innovative leading position with strong intellectual property and significant barriers to entry thanks to Prof. Carpentier's scientific leadership and the technological excellence of Airbus Group

Biomaterials based on pericardium

- Bovine pericardium or ePTFE are the only components in contact with blood.
- Pericardial valves.

WELL-BEING PATIENT



Approved portable system: The implanted patient must be able to return home

CARMAT TEAM

A team of 63 people as of December 31, 2017, consisting of 24 women and 39 men and comprising 2 doctors, 35 engineers, and 7 graduate technicians

In addition of Stéphane Piat, a board of directors of 8 directors, including 4 independent and 2 internationally recognized experts in cardiology

Stéphane Piat, as General Manager, has to support the commercial strategy of CARMAT to address the market

2017 NEW FINANCING

New financial means brought to CARMAT to continue its project. With the support of its shareholders (family offices of Mr. Pierre Bastid and Mr. Antonino Ligresti, also including AIR LIQUIDE and TRUFFLE CAPITAL), CARMAT is strengthening its equity for € 52.9 million in December 2017, through a public offering.

CARMAT PROFILE

Founded in 2008, after more than 15 years of research, CARMAT develops a total artificial heart, orthotopic *, bioprosthetic *, self-regulating and implantable, as well as its power supply system and its control and remote diagnosis systems.

The name CARMAT originated from the meeting in the early 1990s between Professor Alain Carpentier and Jean-Luc Lagardère, then Chairman of Matra Defense (Airbus Group). The resulting rapprochement resulted in a very active cooperation starting 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 has developed treatments for biological tissues of animal origin, which have enabled him to design the most widely used biological valves in the world (Carpentier-Edwards® valves). He has also developed the technics of restorative surgery and mitral annuloplasty used today all over the world, on the principle that a device must always be associated with a reproducible procedure; and

- Matra Defense's (Airbus Group) expertise on embedded systems and their constraints (reliability, severe environments, mass and volume) enabling engineers to work on the concept using simulations, modeling, testing.

The Company's goal is to address a global public health need that is the treatment of advanced heart failure. It is a severe, progressive, and often fatal disease that is constantly increasing in developed countries.

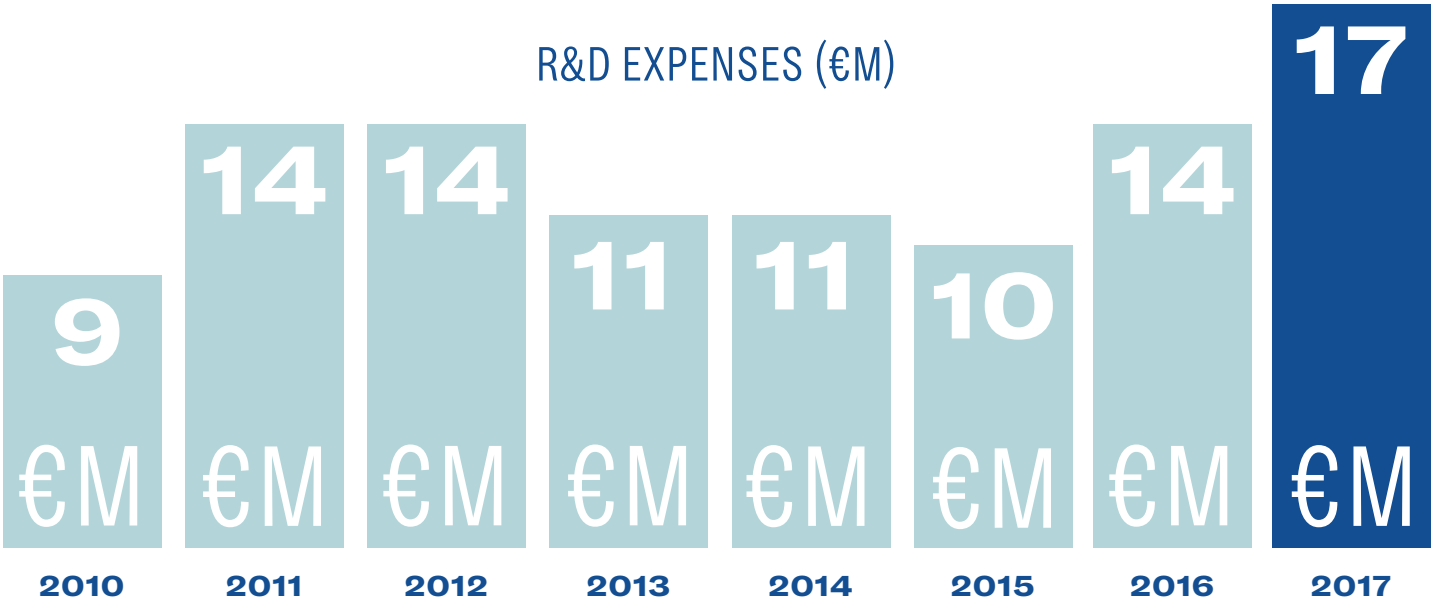
The CARMAT bioprosthetic artificial heart project aims to offer a long-term therapeutic solution to patients with advanced biventricular heart failure who are not eligible for transplantation and who have exhausted all treatment options and to whom no satisfactory solution is currently proposed.

To date, the artificial heart CARMAT highlights 3 major technical achievements, leading to undeniable competitive advantages compared to other medical devices on the market:

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

- The first intelligent artificial heart project that would provide an immediate and automatic response to the patient's metabolic needs;

- Special attention to patients' quality of life, with the development of light external equipment and



quiet operation.

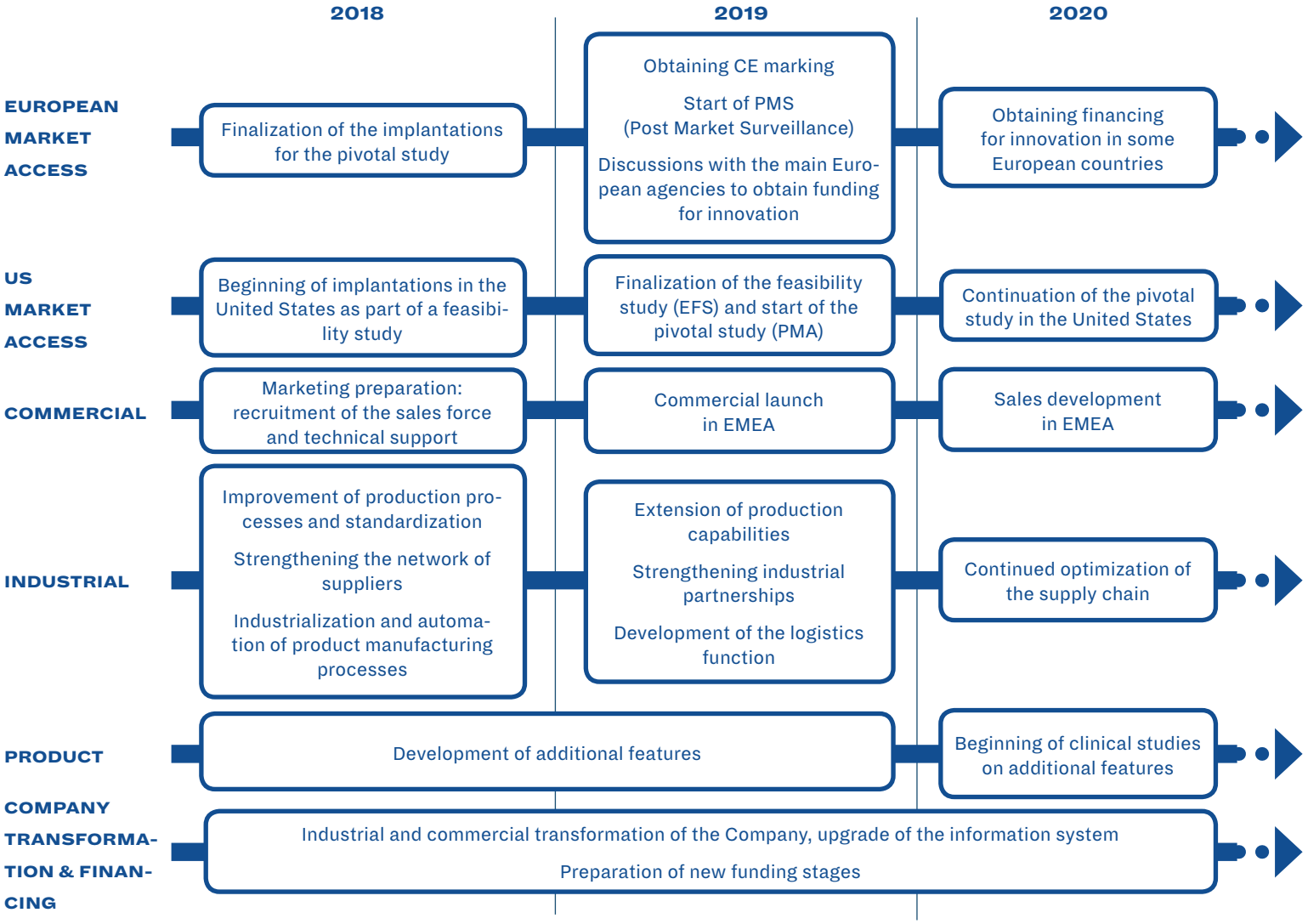
CARMAT is aiming for CE marking to be able to market its prosthesis over the next few years. To this end, CARMAT submits for analysis and review to a certification body, DEKRA, the elements of a dossier comprising a technical part and a clinical part. The clinical part of the dossier will include the clinical results obtained during the preclinical trials, the feasibility study of 4 patients finalized in early 2016 and the pivotal study started 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 objective of the Company is to implant around 20 patients and to demonstrate the survival of these patients over a 6-month horizon.

In addition to obtaining the CE marking, industrial and commercial development will generate additional financial needs: financing of day-to-day operations and R & D during the initial commercial launch phase, working capital requirements related to the development of sales, investment to increase production capacity and automate production processes. To date, the Company estimates that these additional requirements could reach € 100 million. Additional funds will be required, beyond the use of the available balance of the Kepler equity lines.

Beyond the domain of artificial heart bioprosthetic, the Company also intends in the future to develop new applications of its know-how in the cardiovascular field. However, it does not plan to devote resources to these potential applications until the artificial heart project is completed.

SCOPE OF ACTIVITY



Source CARMAT – Provisional project schedule

HISTORY OF THE COMPANY

2008

Creation of CARMAT by Matra Défense (Airbus Group) and Professor Alain Carpentier

33 M€

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

2009

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

Appointment of Marcello Conviti as chief executive officer of CARMAT

2010

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

16 M€

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

2011

Edwards

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

2012

Approval from the CPP (patient protection committee*)

CARMAT presents preclinical hemocompatibility data to the 25th Annual Congress of the European Association for Cardio-Thoracic Surgery

29,3 M€

Capital increase in the amount of €29.3 million (issue premium included)

2013

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

EUROPEAN MEDISCIENCE AWARDS 2012

CARMAT is a winner at the European Mediscience Awards in the Best Technology category

Further elements added to the ANSM file, notably the results of the implants on animals and the intermediate results on the durability tests

First successful implantation performed on December 18, 2013 at the Georges Pompidou European Hospital by Professor Christian Latrémouille

2014

5 M€

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

Authorization received to recommence feasibility trials on the CARMAT bioprosthetic heart

5,3 M€

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

bpifrance

2015

11 M€

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

Kepler Cheuvreux

The patient receiving an implant of the CARMAT bioprosthetic heart at Nantes Teaching Hospital on August 5, 2014 went home and benefited from the prosthesis for almost nine months before he died

In November CARMAT receives authorization from ANSM and from the CPP for completion of the clinical feasibility study

A third implantation of the CARMAT heart is carried out on April 8 by the cardiac surgery department at the Georges Pompidou European Hospital, the patient going home in August. This patient dies in December following respiratory arrest. The analyses carried out do not indicate that the CARMAT prosthesis was involved in the patient's death

2016

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, but the patient dies from medical complications relating to his critical condition

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

52,9 M€

In December 2017, CARMAT received more than € 50 million following the completion of a fundraising exercise open to the public, a transaction carried out notably with the support of two historic shareholders (Pierre Bastid and Antonino Ligresti).

2017

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

50 M€

At the end of April, CARMAT raise €50 million though a private placement, with the support in particular of certain historical shareholders and also with the arrival of new investors

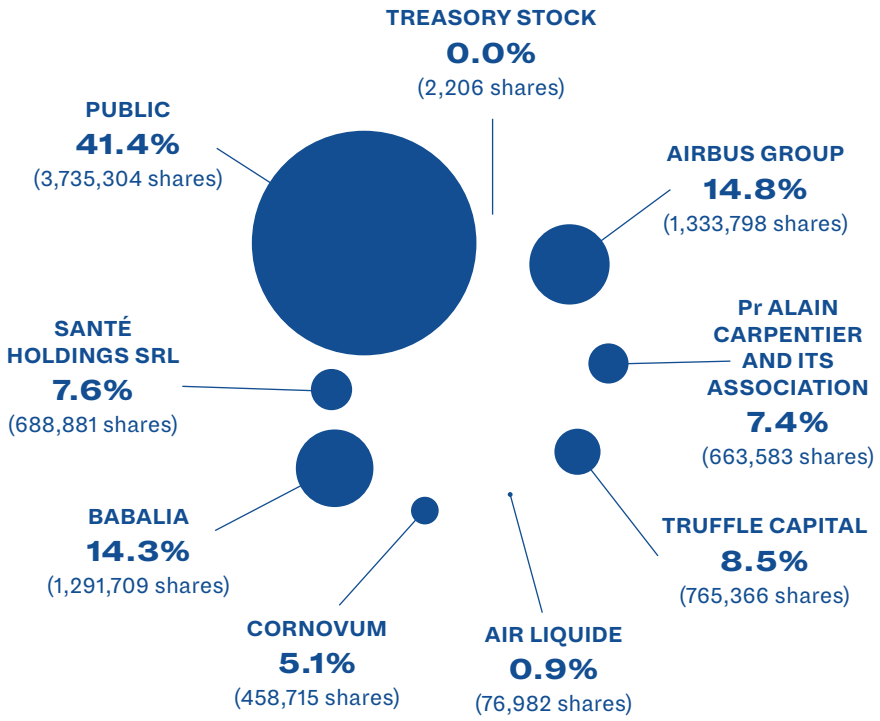
Stéphane Piat replaces Marcello Conviti as chief executive officer to define and support CARMAT's commercial strategy to address the market

The feasibility study relating to four patients being completed, the experience gained (21 months in total in respect of the 4 implantations realized) allows CARMAT to start work on preparation of the pivotal study, after both ANSM and the CPP authorizations

CARMAT AND ITS SHAREHOLDERS

SHAREHOLDERS AS AT DECEMBER 31, 2017

(to the knowledge of the Company)



ANALYSTS' COVERAGE

Broker / Analyst	Opinion	Target share price	Opinion's date
Gilbert Dupont	Buy	€35.00	February 21, 2018
Portzamparc	Buy	€24.80	February 21, 2018
Invest Securities	Neutral	€35.00	September 27, 2017
Edison	Neutral	€106.98	July 31, 2017

INFORMATION ON THE CARMAT SHARE

Market	Number of shares outstanding (December 31, 2017)	Mnemonic & ISIN code	Share price & market capitalization (December 31, 2017)	Average liquidity (12 months during 2017)	Status
Euronext Growth	9,016,544	ALCAR FR0010907956	€21.66 / share €195.3 m	9,488 shares / day	ELIGIBLE PEA PME

CONTACTS

Chairman	Chief executive officer	Chief financial officer and Head of investor relations	Head office	Website
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1

DESCRIPTION OF ACTIVITIES

1.1 HEART FAILURE

1.1.1 PATHOLOGY AND CAUSES *

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. When the failure reaches the left ventricle, we talk of left ventricular failure; when it reaches the right ventricle, we talk of right ventricular failure; when the failure reaches both ventricles, the left and the right, we talk of congestive or biventricular heart failure.

The main cause is coronary disease* (particularly myocardial infarction*), for about 2/3 of systolic heart failure cases [01], high blood pressure* is estimated to be an important contributing factor in many cases.

- In a heart attack, a plaque of lipids or a blood clot forms in one of the arteries of the heart, which are called coronary arteries, and the flow is interrupted. The part of the cardiac muscle that does not receive any blood is no longer oxygenated (ischemia*). It dies and is replaced by scar tissue. If this damaged part is important, the cardiac muscle weakens and the heart tends to expand; this secondary expansion, due to the increase in pressure within the heart, will in turn damage the healthy part of the heart and the heart failure will worsen over time.
- In high blood pressure (HBP), the resistance to blood flow increases in the arteries. The heart must fight against this resistance. As with all muscle subjected to an increased effort, it will first of all increase in size (hypertrophy*). If HBP is not correctly treated, the heart can dilate; its contractile force will progressively weaken and heart failure will develop. This heart failure is frequently aggravated by the tendency of hypertensive hearts to have cardiac arrests.

The left ventricle is the most frequently affected ventricle. Right ventricular failure is usually due to right ventricular pressure overload, i.e. pulmonary arterial hypertension.

But the principal cause of pulmonary hypertension is, in fact, left heart failure [02]. That is why heart failure frequently progresses from the left ventricle to the right ventricle.

Up to 30% of patients whose left heart failure is treated with a left ventricular assist device develop right heart failure [03], [04], [05], [06].

The most frequent complications are the following:

- irregular heart beat: the heart must pump faster to ensure the same flow rate despite its expansion; a serious ventricular arrhythmia can then develop which may go so far as a cardiac arrest;
- thromboembolic accidents (formation of clots): when a clot reaches the brain, it leads to a stroke*, with dramatic and often disabling consequences; and
- renal failure, the kidney being an organ very sensitive to variations in pressure caused by an inadequate cardiac pump.

Being a progressive disease, the prognosis is poor: less than 50% survival 5 years after the diagnosis [07], more than 40% of deaths within a year following initial hospitalization [08].

Practitioners distinguish the severity of failure or extent of the handicap using the NYHA (New York Heart Association) classification which is based on symptoms and includes 4 classes.

01 Adamopoulos S et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. European Heart Journal (2012) 33, 1787-1847.

02 Voelkel NF et al. Right Ventricular Function and Failure : Report of a National Heart, Lung, and Blood Institute Working Group on Cellular and Molecular Mechanisms of Right Heart Failure. Circulation. 2006; 114 :1883-1891.

03 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.

04 Boyle AJ et al. Predictors of poor RV function following LVAD implantation. J Heart Lung Transplant. 2003 ; 22 : S205.

05 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.

06 Cordtz J et al. Right ventricular failure after implantation of a continuous-flow left ventricular assist device: early haemodynamic predictors. EuropeanJournal of Cardio-Thoracic Surgery. 2014 ; 45(5):847-53.

07 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.

08 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.

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

A shift to class III is a determining factor [09]:

- for the patient: it marks the passage between a virtually normal life and a considerably reduced activity, very often involving a loss of autonomy;
- clinically this means more aggressive therapies, a dependence on drugs, and, with class IV, the start of repeated hospitalizations;
- for society, this represents an explosion of the costs, particularly due to hospitalizations: a class IV patient costs the community up to 15 times more than a class II patient [10].

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

09 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.

10 Kulbertus HE et al. What has long medical treatment to offer and what does it cost. Eur Heart J 1987 (suppl F) 26-28. Les patients en classe III et IV représentent entre 20 et 35% du total, la classe IV pouvant atteindre 5% des insuffisances cardiaques.

1.1.2 EPIDEMIOLOGY, PREVALENCE AND INCIDENCE

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

The prevalence of heart failure can be estimated at 1–2% in the western world and the incidence approaches 5–10 per 1 000 persons per year[11] .

In Europe, the disease affects approximately 2% of the general population [12], [13] i.e. approximately 15 million Europeans [14], [15]. The prevalence increases greatly with age. A French epidemiological study has shown that it can affect nearly 12% of patients over the age of 60 [16].

In the United States, over 5.8 million people were suffering from heart failure in 2012, with an annual incidence* of over 550,000 new patients annually. According to a new study published by an American Heart Association working group in May 2013, the prevalence of heart failure in the United States should increase by 46% between 2010 and 2030 [17], bringing the affected population to over 8 million people.

In addition, end-stage chronic heart failure with altered ejection fraction *, focused market for CARMAT, would affect 4.1 million people in Europe and the United States [18], [19] (people under 75).

This progression of the epidemiology is linked to the aging of the population, but also, in the case of advanced heart failure, to the improved survival after a myocardial infarction and to the progress made in the medicinal treatments, such as betablockers* and diuretics* [20] or coronary stents.

The paradox is that the availability of these new medications or new technologies has enabled more effective treatment of acute coronary syndromes and considerably increased patient survival after an infarction which is the strongest predictor of left systolic dysfunction and the risk of heart failure: patients no longer die immediately but are treated long term, during which time the disease

11 Mosterd A, Hoes AW. Clinical epidemiology of heart failure. Heart 2007;93:1137–1146.

12 Cowie MR, et al. The epidemiology of heart failure. Eur Heart J 1997; 18:208-225.

13 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.

14 Remme WJ et al. Public awareness of heart failure in Europe : first results from SHAPE. Eur Heart J 2005 ; 26:2413-2421.

15 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).

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.

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-Anthalt, 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 d'évaluation de santé) – Avril 2001 – E.

continues to develop. Consequently, the total number of people living with a compromised heart function and with clinical heart failure will increase considerably in the coming decades [21]. This evolution also leads to a population of older heart failure patients, suffering from various comorbidities, and thus even less susceptible to have access to transplants [22]. Out of the 8.5 million American people suffering from heart failure predicted by the AHA by 2030, only 2.5 million of these will be under 65 years old.

21 Tendera M. Epidemiology, treatment, and guidelines for the treatment of heart failure in Europe. European Heart Journal Supplements (2005) 7 (Supplement J), J5-J9.

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.

1.1.3 ECONOMIC CHALLENGE

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

According to the most recent study from the American Heart Association working group19 published in May 2013, the total cost of heart failure which was 31 billion dollars in the United States in 2012 is estimated to be 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 co-morbidities, the cost will explode to 160 billion dollars in 2030.

Moreover, this study points out that 80% of the medical expenses are attributable to the hospitalizations.

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 was in the region of 1.5 billion euros [23] (3.3 billion euros for the long term condition class which combines serious cardiovascular diseases - ALD 5 in 2009, only for the general National 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 on the occasion of the European Heart Failure Awareness Day, the French Society of Cardiology and the French Federation of Cardiology recalled 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 a hospital stay in cardiology intensive care was over 2,000 euros.

Overall, heart failure represents between 2 and 2.5% of the total expenditure on health care in Western countries, with costs linked to hospitalization alone representing more than 70% of the total cost of the disease [24]. Due to repeated hospitalizations, class IV chronic heart failure represents between 61% and 92% of the total cost of heart failure [25].

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

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

It should be noted that this disease is incurable in the chronic phase and that current treatments aim solely at reducing the symptoms. Treatments evolve as the disease progresses.

MEDICATIONS

In classes I and II, treatment is essentially drug-based [26] and, depending on the severity and symptoms, combines:

- anticoagulants* and anti-platelet aggregation medication* to prevent the formation of blood clots;
- angiotensin-converting enzyme inhibitors* to reduce vascular resistance;
- betablockers which reduce the cardiac rhythm and output to decrease blood pressure;
- diuretics to remove excess fluids and, in this way, 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;
- etc.

The complexity of treatment and the need for frequent

26 American Heart Association – Heart Failure Medications - http://www. heart.org/HEARTORG/Conditions/HeartFailure/PreventionTreatmentof HeartFailure/Heart-Failure-Medications_UCM_306342_Article.jsp.

adjustments leads to low patient compliance: 40% of patients do not take their treatment correctly after 3 months [27].

DEVICES

From class III, surgical options and the implantation of supporting medical devices are considered, 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;
- mechanical circulatory support systems, implantable or not, 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, if these approaches temporarily relieve some patients, they face important difficulties in selecting patients [28] or technical implementation [29], which restrict their adoption and do not prevent the progression of the disease.

Finally, the use of stem cells to regenerate damaged heart muscle is a promising avenue of research, but remains very controversial [30], in particular due to difficulties in collection or generation, then in administration (a large number of cells "die" during the injection) and the lack to date of a clinical demonstration of long-term regeneration of the myocardium.

The mechanical circulatory support systems are the devices which could be considered as the closest, in function and indication, to the CARMAT artificial heart project. Their characteristics and evolution are detailed in Paragraph 1.2.2. « Technologies and market players ». However, in contrast to artificial hearts which replace both ventricles, the diseased heart is left in place and can continue to degrade.

Positive inotropes* are generally introduced at the most advanced stage of the disease. These are drugs, administered intravenously in the hospital setting, which increase the contractility of the cardiac muscle and that 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 failure with a mean survival of 3 and a half months [31].

TRANSPLANTATION

Indeed, in the end-stage form of the disease, the only treatment possible is the replacement of the diseased ventricles by the transplantation* of a healthy heart*, i.e. the heart of a donor.

Professor Christiaan Barnard 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 (reaction of the host against the transplant which it considered as a foreign biological body). Several important advances have allowed the improvement of patient survival:

- the preservation of donor hearts thanks to refrigeration, allowing the removal at a distance from the place of transplantation;
- endomyocardial biopsy allowing the early diagnosis of rejection: a probe is introduced, under X-ray control and under local anesthesia, into a large vein and pushed until it is in the right ventricle, permitting a small piece to be sampled which is then analyzed under a microscope;
- finally, and above all, the arrival of ciclosporin, an immunosuppressant* the therapeutic use of which offered great hopes in organ transplantation from the early 1980s by preventing acute rejection.

Today, heart transplant survival is slightly higher than 50% at 10 years [32]. Survival after one year has progressed from 76% to 87% over the past 20 years [33].

The hopes founded on this treatment continue to face major problems that limit its mainstreaming.

The first reason can be found in the very strict eligibility criteria both for the harvesting of the organ and for the transplant. Notably, the donor [34] must, in principle, be under the age of 61 years, brain dead, not a carrier of

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

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

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

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

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

32 Stehlik J et al. The Registry of the International Society for Heart and Lung Transplantation : Twenty-eighth Adult Heart Transplant Report. J Heart Lung Transplant 2011 ; 30:1078-1094.

33 Lund LH, Edwards LB, Dipchand AI, et al. The Registry of the International Society for Heart and Lung Transplantation: Thirty-third Adult Heart Transplantation Report-2016; Focus Theme: Primary Diagnostic Indications for Transplant. J Heart Lung Transplant. 2016 Oct;35(10):1158-1169.

34 Latrémouille C et al. Transplantation cardiaque. EMC - ©Elsevier, Techniques chirurgicales - Thorax, 42-748, 2006.

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 [35].

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.

Considering this shortage of organs, the eligibility criteria of the recipient are even stricter [36] 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 etc. 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 addicted to alcohol or drugs are not considered.

Age of the patient, which must be usually below 65 years, even if there is no legislation in this area, is a particularly discriminating criterion. The organs are therefore reserved for the youngest patients, while the vast majority of chronic heart failure patients are over 60 years or suffering from comorbidities making them ineligible.

Furthermore, post-transplant survival decreases significantly with age. Only 80% of patients over 60 years are still alive after one month, and 67% after one year [37].

In this way, 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 end-stage heart failure is shown in the following table where we can see the small number of patients who could expect to benefit.

The limitations of transplantation also emerge in the difficulties in treating transplant patients and complications - either the transplant itself or complications caused by the immunosuppression. So, 5 years after a heart transplant, 95% of patients suffer from hypertension, 81% from hyperlipidemia*, and 32% from diabetes. Furthermore, 25% to 50% develop coronary disease of the graft, and 33% suffer from chronic renal failure [38].

A heart transplant is a heavy treatment at a very high price. The Milliman Institute has published a detailed report on the estimated cost of organ transplants in the United States. In terms of heart transplantation, its 2014 conclusions show a cost of 1,242,200 dollars, including 30 pre transplantation days and 180 post-transplantation days which are broken down as follows (in US dollars).

35 Agence de la biomédecine - Synthèse nationale de prélèvement et de greffe 2012 et annexe au bilan 2012.

36 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.

37 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.

38 Lindenfeld JA et al. Drug Therapy in the Heart Transplant Recipient. Circulation.2005 ; 111:113-117.

	France *	United States **	Germany ***	UK ****
Transplantations	423	2,066	292	193
Patients on waiting list	364	3,634	842	246

* : 2013 – Agence de la biomédecine (Biomedicine Agency) – annual report 2014 http://www.agence-biomedecine.fr/annexes/bilan2013/donnees/organes/03-coeur/synthese.htm.

** : 2014 – > 18 years – Organ Procurement and Transplantation Network – Scientific Registry of Transplant Recipients.

*** : 2014 – Eurotransplant statistics.

**** : 2013/2014 NHS Organ Donation Annual Report.

30 days pre-transplant	Harvesting	Admission	Procedure	180 days post-transplant	Immunosuppressants and other treatments	Total
50,900	97,200	771,500	88,600	198,400	35,600	1,242,200

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

1.2 MARKETS AND ACTORS PRESENT

1.2.1 ADDRESSABLE MARKET FIGURES

CARMAT intends to market an artificial bioprosthetic valve for patients in NYHA classification end stage class IV heart failure which is either chronic or ischemic heart disease (of which «acute myocardial infarction» is only a sub-group) in a preferred indication for the final treatment or Destination Therapy, not excluding the indication Bridge To Transplant, i.e. pending transplantation (refer to paragraph 1.2.2 « Technologies and market players »). The figures below refer to the indication for destination therapy.

Chronic heart failure affects approximately 15 million European patients [39] and 5 million patients in the United States [40], i.e. a total of approximately 20.8 million patients in this geographical area.

Referring to the indications obtained by similar devices, this artificial bioprosthetic heart could be indicated for patients suffering from acute or chronic end stage heart failure under 70 years old who cannot be transplanted, without obvious indication like cancer, reducing their life expectancy to less than 6 months.

Considering that:

- 2.3% of these patients will reach the end stage of the disease annually - involving the first hospitalisation - i.e. a population of approximately 478,400 patients [41] ;
- 38% of this population is under 70 years old, i.e. a population involving approximately 182,000 patients [42], [43] ;
- around 5,000 eligible patients are transplanted per 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);

there are therefore approximately 126,700 potential patients in Europe and the United States for the indication class IV end stage chronic heart failure.

39 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29, 2388-2442 (sur les 900 millions d'habitants des 51 pays adhérents de la Société européenne de cardiologie).

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

41 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 millions people. Circulation 2009 ; 119:515-523.

42 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29, 2388-2442 (sur les 900 millions d'habitants des 51 pays adhérents de la Société européenne de cardiologie).

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

1.2.2 TECHNOLOGIES AND MARKET PLAYERS

Heart transplantation, especially in light of the lack of organs, cannot fulfill the needs of patients in class IV end-stage heart failure (refer to Paragraph 1.1.4 « Available Treatments »). Alternative medical devices exist, – often grouped under the term mechanical assisted circulatory support (MCS: Mechanically Circulatory Support).

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 transplantation (BTT: Bridge to Transplant)

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 short-term indication. However, they are limited by cost – the cost of the implantation of the device adding to the cost of the transplant;

- definitive treatment (DT: Destination Therapy)

This indication was, until recently, reserved for patients who were ineligible for a transplant, or who did not wish to have a transplant. However, under the pressure of a fast increasing prevalence and the shortage of organs, numerous patients temporarily implanted actually become destination therapy patients.

The aim of Destination Therapy is to offer a system

providing a real quality of life to the patient, i.e. a reasonable autonomy and a return home, and even a professional or social life, which is accompanied by an increase of at least 2 NYHA classes, without major complications.

Furthermore, since the first approval of this indication for the HeartMate®II by the FDA in 2010 and the Syncardia obtaining a status as a device for compassionate use for first line destination treatment in the United States in March 2012 (refer to paragraph 2.3.2.2 Total orthotopic artificial hearts), this indication has increased considerably in North America and also in other European countries such as Germany.

The devices can then be distinguished into two categories:

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

VENTRICULAR ASSISTANCE DEVICES [44]

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

However, as their name indicates, they are implanted in parallel to the native heart, to assist it by supplementing its flow to meet the metabolic needs, but do not replace it. The historical leader in this category is the Thoratec® company with the HeartMate II® - the HeartWare® company is its main competition.

Thoratec® announced that it exceeded 18,000 implants for its HeartMate II® in 2014 (i.e. scarcely 5 years after its approval by the FDA for the destination treatment indication) and it was on this basis particularly that in the middle of 2015 this Company was acquired by Saint Jude Medical, based on a value of 3.3 billion dollars. In October 2015, the Company announced that it had obtained the CE mark for its product HeartMate 3®.

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

The products of Thoratec®, entity now belonging to the Abbott Group, can theoretically assist the left (Left Ventricular Assist Device – LVAD) or right (Right Ventricular Assist Device – RVAD) ventricle 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, all the devices having been designed for the left ventricle.

Nevertheless, the wider diffusion of these left ventricular assist devices has led to an increase in the need for biventricular assistance [45]. Indeed, the development of a right heart failure is a major complication of left ventricular assist devices. 20% of patients implanted with the HeartMate II® develop right heart failure [46]. The indication to add a right ventricular assistance device involves up to 37% of cases depending on the study [47], [48], [49], [50].

Assessment methods are being developed for this risk to identify patients liable to benefit from early stage biventricular assistance as it has also been shown that early implantation results in a very significant improvement in survival compared to later implantation [51], [52], [53]. This could contribute to an increase in the use of biventricular devices, such as the one from CARMAT, as a first-line treatment.

These non-pulsating devices, such as the HVAD® by HeartWare® are designed to supplement the cardiac function and not as a substitute for it. They consequently have limitations in terms of their flow rate. The flow rate of the centrifugal pumps of these left ventricular assist devices

44 Les dispositifs indiqués en attente de récupération (Bridge to Recovery : BTR) ne sont pas mentionnés ici. En effet, leurs indications et leurs technologies sont très différentes. Ils ne peuvent fournir qu'une assistance limitée (environ 2 litres/minute vs. 9 litres/minute pour le cœur CARMAT) pour une durée très limitée (de quelques heures à quelques jours) et s'adressent à des patients sans détérioration ventriculaire permanente, qui ont besoin d'un support hémodynamique temporaire, par exemple après une intervention chirurgicale ou une hémorragie post-traumatique.

45 Miller LW, Guglin M. Patient selection for ventricular assist devices: a moving target. Journal of the American College of Cardiology. 2013 ; 61(12):1209-21.

46 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. J Thorac Cardiovasc Surg ; 2010 ; 139(5):1316-24.

47 Potapov EV et al. Tricuspid incompetence and geometry of the right ventricle as predictors of right ventricular function after implantation of a left ventricular assist device. J Heart Lung Transplant 2008 ; 27 : 1275-81.

48 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.

49 Klotz S et al. Pre-operative prediction of post-VAD implant mortality using easily accessible clinical parameters. J Heart Lung Transplant 2010 ; 29:45-52.

50 Boyle AJ et al. Predictors of poor RV function following LVAD implantation. J Heart Lung Transplant 2003 ; 22:S205.

51 Fitzpatrick JR et al. Risk score derived from pre-operative data analysis predicts the need for biventricular mechanical circulatory support. J Heart Lung Transplant 2008 ; 27:1286-92.

52 Fitzpatrick JR et al. Early planned institution of biventricular mechanical circulatory support results in improved outcomes compared with delayed conversion of a left ventricular assist device to a biventricular assist device. J Thorac Cardiovasc Surg 2009 ; 137:971-977.

53 Takeda K et al. Outcome of unplanned right ventricular assist device support for severe right heart failure after implantable Left Ventricular Assist Device insertion. J Heart Lung Transplant 2014 ; 33(2):141-8.

is determined by the specific geometry of each device, the speed of rotation of the pumps in turns per minute, and the difference in pressure between the entry into the pump (ventricular pressure) and the ejection from the pump (aortic pressure).

The right ventricle is very different from the left ventricle. The blood pressures are significantly lower in the right side of the heart. On the left side, the blood needs to reach all the organs, the brain at the highest point, the extremities of the limbs, at the furthest. On the right side, it is «sufficient» to send the blood to the neighboring lungs for reoxygenation. The actual design of a left ventricular assist device with a centrifugal pump and the constant flow rate would have to be significantly modified to adapt it to assist the right ventricular.

To our knowledge, only one manufacturer of implantable left ventricular assist devices with a centrifugal pump, meaning the HeartWare® company, has expressed an intention to seek authorization for a right ventricular assist device [54]. This company was acquired by Medtronic in August 2016, for a total valuation of $ 1.0 billion.

A few constant flow rate centrifugal pump left ventricular assistance devices have been tested experimentally for biventricular assistance [55], [56]. Very few publications exist on the subject. All indicate that the design for the left side of the heart is a major flaw: currently « The right pump, in a circuit of normal pulmonary pressure, would pump more volume than the left and would result in pulmonary edema.»

« TOTAL » ORTHOTOPIC ARTIFICIAL HEARTS (TOTAL ARTIFICIAL HEART: TAH)

Like a heart transplant procedure, orthotopic «total» artificial hearts replace both failing ventricles, by implanting in their place (orthotopic replacement) two ventricular volumes and a system that ensures a blood flow. The CARMAT bioprosthetic artificial heart project belongs to this category.

The only total artificial heart currently on the market in Europe and the United States belongs to the eponymous private equity company Syncardia [57]. After facing financial difficulties («Chapter 11»), the company received in September 2016 the support of the private equity fund Versa Capital Management, which could relaunch this company in a peiran way.

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 transplantation stage for the first time after surviving for 9 days with the artificial heart. In 1990, the FDA closed the Symbion, Inc. company which held the rights for Jarvik 7 and stopped the ongoing clinical study (IDE*) – because of breach of its regulations. The technology was taken up again by an Arizona University Centre under the name CardioWest™. A new clinical study started again in 1992 in the United States and lasted 10 years. This led to FDA approval in 2004 for a bridge to transplantation indication and the CE mark in 2005. Meanwhile, a new privately funded company, Syncardia Systems, Inc., was created in 2001 to prepare for and then proceed to marketing [58]. Syncardia announced the 1000th implantation of its artificial heart in February 2012, which is 19 years after the first implant in December, 1982.

So, it is an artificial heart whose design dates back more than 40 years. Its functioning is based on a pneumatic actuation. The internal polyurethane diaphragms are activated by the compressed air, generated by a compressor, which is itself powered electrically. Four mechanical valves are used in each device. Two percutaneous plastic tubes approximately 2 metres long (7 feet) connect the device to the external compressor, the portable version of which, the Freedom™ portable driver, weighs 6.12 kg (13.5 pounds) excluding carrying accessories such as the backpack or sling bag, for 3 hours independent operation [59].

CARMAT can only welcome the regulatory, financial and commercial success of the market players. Indeed, they maintain the attention of the scientific and financial communities, highlighting the expected advantages of CARMAT's innovations and preparing the route.

The orthotopic total heart is also the most dynamic area of research on the market, confirming the important need for this type of device and the leadership of CARMAT in this field.

54 Site internet HeartWare® HeartWare International 2013 Fourth Quarter and Year-End Results Conference Call - Thursday, February 27, 2014.

55 Hetzer R et al. Long-term biventricular support with the HeartWare implantable continuous flow pump. J Heart Lung Transplant 2010 ; 29:822-4.

56 Loforte A et al. Biventricular support with the HeartWare implantable continuous flow pump: An additional contribution. J Heart Lung Transplant 2010 ; 29:1443-4.

57 www.syncardia.com – l'ensemble des informations concernant Syncardia sont tirées de leur site internet, sauf mention spécifique.

58 Les informations historiques sur le Jarvik 7 peuvent être consultées sur le site de la société Jarvik Heart www.jarvikheart.com.

59 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.

Compared to a transplant, the respective advantages and disadvantages of the current systems are summarized in the following table [60] :

	Transplantation	Assist systems and Artificial hearts
Advantages	- State of the art in terms of destination treatment - Normal physical activity possible - Good long term prognosis	- Immediate availiability - Planned procedure - Good level of physical activity
Disadvantages	- Lack of donors and organs - Risk of rejection - The transplant is exposed to diseases - Risk of coronary diseases in the transplant - Risk of immunosuppression - Renal impairment - Neoplasia (cancer) - Susceptibility to infections - Diabetes - Hypertension	- Dependency on the device - Operational independence dependent on a continuous electrical supply - Infection of the percutaneous wire(s) - Risks of anticoagulation - Severe hemorrhage - CVA Regarding assist devices: - Serious cardiac arrhythmias - Aortic regurgitation - Pump thrombosis

Thanks to the use of breakthrough technologies, such as biological or hemocompatible materials to limit the risks linked to anticoagulation, or fuel cells to increase patient's autonomy and quality of life, CARMAT aims to appreciably reduce the majority of these disadvantages and to offer a real alternative to transplantation.

60 Adapté de Strüber M et al. The Current Status of Heart Transplantation and the Development of "Artificial Heart Systems". Dtsch Arztebl Int 2009 ; 106(28-29):471–7.

Thus, facing its main market competitors, whether they are positioned on the market of total orthotopic artificial hearts or ventricular assistance devices, CARMAT has significant advantages:

	Total orthotopic artificial heart CARMAT	Total orthotopic artificial heart SYNCARDIA	Ventricular assistance devices THORATEC	Ventricular assistance devices HEARTWARE
Visual of the prosthesis				
Corporate information	Listed company € 50 million fund raising in April 2016	« Chapter 11 » procedure in 2016 Support of the private equity fund Versa Capital Management in September 2016	Acquired by Saint Jude Medical in 2015 for $ 3.3 billion	Acquired by Medtronic in 2016 for $ 1.0 billion
Market access	Pending Pivotal study ongoing process	Bridge to Transplant approval: October 2004 Study for destination Therapy: Pending	Bridge to Transplant approval: April 2008 Destination Therapy approval: January 2010	Bridge to Transplant approval: November 2012 Study for destination Therapy: Pending
Technology	Bioprosthetic artificial heart, biocompatible, autoregulated	Artificial heart, with pneumatic technology designed in the 70's (Jarvik 7)	Ventricular asistance device, with axial rotary pump	Ventricular asistance device, with centrifugal pump
Avantages / Drawbacks	Biocompatibility of materials used, minimizing the risk of vascular accidents or hemorrhages Self-regulation of the system, according to the patient's physiological needs Operation facilitating the quality of life of the patient	Relatively high risks of thrombosis, hemorrhages or infections due to the use of non-biocompatible materials in contact with patients' blood (use of anticoagulants) Product design using pneumatic technology limiting patients' quality of life (size of the device)	System that may be relevant as a temporary solution. Risks of thrombosis due to the use of non-biocompatible materials in contact with patients' blood (use of anticoagulants) Risk of right ventricular failure Fixed operating speed, not adapted to the needs of the patient. Renal and hepatic complications in a medium term Complications related to the maintenance of the native heart (regurgitation of the aortic valve, ventricular arrhythmias, ...)	

1.3 THE FIRST SELF-REGULATED BIOPROTHETIC ARTIFICIAL HEART

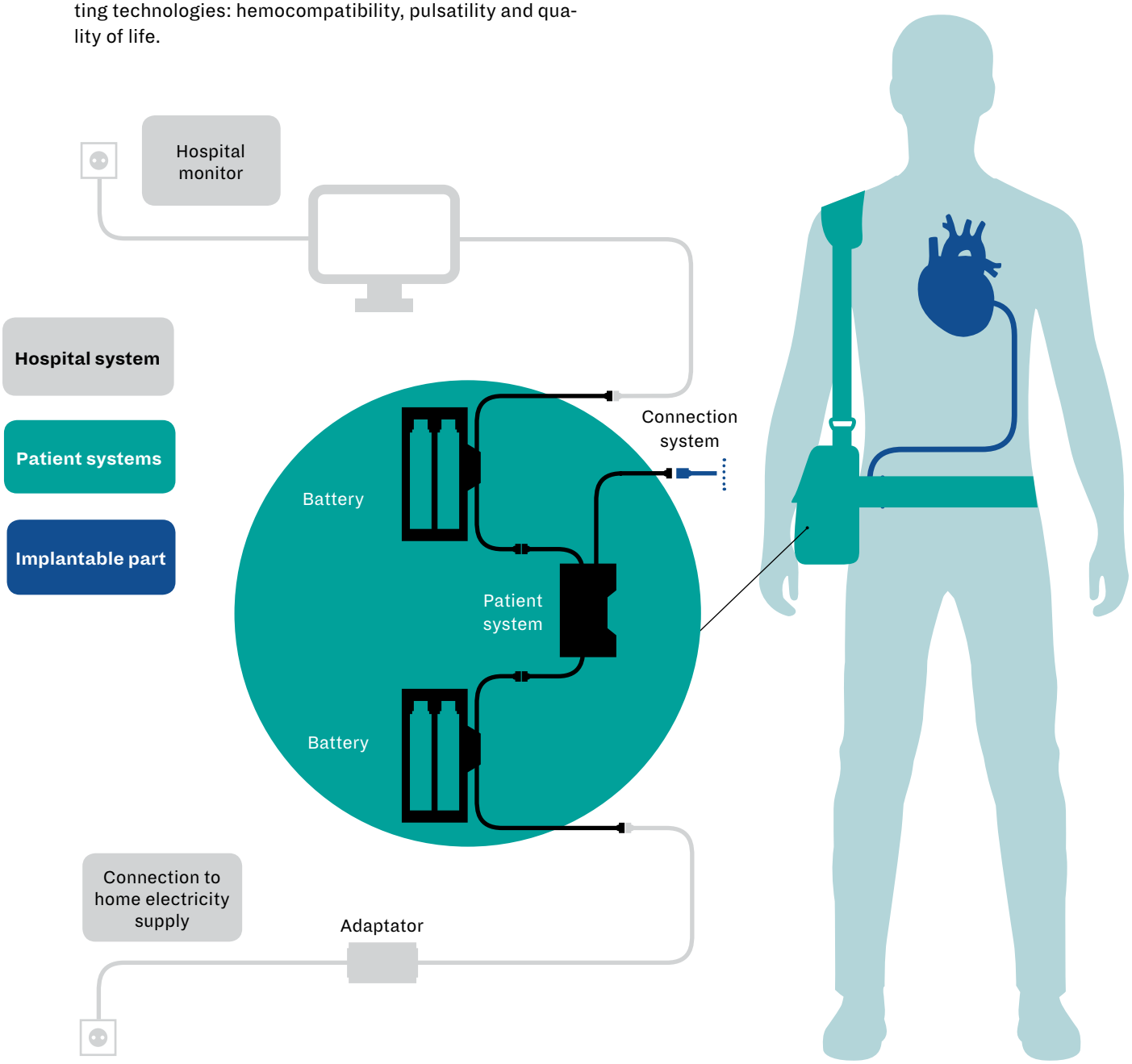
1.3.1 POSITIONING ON THE MARKET

The artificial heart CARMAT is intended to offer a permanent solution to patients with terminal heart failure who are facing a therapeutic stalemate due to the lack of human grafts.

The innovations carried by the artificial heart CARMAT aim initially to meet the needs inadequately covered by existing technologies: hemocompatibility, pulsatility and quality of life.

Depending on the benefits demonstrated in terms of lifetime, the artificial heart CARMAT could then address patients with better prognosis. Eventually, it could become the No. 1 alternative to heart transplantation.

CARMAT will propose a price that will ultimately allow the healthcare system to be effective in relation to the sustained costs for the solutions used today.



Source CARMAT – The complete CARMAT system

1.3.2 DESCRIPTION OF THE CARMAT PROSTHESIS

As presented on the previous page, the system consists of:

- an implantable part, the bioprosthetic artificial heart, as such;
- patient systems allowing the return home;
- a hospital system allowing complete configuration of the prosthesis and patient monitoring.

THE PROSTHESIS

The implantable parts include the prosthetic heart and the connection to the power supply, either by battery or by the mains.

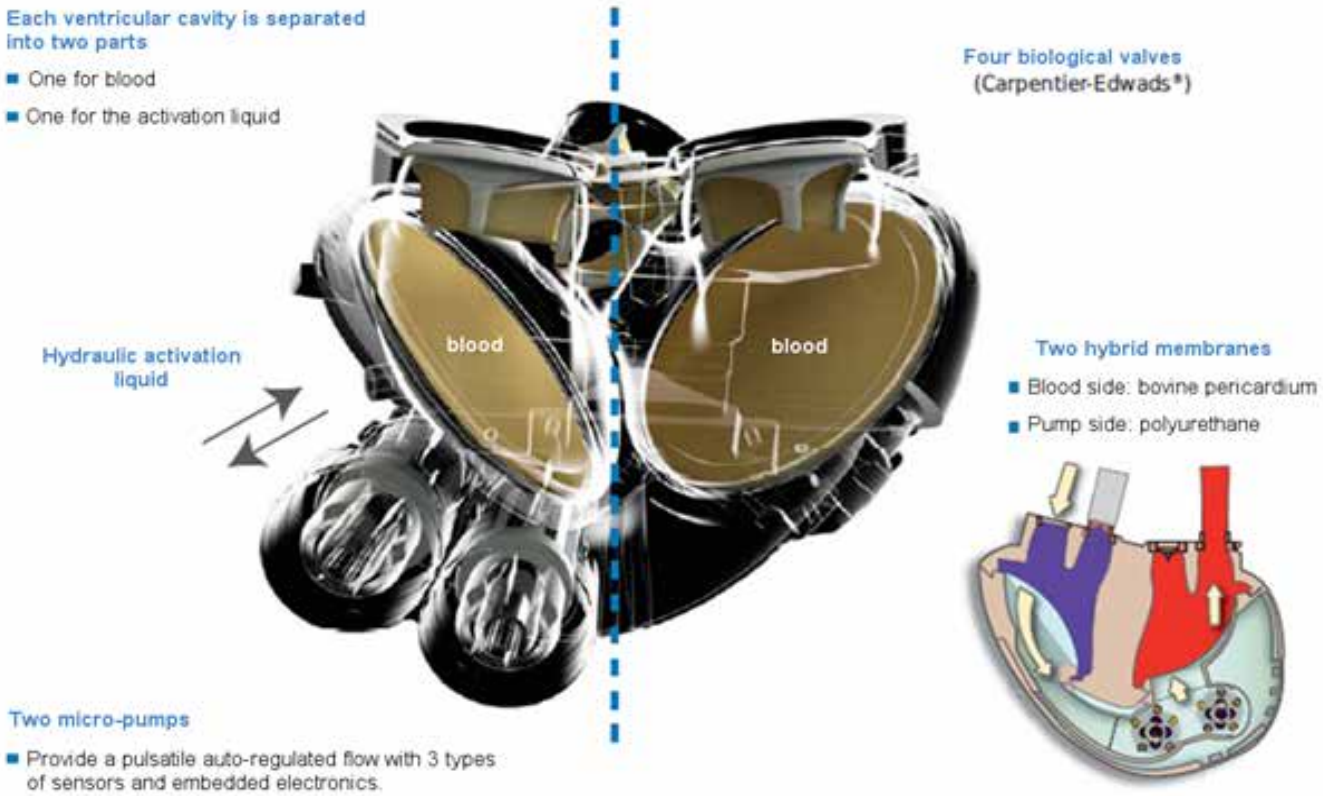
The prosthesis reproduces the operation of the natural heart by using hydraulic actuation, an actuation liquid serving as an intermediary for deploying a blood-throbbing membrane. The cardiac rhythm is broken down into two periods, diastole* when the ventricles fill up with blood, and systole* when the blood is pumped into the great vessels and organs.

The prosthesis comprises two ventricular cavities, one on the right and one on the left, with each separated by a flexible hybrid membrane into two volumes, one for blood, one for the actuation liquid. The movement of this membrane reproduces the viscoelastic nature of the cardiac muscle and acts in the same way on the blood, pumping it when it contracts.

A motor-pump group - consisting of two miniature pumps - moves the actuation liquid to the ventricles thus generating systole or by reversing the direction of rotation, towards the external pouch during diastole.

An electronic device integrated to the prosthesis regulates the flow according to patients' needs using information given by sensors and processed by a microprocessor.

A flexible external pouch contains the actuation liquid and beats at cardiac rhythm.



Source CARMAT – Functioning of the bioprosthetic artificial heart project

THE ELECTRICAL CONNECTION

The transfer of electrical energy from the monitoring console or portable batteries to the prosthesis will be percutaneous for the early clinical trials. This solution has the merit of being proven as it is used by the majority of implantable ventricular assistance systems currently available.

The percutaneous cable, however, is a major cause of infection. Compared to the various solutions considered to date, the most promising one appears to be positioning an implantable connector that will offer the potential to treat potential infections, an additional differentiation point. This solution will be incorporated in the near future, pending the implementation of completely implantable solutions.

THE HOSPITAL MONITORING CONSOLE

The hospital monitoring console (CSH) – which is already available – is only used in implantation centres by certified medical staff. It allows to the medical team to pilote the prosthesis during implantation, and to assume the follow up during periodic control visits, and it also allows the downloading while functioning of new functions or versions of the prosthesis'softwares, like for example, the software that allows automatic adaptation to the patient's metabolic needs

The console can import the monitoring data from the patient's systems and, in the long run, it could interface with the doctor's computer to receive and analyze data transmitted by remote transmission. It offers surgeons detailed functions for the analysis of the prosthesis' functioning and of the physiological parameters measured.

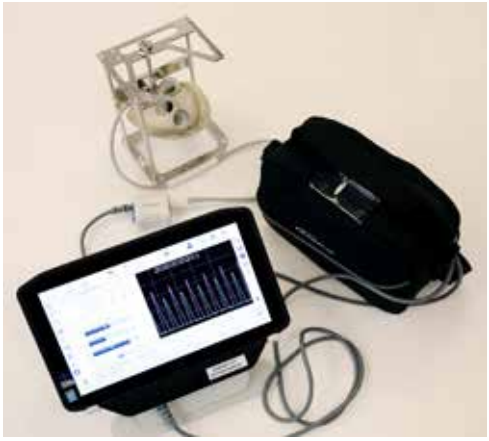
THE PATIENT SYSTEM

The systems that the patient takes home contribute significantly to their quality of life as they give them the mobility and autonomy essential for a life close to normal.

- The first portable system weighing 3 kg (including bag) provided over 5 hours of independent operational life - (at a fixed flow rate of 6 litres per minute) - with Lithium-Ion batteries and offered good mobility. However, autonomy in the true sense of the term is not limited to 5 hours, since the patient may carry extra previously-charged batteries, or connect directly to a power outlet where possible.

- The second generation portable power supply, which is subject to fuel cell research, aims to give patients autonomy of more than 12 hours, with a weight of less than 3 kg. The use of a fuel cell should be a first in the medical field. It should provide an original solution integrating the production of hydrogen on demand and optimizing patient security while being ergonomic.

Other additional accessories such as a battery charger, connection materials to the home electricity supply, carrying bags or belts or materials to protect the system when showering are also intended. All the elements of the system intended for the patients aim to allow them to feel safe, to have a good quality of life at home and to ensure their mobility for the requirements of everyday life.



Source CARMAT – Monitoring system, patient system and connection

1.3.3 INNOVATIONS AND COMPETING ADVANTAGES

To date, the artificial heart CARMAT highlights 3 major technical achievements, leading to undeniable competitive advantages compared to other medical devices on the market:

- The only artificial heart project where surfaces in contact with the blood are made of biologically compatible material to reduce thromboembolic risks;
- The first intelligent artificial heart project that would provide an immediate and automatic response to the patient's metabolic needs;
- Special attention to patients' quality of life, with the development of light external equipments and quiet operation.

To the knowledge of CARMAT, no existing or planned device includes or foresees the use of biological material, nor self-regulation by means of multiple embedded sensors. These two characteristics constitute the key of the technological breakthrough CARMAT intends to offer to patients.

HEMOCOMPATIBILITY

All the implants and assist or organ substitution devices in contact with blood pose the major problem of their hemocompatibility: they must not cause the destruction of red blood cells* (hemolysis*) or activate the coagulation cascade*, thus favoring the formation of a clot blocking a blood vessel which can cause a pulmonary embolism* or a stroke.

The causes of these problems are based around two points:

- hemodynamics, respecting the blood flow, which should prevent stasis (abnormal stagnation and accumulation of blood) or «shearing» of red blood cells (shear stress). This issue also covers the aspect related to the necessary variability required by a device intended to supplement or replace the original functioning of the natural heart. The organ must ensure a non-continuous flow of blood according to the activity of the individual. This essential constraint is now covered by the pulsed effect of the CARMAT prosthesis;
- the surface condition and toxicity of the materials in direct contact with the blood. These materials may be of a varied chemical nature, but their surface condition must be either perfectly smooth and water-repellent so as not to cause any adherence, or else of a microporous structure so as to guarantee satisfactory adherence of proteinic biological tissues.

The CARMAT bioprosthetic artificial heart project contributes original solutions to overcoming this major obstacle by developing a type of blood flow pulsatile actuation which is compatible with physiological blood pressure, thanks to the optimized design of ventricular cavities and the use of microporous biological and synthetic biomaterials which allow by hypothesis a continuous proteinic* coverage, adhering to all surfaces in direct contact with the blood.

Research into non-thrombogenic materials which are essential for the final performance of the system has been a goal which many companies have pursued without success, particularly in ventricular assistance.

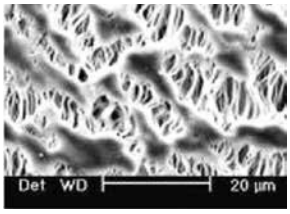
The CARMAT artificial bioprosthetic heart project has followed on from the hemocompatibility principles demonstrated in the research carried out on the Carpentier-Edwards biological valves designed by Professor Alain Carpentier, which have proven clinical experience of 30 years, having been implanted in over a million patients with implantation times of over 25 years [61], [62]. These biological valves, unlike mechanical valves, allow the considerable reduction, or even elimination in certain cases, of the anticoagulant treatment, which is especially restrictive for the patient.

An agreement with an initial term of one year, automatically renewable for one year at a time, was entered into on November 5, 2010 between CARMAT and Edwards Lifesciences, the world leader in the heart valves sector and in hemodynamic monitoring, for the use and supply of Carpentier-Edwards biological heart valves® for the CARMAT bioprosthetic artificial heart project.

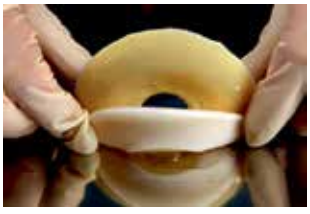
Four Carpentier-Edwards pericardial valves realized with bovine pericardium are incorporated into each CARMAT bioprosthetic artificial heart. The surfaces in contact with blood of the atrial connection interfaces are also covered by treated bovine pericardium. The face in contact with the blood of the biosynthetic membranes loaded in the ventricle to put the blood in movement is also covered with bovine pericardium, the cavity is covered by micro-porous synthetic hemocompatible material. This will mean that all the components coming into contact with the blood are in micro-porous hemocompatible or biological materials, setting them apart from other artificial heart projects which specifically use mechanical valves.

Biosynthetic membrane

Ventricle in micro-porous PTFE



Biosynthetic interface with the atria



Carpentier-Edwards® pericardial valve

Source CARMAT – Hemocompatible materials

61 Ayegnon KG, et al. A 25-year experience with Carpentier-Edwards Perimount in the mitral position. Asian Cardiovasc Thorac Ann. 2011 Feb ; 19(1):14-9.

62 Aupart MR et al. Perimount pericardial bioprosthesis for aortic calcified stenosis : 18-year experience with 1 133 patients. J Heart Valve Dis. 2006 Nov ; 15(6):768-75; discussion 775-6.

AUTOREGULATION

To improve patients' quality of life, the CARMAT bioprosthetic artificial heart project was designed to permanently analyze the hemodynamic situation of the patient and to adapt thereto in real time.

Thus, for example, if a patient climbs the stairs the cardiac output of the artificial heart will increase as a natural heart would do. If they lie down to sleep, the heart will slow down to ensure a comfortable sleep.

The output of the artificial heart is therefore pulsatile*, in the same way as a natural heart, and its hemodynamic operation is based on Starling's law which governs the functioning of the human heart. In accordance with this law, changes in heart rate occur principally from variations in venous return (pre-load) but are also sensitive to the influence of arterial pressures (after-load).

The artificial heart also simulates the reactions of the natural heart to stimuli from the nervous system particularly in maintaining aortic pressure in order to permanently ensure satisfactory perfusion of organs, especially the cerebral arteries.

Unlike other research projects on bioprosthetic artificial hearts that offer little or no adaptation to the needs of the patient, the medical self-regulation of the CARMAT bioprosthesis aims to reproduce the physiological functioning by implementing:

- an original algorithm allowing replication of the visco-elastic characteristics of the cardiac muscle which changes shape under the effect of pressure depending on its initial elongation, respecting Starling's law;
- an algorithm simulating cardiac function in response to peripheral resistance modifications, which themselves are dependent on the nervous system. The analysis of aortic pressure allows the beat rate to be corrected.

OTHER COMPETING ADVANTAGES

Miniaturization:

In the absence of embedded self-regulation, the other artificial heart projects bypass the problem of adjustment by the use of external control consoles, or by the use of portable extracorporeal devices. These bulky devices, often reserved for hospital doctors, do not allow an acceptable quality of life for the patient.

Taking advantage of progress made in the miniaturization of electronics, the trend among research projects today is to design hearts which integrate the command and adaptation systems as much as possible. But the intrathoracic space is limited. This integration is often realized at the expense of the ejection volume, which requires the artificial acceleration of the beat rate to provide a physiological blood flow.

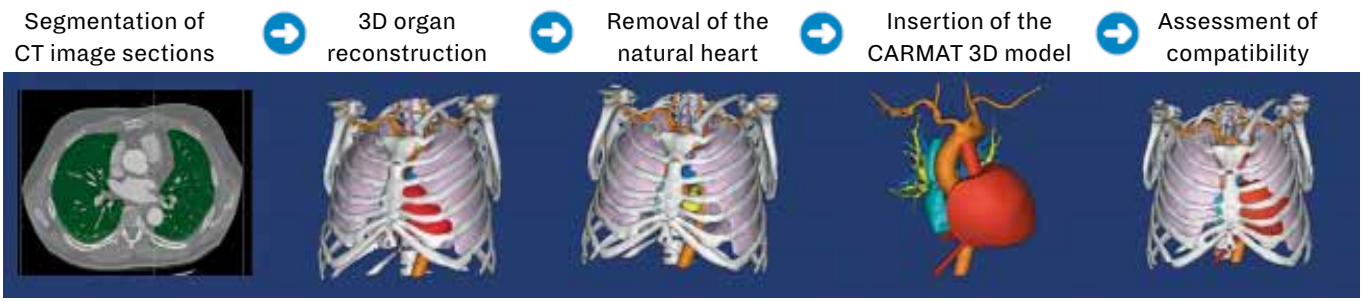
The shape of the CARMAT artificial bioprosthetic heart has been completely optimised to the anatomy of the thorax in order to fit the largest number of patients, at the same time maintaining a physiological ejection fraction using all of the space available around the volumes reserved for blood.

This anatomical shape has been studied taking several criteria into account, such as its total volume, its ventricular volume, its interfaces with the aorta*, the pulmonary artery* and the atria.

Respecting the obligation of as large a ventricular volume as possible to avoid continuous operation at high frequency, while conserving a very significant reliability of onboard elements, has required significant miniaturization efforts for all the sub-assemblies involved in its activation: motor pump unit, control electronics and sensors.

The Company is currently working to lighten the portable system, currently weighing 3 kilograms, to improve usage comfort for the patient.

An advanced virtual 3D implantation system has therefore been developed, based on a sophisticated three-dimensional simulation, which allows, in a completely



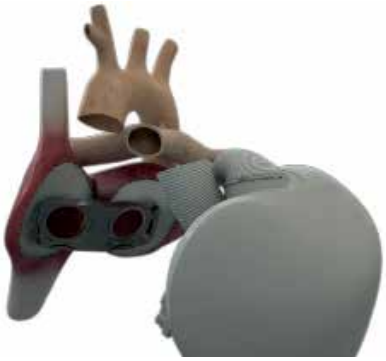
Source CARMAT – 3D virtual transplant simulator

non-invasive manner, the removal of the natural heart and grafting of the prosthesis to check its anatomical compatibility with a given patient.

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 of the operating theater to design and develop a procedure that all cardiac surgery teams can perform in good conditions, even in cases of emergency.

Notably an original interface with the patient's atria was developed, interface which allows the surgeon to have much more room to work, and a better subsequent alignment of the prosthesis. Consequently, the procedure is considerably easier and faster. Indeed, the implantation time must be as short as possible to limit the neurological risks of a prolonged extracorporeal circulation.

Once this interface is sutured to the atria, the prosthesis can simply be clicked into place. The cover of this interface consists of a hybrid material of which the side in contact with the blood is made of bovine pericardia to respect the hemocompatibility philosophy of the prosthesis.



Source CARMAT – Rapid atria connection interface

Power supply and independent operation:

Experiences of ventricular assistance have been revelatory in terms of showing the current limits of portable electrical energy technology. These systems use rechargeable batteries with different technologies (Nickel metal Hydride, Lithium-ion...). The autonomy on offer is in the region of just 4 to 6 hours, thus forcing the patient's life into a rhythm that is both restrictive. Progress is being made every year, but this does not enable any major improvements to be anticipated in the short term. For this reason, this mode of power will be adopted for the first versions of the system intended for patients.

Source PaxiTech – Portable fuel cell

In order to provide significantly better independent operation, after having developed a first promising prototype of fuel cell with the company PaxiTech, CARMAT evaluates the feasibility of the industrial development of such a product with Air Liquide. The challenge would be to offer implanted patients increased mobility of at least ten hours without having to connect to the home network.

1.4 GOING ON THE MARKET PROCESS

The process of placing the bioprosthetic artificial heart CARMAT on the market is based on the results obtained during a phase of preparation of the clinical trials, which consisted in studying, designing and manufacturing human implantable cardiac artificial heart systems CARMAT, and to carry out all the tests and validations required to obtain an authorization for clinical trials by the ANSM in France or by the regulatory authorities of other countries.

CARMAT is currently pursuing the last two phases of the process of placing the prosthesis on the market:

- a phase of clinical trials in progress, including a feasibility test, which was finalized in early 2016, and a pivotal study, which was initiated in mid - 2016, after endorsement by the Patient Protection Committee (CPP) and the French National Medicines and Health Products Safety Agency (ANSM);

- A phase of obtaining the CE marking which aims to complete the in vitro and clinical validations for the

submission of the CE marking dossier and which also integrates the industrialization of manufacturing processes. This third phase takes place in parallel with the clinical trials and allows the company to complete its preparation for the marketing of the product.

1.4.1 PREPARATION OF THE CLINICAL TRIALS

The phase of preparation of the clinical trials, now finalized, took place in 3 stages:

- Study and detailed design of the system and its subassemblies.
- The development of the various subsets as well as their qualifications and the integration of the system. During this phase the Company successfully conducted a very broad preclinical testing program:
  - Biocompatibility tests
  - Test bench tests: functional tests, software tests, environmental tests, validation and verification tests of the integration process, endurance tests.
  - Ex vivo tests and in vivo tests (implantations on animals)
- The manufacture of systems for preclinical testing purposes and the commencement of clinical trials.

BIOCOMPATIBILITY TESTS

It is reminded that the prosthesis uses hybrid materials forming the ventricular cavity and suture flanges. These materials constitute one of the original features of the CARMAT system. As well as proving their long-term in vitro physicochemical stability, the Company has chosen during the preparation phase to demonstrate their good long-term implantation properties on the basis of their calcification resistance and excellent hemocompatibility.

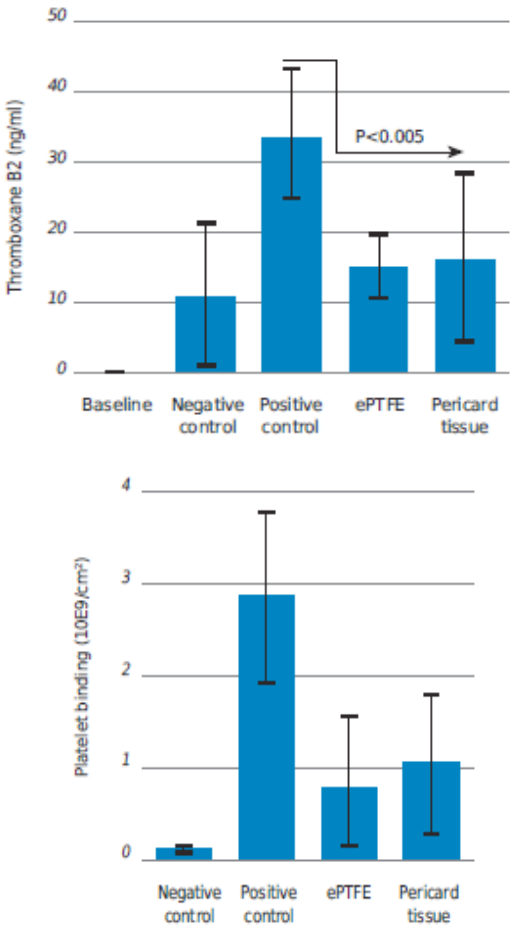
Atrial connection interface

Hybrid biomembrane

The demonstration of the biocompatibility of the material used by CARMAT in direct contact with biological tissue is very promising and has been published in a scientific journal [63].

The Company has a high degree of certainty as to the hemocompatibility of its materials.

Coagulation factors *



Source CARMAT – Results of the hemocompatibility of the hybrid biological interfaces

63 Jansen P, van Oeveren W, Capel A, Carpentier A. In vitro haemocompatibility of a novel bioprosthetic total artificial heart. Eur J Cardiothorac Surg. 2012 Jun ; 41(6):e166-72.

CARMAT has limited the materials interfacing with blood to bovine pericardium and expanded PTFE, which are known for their biocompatibility. As the inlets and outlets, the ventricles have been designed to optimize the blood flow through the device and so minimize contacts and the risks of thrombosis.

TESTS ON TESTS SYSTEMS

All of the test-bench experiments were conducted with constant attention paid to ensuring that every constraint of every component of the system is taken into account with the view of improving the overall quality of the device. CARMAT's testing strategy was to specify the critical components of its device in order to study them separately and then to bring these components together and to test the overall system to obtain a sufficiently high level of confidence for its device. Thus, the Company set up a general test program for its device and specified the sub-components: motor-pump units, hybrid membrane and pouch, sensors, electronics and software according several test categories (functional tests, software tests or endurance tests). All these tests and verifications have been successfully passed.

TESTS EX VIVO AND IN VIVO

Since 2010, the Company has carried out 23 ex vivo and in vivo implantations in order to confirm anatomical compatibility, to develop ancillary implantation instruments, to develop the surgical procedure and train teams.

Despite the limitations of the animal model for the CARMAT artificial heart project, implantation on animals was an indispensable procedural training tool. CARMAT therefore carried out between the end of 2011 and the date of this registration document the implantation of prostheses on about sixty animals.

During these tests with a duration of up to 10 days, the prosthesis operated most of the time at its maximum flow rate (9 liters / minute), without the use of anticoagulants and without dysfunction or stopping and the post-mortem examinations did not detected the presence of blood clots in the device and in the organs of the animal. The results were published in the European Journal of Cardiothoracic Surgery (European Journal of Cardiothoracic Surgery).

1.4.2 CLINICAL VALIDATION

FEASIBILITY STUDY

In 2013, CARMAT obtained authorization from ANSM and the favorable opinion of the Patient Protection Committee (CPP) to start the feasibility study. Its objective was to verify the safety and the exploration of the main performances of the prosthesis. This study was approved by the ANSM for 4 patients and 5 research centers in France.

The indication concerned patients whose disease had progressed at a very advanced stage and whose life-course prognosis was initiated in the short term. Under these particular conditions, a clinical follow-up of 30 days or more after implantation of the artificial heart was considered as encouraging. Success criteria included survival at 30 days.

Five centers were formed to participate in this study:

- Georges-Pompidou European Hospital in Paris (Professor Latrémouille);
- The Surgical center Marie Lannelongue in Plessis-Robinson (Professor Dartevelle and Dr Nottin);
- Laënnec Hospital of the University teaching hospital in Nantes (Professors Duveau and Roussel);
- La Pitié Salpêtrière Hospital in Paris (Professor Leprince);
- The new Strasbourg Civil Hospital (Doctor Kindo).

The following table summarizes the results of the feasibility study. Details of the first two cases were published in the medical journal «The Lancet» [64].

	Transplantation date	Hospital	Characteristics and monitoring
1	December 18, 2013	Georges-Pompidou European Hospital in Paris	Male of 76 years. Support 74 days in the hospital, died following a functional drift of the prosthesis.
2	August 5, 2014	Laënnec Hospital of the University in Nantes	Male of 68 years. Exceptional recovery; Returned home for 4 months. Support 270 days; Died due to a functional drift of the prosthesis
3	April 8, 2015	Georges-Pompidou European Hospital in Paris	Male of 74 years. Support 254 days; Returned home for 4 months. Died during hospitalization due to respiratory and renal failure.
4	December 22, 2015	La Pitié Salpêtrière Hospital in Paris	Male of 56 years. Support 20 days; Died during his resuscitation.

The test was voluntarily suspended by CARMAT during the analysis phases of the prostheses of patients 1 and 2. These analyzes resulted in an improvement in the selection and the validation of components of the prosthesis.

At the beginning of 2016, the feasibility study was completed with the 4th implantation. The primary endpoint (survival at 30 days) was reached in 75%. At the end of this process, the CARMAT system has accumulated a clinical experience of 21 months of operation, enabling the Company to initiate further clinical validation with the introduction of the pivotal study in mid-2016, after both approval of the ANSM and the CPP.

PIVOTAL STUDY

On August 29, 2016, with the approval of both ANSM and CPP, CARMAT announced the first implantation of its artificial heart bioprosthetic as part of the pivotal study. The aim is to validate the safety, efficiency and performance of the system and to contribute to the filing process in order to obtain the CE marking.

In view of the satisfactory results of the feasibility study, the protocol of the pivotal study may include patients with better prognosis, which would increase and accelerate recruitment.

The pivotal study initiated by CARMAT mid-2016 was suspended after the death of the first patient implanted in this pivotal study, ie the fifth patient implanted in total benefiting from the CARMAT prosthesis. The Company confirmed then that the prosthesis functioned correctly during its use by the first patient in the pivotal study. The death of this patient was linked to the interruption of the power supply of the system, following a mishandling of the batteries by the patient who caused the stopping of the prosthesis. Thus, CARMAT Support-Training teams actively worked on this postoperative follow-up aspect in order to enhance the safety of future patients.

On May 2, 2017, the ANSM (French National Agency for the Safety of Medicines and Health Products) gave CARMAT permission to resume its pivotal study in France. This decision follows the positive outcome of the analyses and actions requested by the regulator.

64 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.

The setting up of an international multicenter study is part of good clinical practices and ensures a global basis for a product which is not intended to be limited to the domestic market. It reinforces the ability of CARMAT to put in place a multicenter pivotal study and to establish an international base of trained cardiac surgeons upstream of commercialization.

CARMAT wishes to extend the participation in its pivotal study to other European centers, and has already identified centers in Europe who have confirmed their interest in participating in the pivotal study, in particular important centers, in both volume and in renown in the field of circulatory support, in Germany and Austria.

The extension of the clinical investigation plan to these international centers requires an effort from the Company in terms of locating all the documentation intended for the doctors and the patients and the establishment of local clinical resources and requires the obtaining of the regulatory authorization to conduct the clinical trials in each of the centers, in particular the authorization of the local ethics committees.

During the 2017 year, CARMAT stepped up its efforts to open the pivotal study to other countries in the European zone. These efforts have resulted in the obtaining of the authorization to implement implantations in Kazakhstan and the Czech Republic.

CARMAT is able to carry out implantations at Astana's National Research Center for Cardiac Surgery, in Kazakhstan, under the supervision of the teams of Dr. Yuryi Pya, general manager of the center and internationally recognized surgeon in implanting cardiac devices. The National Research Center for Cardiac Surgery is a world-leading site in cardiology and a leading center for conducting clinical studies of cardiac devices for the European market, with more than 8,000 procedures per year including 31 implanted cardiac devices and 15 transplants. achieved in 2016. The center benefits from excellent post-operative follow-up of patients. It also has strong patient recruitment potential and extensive experience in clinical trials prior to the commercialization of innovative medical devices. The site is currently in the process of recruiting and screening CT scans (chest scanners) to identify patients eligible for CARMAT bioprosthesis implantations.

CARMAT is also able to perform implantations of its total artificial heart in humans at the Institute of Clinical and Experimental Medicine (IKEM) in Prague, Czech Republic. The IKEM Center is recognized for its scientific research

and its pioneering role in the adoption of the latest innovations in medical devices. Its department of Cardiovascular Surgery is one of the leaders in the field with the longest tradition of treatment of end-stage heart failure in the Czech Republic, including the realization of the first heart transplantation in 1984. Today it is recognized as one of the leading centers in Central Europe for its expertise in the treatment of advanced heart failure.

The Company announced on October 19, 2017 the realization of the first international implantation of the artificial bioprosthetic heart carried out at the National Research Center for Cardiac Surgery (Astana, Kazakhstan), then on November 27, 2017 the realization of a second implantation performed at the Institute for Clinical and Experimental Medicine (IKEM) (Prague, Czech Republic), both in accordance with the protocol of the pivotal study approved by the ANSM and in accordance with local authorizations.

In addition, discussion with the US Food and Drug Administration («FDA») continued to evaluate clinical development opportunities in the United States for the launch of a clinical trial in 2018. The objective of the Company would be to conduct a preliminary feasibility study. The Company has surrounded itself with US consultants in order to assist it in its efforts.
More recently, CARMAT announced it has received the approval to perform implants of its total artificial heart in patients at the Heart Center of the Rigshospitalet hospital, Copenhagen, Denmark.

The Heart Center of the Rigshospitalet is an internationally recognized center for the diagnosis and treatment of all types of heart diseases. It has developed a strong expertise in treating advanced heart failure and has participated in front-line clinical studies with innovative medical therapies and devices in this field. The study will be conducted by Professor Finn Gustafsson, a leading heart failure and transplantation cardiologist whose research focuses on the use of invasive hemodynamics in patients.

A total of between 20 and 30 patients should be implanted with the CARMAT artificial heart to provide the clinical validation required to submit a file for the CE mark.

COMMUNICATION OF THE CLINICAL STUDY RESULTS

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

1.4.3 CE MARKING

This phase, prior to the placing on the market of the prosthesis, aims to validate its compliance with European regulatory requirements. It is a process of analysis and validation by a notified body of a file prepared by CARMAT and containing all the elements of conception, production, quality and clinical effectiveness of the prosthesis.

The actions linked to this phase take place in parallel with the pivotal study and include in particular:

- The submission of the various modules constituting the technical marking dossier to the DEKRA notified body responsible for their evaluation;
- Continued endurance testing of systems;
- The location of the documentation - regulatory as intended for users - with a view to extending clinical trials, CE marking and later commercialization outside France.

During 2017 year, the technical teams have made considerable progress in setting up the file for obtaining CE marking, which is a necessary precondition for marketing the bioprosthesis.

The steps include the modular submission of the technical file to DEKRA which will ensure the evaluation and submission of the clinical module at the end of the pivotal study (scheduled for late 2018).

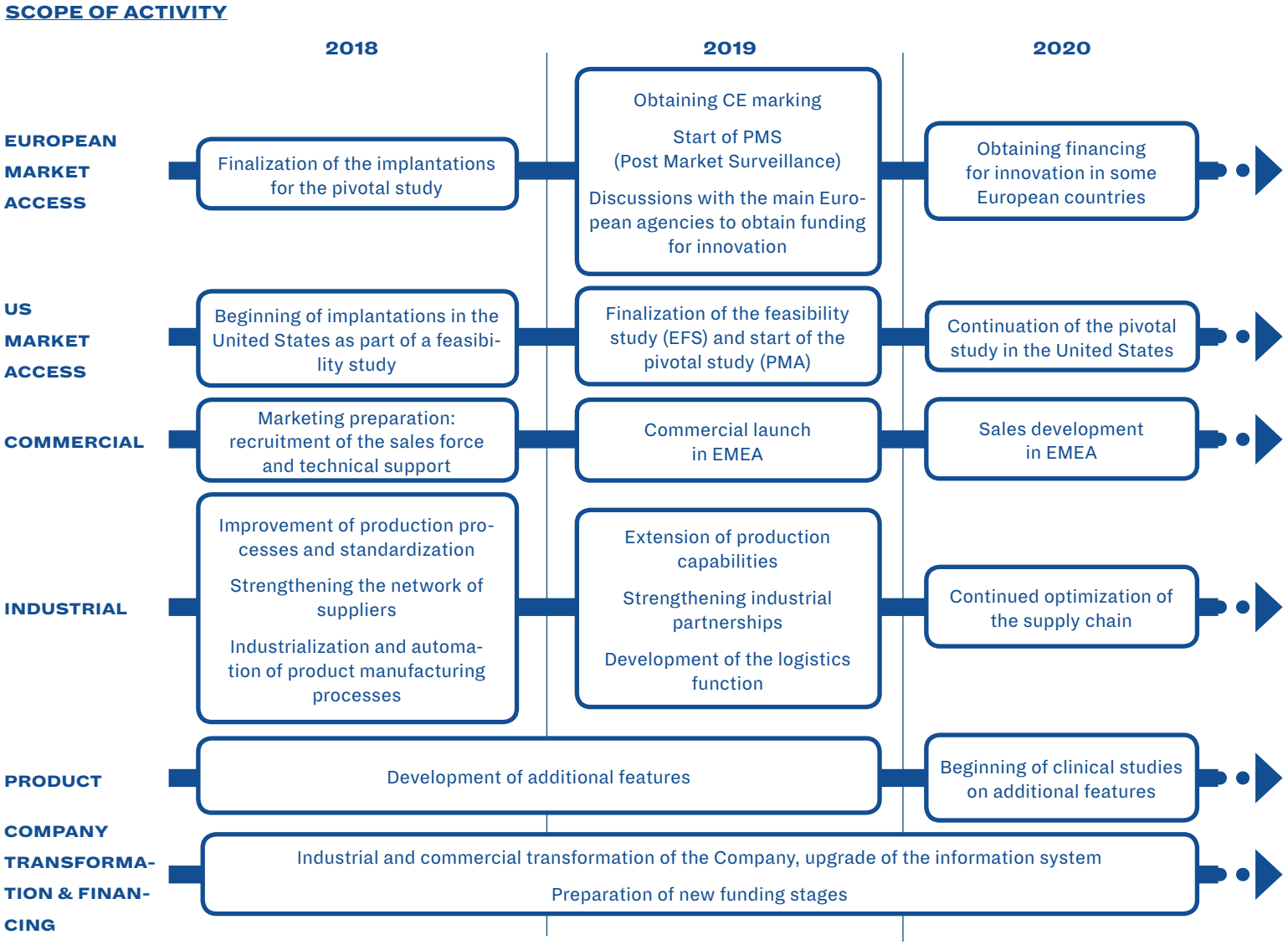
More than half of the 14 modules were finalized in 2017 and the Company's objective remains to obtain CE marking in 2019.

1.4.4 PROVISIONAL PROJECT SCHEDULE

In 2017, CARMAT continued its development and the implementation of the measures required to secure its project in accordance with the following fundamental routes:

- clinical: ongoing screening of patients eligible for the PIVOTAL study and training of the implant centers with a particular emphasis on the quality of the postoperative follow-up, a key criterion in this type of clinical trial, while developing actions to extend the pivotal study internationally;
- reliability: putting in place tools and procedures enhancing the safety of the patients participating in the trial, in accordance with the ANSM's demands;
- production: work on the new automated assembly plant is ongoing, and the site should be completely operational in early 2018. It will allow manufacturing on a larger scale with a higher yield to meet prosthesis requirements during the entire pivotal phase and after.

Given the progress made simultaneously on all these critical routes, CARMAT is today able to confirm its objective of completing the pivotal study and obtaining the CE marking during 2019 year. The CARMAT provisional project schedule is updated as follows:



Source CARMAT – Provisional project schedule

The reader is invited to refer to Chapter 2. « Risk Factors », for an informed appreciation of this timetable, as well as to the Company's regular press releases on the progress of the project.

1.5 STRATEGY OF THE COMPANY

1.5.1 REGULATORY STRATEGY

FRENCH AND EUROPEAN CONTEXT

The CARMAT heart is an active implantable medical device (AIMD) and, as such, must satisfy the Key Requirements of directives 90/385/EEC and 93/42/EEC to obtain the CE marking.

It is a very rigorous process of which CARMAT has already successfully passed the first step thanks to the ISO 13485-9001 certification in July, 2011. The annual audits of re-certification have also been successfully passed in May, 2012, May, 2013, and June, 2014.

The key requirements mentioned in various directives applicable to medical devices are as follows:

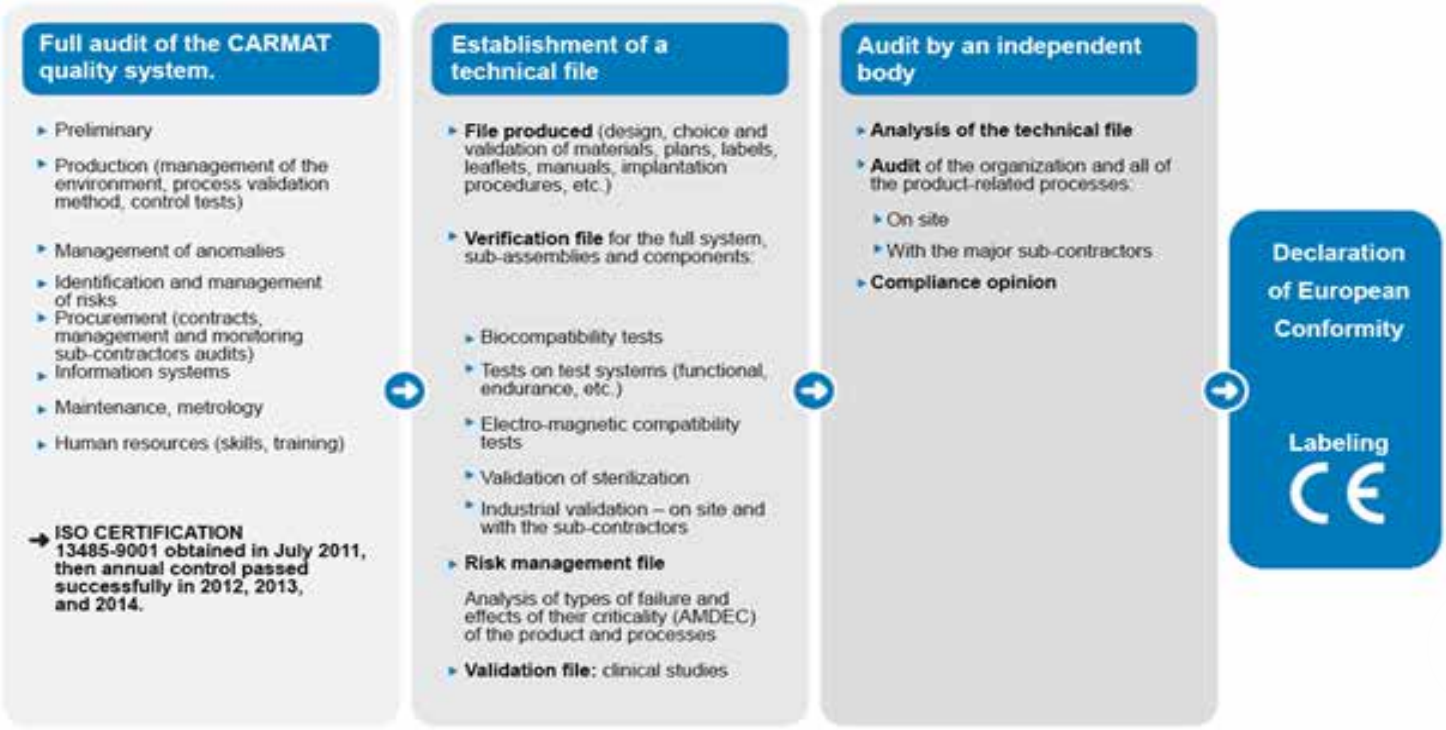
- the medical devices must not compromise the clinical state or the security of the patient;
- additionally, they must not present risks for the people who implant them, or for third parties;
- these devices are required to meet the performance determined by the manufacturer;
- they must be designed such that they can resist storage and transportation conditions.

These requirements are described in rather general terms in order to cover a large range of technologies. The manufacturer must review each key regulation in order to determine if it applies to the device, then identify the harmonized European standard that allows compliance with that key regulation to be shown. The requirement to comply with the key regulations must be the manufacturer's priority in order to ensure that all the necessary measures have been taken so that the device does not compromise the safety and health of the patients, the user and, if required, other people, once installed, maintained and used correctly, depending on the planned use, it being understood that any risks linked to its use constitute acceptable risks with regard to the benefit brought to the patient and compatible with a high level of protection of health and safety.

Compliance with key regulations must be considered both as an objective (compliance with safety and health), and as a means of obtaining the objective. According to the European directives, each stage of the CE marking process must take into account, in addition to the considerations of security and planned usage of the device, other aspects such as the design or properties related to the construction, protection against radiation, mechanical, thermal or electrical risks, or function measurements or even labeling.

CE marking via the declaration of CE compliance is based on a complete audit of the quality assurance system with an assessment of all the Company's processes and focusing on activities linked to the product. An exhaustive technical file must then be prepared, consisting of, in addition to the design elements, the risk management file and all the verification and validation data – in particular the results of clinical trials. The Company will then have to be audited by an independent notified body which will confirm the technical file and all of the product and organization related processes at CARMAT and if necessary at its sub-contractors. Once this audit has been successfully passed, CARMAT will be able to obtain the CE marking, which authorizes the commercialization of the product throughout the European community. Certain member states have put in place additional conditions concerning, for example, the registration or notification of market introduction.

If the clinical studies are successful and subject to no difficulties particularly in continuing the studies or the patient recruitment rate, the full CE mark file for the model artificial bio-prosthetic heart will be submitted to the notified body. So, the validation process by the notified body takes, in general, from six weeks to a few months. This process is summarized in the illustration below (refer to Paragraph 2.2 « Risks Relating to the Company's Activity » and 2.3 « Regulatory and Legal Risks », for the risks associated in particular with clinical trials and CE marking).



Source CARMAT – CE marking procedure

AMERICAN REGULATIONS

The marketing of the CARMAT heart in the United States of America is subject to obtaining approval (PMA: Premarket Approval) awarded by the American Health Authority (FDA: Food & Drug Administration). Before submitting a PMA application to the FDA, CARMAT will be required to supplement the existing clinical file with new preclinical tests and data from a new multicenter clinical study performed on a larger population (refer to Paragraph 2.2.4 « Risks Connected With Clinical Studies in the United States »). Carrying out this study in the United States is itself subject to obtaining authorization (IDE : Investigational Device Exemption) from the FDA, based in particular on all of the pre-clinical data (technical studies, animal studies, etc.) required by the sponsor and clinical data collected in other countries.

In October 2013, the FDA published a guidance document «Early Feasibility Studies». This approach to feasibility studies was designed to acquire 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 may be an interesting approach for CARMAT.

In 2014 the Company began exploratory work to produce its regulatory strategy for the United States. With a view to prudence, the Company has, for the moment, planned to wait to be at least midway through its European pivotal study before starting its regulatory activities in the United States, activities which could last between 2 and 4 years depending on the resources allocated to this effort, the type of study authorized and the pace of recruitment for this study.

This cautious strategy would allow the integration of certain clinical data acquired in Europe into the FDA file (the aim is that the majority of the European centers selected for the pivotal study would be approved by the FDA).

This schedule could be accelerated if the Company secures more significant resources or enters into an agreement with a local industrial or financial partner (see Paragraphs 2.2 « Risks Relating to the Company's Activity » and 2.3 « Regulatory and Legal Risks for the risks » associated in particular with preclinical and clinical trials in the United States).

1.5.2 MARKETING STRATEGY

The Company will be able to market its product throughout Europe once it has been granted CE marking, subject to applying the national systems covering the cost of the device (refer to Paragraph 2.3.4 « Risks connected with changes in reimbursement policies for medical devices »).

The Company considers that the absence of reimbursement is not synonymous with the absence of sales or revenue. Hospitals in some countries have their own budgets to finance innovation and pre-reimbursement financing exists in many countries (NUB in Germany, STIC or Forfait Innovation in France, etc.).

Moreover, the Company has been selected, as part of the SEED program, to benefit from a preliminary dialog with the main European health technology assessment agencies upstream of the CE marking. This preliminary dialog allows CARMAT to understand the expectations of the authorities, particularly concerning the compliance of clinical data required to obtain an appropriate reimbursement. If, of course, this dialog does not imply a guarantee regarding a time frame or obtaining of a reimbursement, it allows CARMAT to understand and apply all the means necessary to obtain it in the shortest delay possible [65].

The Company currently plans to proceed with this commercialization through a direct sales force in the principal European countries, and a distribution network in the countries deemed less strategic, at least during the initial phase.

This choice stems from two factors:

- rigorous 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 center of the target, i.e. the active heart transplantation centers (at least 20 cardiac transplants per year) followed by the less active centers, then the centres with teams dedicated to heart failure (surgery and cardiology) but who are not approved for transplantation and finally, if the local regulations permit, all cardiac surgery centers.

This approach should allow incremental investment. In view of the very small number of transplants, the number of truly active cardiac transplantation centres, i.e. those which use their approval and carry out a sufficient volume of transplants to maintain available trained teams, is very low and less than around ten in each major country. For example, only 8 centers in Germany, 5 in France and 2 in the United Kingdom perform more than 20 transplants a year.

The Company therefore considers that, to cover this target consisting only of centers of excellence, a direct sales force is the most appropriate response in the initial phases of commercial development (a 3- to 5-year period post-commercial launch in Europe). In the longer term, when the Company has built up a solid clinical and medical-economic database and has confirmed the adoption of the therapy by the implantation centers, it may turn its efforts to educating referral centers in order to expand recruitment and promote growth.

The development of a commercial approach to the American market is premature at this stage, but will probably require a collaboration with a local financial or industrial player.

With regard to the politics of fixing the price, the price objective of the CARMAT bioprosthetic artificial heart project remains in line with current practices of reimbursement for available devices. For example, a left mono-ventricular implantable assist device is, today, reimbursed between €60,000 and €110,000 (excluding taxes) in Europe (approximately €90,000 excluding taxes in France [66]). Being a system that consists of an implantable part, but also external parts and associated pre- and post-operational services, the adjustment variables are many and could allow the adaptation to volume and reimbursement conditions specific to each center or each market.

The reimbursement procedures are many and different for each country. Therefore, the sales force will initially consist of (i) profiles with a strong clinical background to ensure the training and adoption of the device by the medical-surgical community and the collection of medical-economic data, and (ii) of specialists in reimbursement.
It is in this perspective that CARMAT announced on September 1, 2016 the arrival of Stéphane Piat as chief executive officer, replacing Marcello Conviti. With his experience in the commercialization of medical devices, particularly at Johnson & Johnson Cordis or Abbott, Stéphane Piat intends to implement this strategy.

65 See press release January 22nd 2015 - http://www.eunethta.eu/seed - http://www.earlydialogues.eu/has/

66 Liste des Produits et Prestations remboursables – LPP (ameli. fr) : regulated price per unit for the HeartMate II® is € 87 565.

1.5.3 INDUSTRIAL STRATEGY

CHOICE OF INTEGRATION MODEL

The Company designs or specifies all of the elements making up the CARMAT artificial heart project, including its external elements as well as all the ancillary tools, packaging, systems and methods intended for the validation (test benches) and production of components, sub-assemblies and systems (clean room). It has also developed strong intellectual property rights concerning all of these elements. 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 especially to produce them all internally.

The Company has therefore adopted a model of integration: it designs and specifies, but entrusts the manufacturing of most of the elements to specialized subcontractors, recognized in their domain of activity and selected following rigorous consultation - elements that are then integrated into the Company's clean room.

CARMAT integrates the components and sub-assemblies provided by manufacturers of very different sizes, methods and areas of expertise. Thus the Company has more than 80 manufacturers of elements or service providers linked to the implantable part of the CARMAT system.

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

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. The creation of this network constitutes an accomplishment in its own right, and creates value for CARMAT as well as for all industry in France.

In parallel, the Company actively continues a strategy of developing a secondary source of supplies, in particular the transformation of critical raw materials or the supply of key components. To initiate a second source involves the selection of a new supplier, help in producing the 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 which comes with them to satisfy traceability. It is important work but vital to reduce the dependency of the Company with regards to their suppliers and to anticipate the industrialization phase.

The Company is continually adapting to the challenges of industrialization and production of prostheses in larger quantities with controlled, correctly managed quality.

INTERNALIZED PRODUCTION AND PRODUCTION CAPABILITIES

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

Vélizy CARMAT's clean room has two distinct areas, one is ISO class 5 used for the manufacturing and sterilization of biosynthetic and ventricular internal elements, the other is ISO class 7 where other elements, essentially outsourced, are assembled around the sterile «heart of the heart». The manufacturing, integration and sterilization of the prosthesis are also performed in this controlled environment by specialized and highly qualified personnel.

2017 year was marked by the construction of a dedicated site to manufacture up to 500 units per year, site which is scheduled to open in Q1 2018. The site, with an area of 1,600 m², located in Bois d'Arcy in the immediate suburbs of Paris, will have a 270 m² clean room complying with ISO 7 standards.

The teams also remain mobilized for the installation and qualification of industrial production means deliverable to continue to improve the security of the units produced and increase productivity:

- automatic hybridization of the membrane,
- means of assistance to bagging operations and hemocompatible coating, and
- automated device test and device leak test.

On the industrial front, the Company will continue its efforts to secure supply, improve information systems and adapt production processes for components and equipment. The goal is to achieve better replicability and increase production capacity.

MAIN PARTNERS

In connection with Bpifrance financing (refer to Paragraph 3.1.10 « Important Contracts »), the bioprosthetic artificial heart project is based around CARMAT as leader, with four other partners in complementary research and development areas, thereby allowing the participation in the development of a high-technology sector in the field of medical devices:

- Dedienne Santé is an SME specializing in the design, manufacture, market introduction and distribution of surgical implants, mainly in the orthopedic domain. For the bioprosthetic artificial heart project, Dedienne Santé did use biocompatible PEEK to develop the assemblies which make up the structural parts of the prosthesis;

- Iréis (formerly called HEF R&D) is a subsidiary of the HEF group which specializes in surface engineering and has invented many tri-biological or anti-corrosion surface treatments and coatings since 1953. In connection with the total artificial heart project, Iréis performs the qualification of the motor-pump unit, which is a critical part of the prosthesis;

- PaxiTech is a technological spin-off of the CEA created in September 2003, whose objective is to produce and market portable fuel cells and fuel cell components, regardless of their power range. In connection with the bioprosthetic artificial heart project, PaxiTech developed a fuel cell which would eventually be used as a source of portable external energy. After having developed a first promising prototype with the company PaxiTech, CARMAT evaluates the feasibility of the industrial development of such a product with Air Liquide. The challenge would be to offer implanted patients increased mobility of at least ten hours without having to connect to the home network;

- with strong experience of almost 50 years (the company was created in 1959), Vignal Artru Industries (Pack'Aero group) is a specialist SME in the production of high precision mechanical micro-systems. In connection with the bioprosthetic artificial heart project, VAI produces the «motor-pump unit» (MPU) assemblies, made up of two micro-pumps and a duct. VAI is in charge of integrating these units, the various characterization and running-in tests, as well as the receiving files of motor-pump unit assemblies.

During the fourth quarter of 2017, CARMAT signed a partnership agreement with AddUp, the Joint Venture specialized in 3D printing set up by the Michelin and Fives groups. The aim of this collaboration is to strengthen the industrial development of the CARMAT heart and contribute to increase the Company's production capacity in preparation for the large scale production phase. To this effect, CARMAT and AddUp plan to use the possibilities offered by the technology of additive manufacturing to simplify and optimize the production of mechanical primary pieces.

Thanks to AddUp's expertise, CARMAT will ultimately be able to provide surgeons and patients with a version of its artificial heart that incorporates all the technological benefits of 3D printing, and in particular:

- optimized anatomical interfaces leading to enhanced anatomical compatibility and surgical comfort;

- reduction in the number of components, thus better securing the device's assembly.

1.5.4 INNOVATION AND R&D MANAGEMENT

APPLICATION OF SKILLS

CARMAT is a young company, created barely ten years ago, but it already enjoys – thanks to its involvement with the bioprosthetic artificial heart project and thanks to its teams – an exceptional and unique dual expertise accumulated over more than 15 years of development and collaboration with the medical world and the world of space and aeronautics, in the application of biomaterials and advanced technologies in the field of bioprosthetic artificial hearts.

Over and above the contributions of the world of medicine and the world of space and aeronautics, the Company has also found ways of bringing together skills in areas that have never been in the habit of working together on so complex a project, each acquiring expertise belonging to these fields.

Emboldened by this unique capacity for creating synergies between skills from industry and from the medical world, CARMAT's future ambition, in addition to the field of the bioprosthetic artificial heart, is to tackle the development of new applications of its know-how in the cardiovascular domain. Original simple devices derived from research already carried out by CARMAT and the patents that it holds, in particular with regard to hemocompatible biomaterials, could also be developed. Products derived from patents which have 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 could also be commercialized.

However, the Company does not foresee devoting resources to these potential applications while the artificial heart project is not successfully completed. The Company continues an aggressive protection policy of its intellectual property and ensures a permanent technological watch of technologies and methods corresponding to its areas of activity.

INTELLECTUAL PROPERTY

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

- Patents:

CARMAT's portfolio of patents is made up of 12 patents held in the name of the Company, 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
« Independent ventricular chamber implantable cardiac prosthesis »	France	FR9812941 FR2784585	October 15, 1998	Granted on January 26, 2001 Expiring on October 15, 2018
« One-piece heart prosthesis implantable in an anatomical position »	France	FR0605333 FR2902345	June 15, 2006	Granted on September 05, 2008 Expiring on June 15, 2026
	Europe	EP07290725.6 EP1867352	June 11, 2007	Granted on July 15, 2009 Expiring on June 11, 2027
	International	PCT/FR2007/000962 WO2007/144497	June 11, 2007	Published on December 21, 2007
« Implantable one-piece heart prosthesis »	France	FR200800184 FR2926223	January 14, 2008	Granted on January 22, 2010 Expiring on January 14, 2028
	Europe	EP09290009.1 EP2078533	January 07, 2009	Granted on January 12, 2011 Expiring on January 07, 2029
	International	PCT/FR2009/000008 WO2009/112662	January 07, 2009	Published on September 17, 2009
« Composite hemocompatible material and the process through which this is obtained »	France	FR0511430 FR2892939	November 10, 2005	Granted on January 22, 2010 Expiring on November 10, 2025
	Europe	EP06291657.2 EP178515	October 25, 2006	Granted September 23, 2009 Expiring October 25, 2026
	International	PCT/FR2006/002471 WO2007/054637	November 07, 2006	Published on May 18, 2007
« Reduced radial volume rotatory volumetric pump »	France	FR0604206 FR2900988	May 12, 2006	Granted on January 01, 2010 Expiring on May 12, 2026
	Europe	EP7290571.4 EP1855005	May 07, 2007	Granted on January 28, 2009 Expiring on May 07, 2027
	International	PCT/FR2007/000778 WO2007/135261	May 07, 2007	Published on November 29, 2007

Title	Geographical area	Submission / publication no.	Date of Submission	Status
« Rapid connection device between a totally implantable cardiac prosthesis and natural atria »	France	FR0605331 FR2902343	June 15, 2006	Granted on September 05, 2008 Expiring on June 15, 2026
	Europe	EP07290723.1 EP1867350	June 11, 2007	Granted on September 24, 2008 Expiring on June 11, 2027
	International	PCT/FR2007/000959 WO2007/144495	June 11, 2007	Published December 21, 2007
« Connection device between a cardiac prosthesis and natural atria »	France	FR0605332 FR2902344	June 15, 2006	Granted on September 05, 2008 Expiring on June 15, 2026
	Europe	EP07290724.9 EP1867351	June 11, 2007	Granted on September 24, 2008 Expiring on June 11, 2027
	International	PCT/FR2007/000960 WO2007/144496	June 11, 2007	Published on December 21, 2007
« Process for producing a hemocompatible item with a complex configuration and item thereby obtained »	France	FR0703339 FR2915903	May 10, 2007	Granted on June 04, 2010 Expiring on May 10, 2027
	Europe	EP08290405.3 EP1992369	April 28, 2008	Granted on May 06, 2015 Expiring on April 28, 2028
	International	PCT/FR2008/000607 WO2008/145870	April 28, 2008	Published on December 04, 2008
« Process for obtaining a composite hemocompatible material and material obtained »	France	FR1001724 FR2959134	April 22, 2010	Granted on July 13, 2012 Expiring on April 22, 2030
	Europe	EP11161291.7 EP2380608	April 06, 2011	Granted on September 12, 2012 Expiring on April 06, 2031
	International	PCT/FR2011/050768 WO2011/131887	April 06, 2011	Published on October 27, 2011
« Process to ensure the connection of an anatomical duct »	France	FR1152364 FR2972919	March 22, 2011	Granted on July 04, 2014 Expiring on March 22, 2031
	Europe	EP12158011.2 EP2502577	March 05, 2012	Granted on November 02, 2016 Expiring on March 05, 2032
	International	PCT/FR2012/050449 WO2012/127145	March 05, 2012	Published on September 27, 2012
« Tissue endoprosthesis and the process through which this is produced »	France	FR1500457	March 10, 2015	Granted on March 24, 2017 Expiring on March 10, 2035
	Europe	EP16159051.8	March 07, 2016	Published on September 14, 2016
	International	PCT/FR2016/050525 WO2016/142617	March 07, 2016	Published on September 15, 2016
« Flexible barrier membrane and method of manufacturing the flexible barrier membrane »	France	FR1756847	July 19, 2017	-

- Exclusive licence agreements:

Exclusive licence contract with the Pierre et Marie Curie University

In the terms of an exclusive licence contract dated 17 June 1993, modified by amendment no. 1 of June 27, 1995 and by amendment no. 2 of November 12, 1997, the Pierre et 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 initially it was Matra Défense which used the intellectual property rights thus granted, the benefit of this license was subsequently assumed by CARMAT, to which the Université Pierre et Marie Curie consented by way of an agreement duly signed by the Université Pierre et Marie Curie, Matra Défense, the Scientific Research Association of the Alain Carpentier Foundation and CARMAT. Under this agreement (i) the Université Pierre et Marie Curie 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 the intellectual property rights that could have been attributed to the Université Pierre et Marie Curie; and (ii) in return, the Scientific Research Association of the Alain Carpentier Foundation granted at no cost, in its name and for its 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 the Université Pierre et Marie Curie.

Patent No. 8800381 has now expired since 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.

- Trade marks:

The Company has registered the « CARMAT » trademark in the following countries or geographical zones

Registration number	Statut	Date filed	Renewal date	Territories	Classes
023184827	Recorded	Sept. 23, 2002	Sept. 23, 2022	France	9, 10, 42
007374821	Recorded	Oct. 29, 2008	Oct. 29, 2018	Community (European Union)	9, 10, 42
1022720	Recorded	June 19, 2009	June 19, 2019	International Designations: China, Japon, Switzerland, Russia	9, 10, 42 1
3663230	Recorded	January 07, 2009	August 04, 2019	United States (USA)	10, 42
1442665	Recorded	June 25, 2009	Sept. 27, 2026	Canada	10, 42
200911637	Recorded	June 24, 2009	June 24, 2019	South Africa	10
200911637	Recorded	June 24, 2009	June 24, 2019	South Africa	42
1838058	Recorded	July 09, 2009	July 09, 2019	India	10, 42

Global monitoring is carried out on the name « CARMAT » among the trademarks filed in classes 9, 10 and 42. This surveillance was renewed until April 1, 2018.

Global monitoring is carried out on the name « CARMAT » among the domain names. This monitoring was extended until May 15, 2018.

- Domain names:

The Company has filed the following domain names:

Domain name	Date reserved	Renewal date
carmatsas.com	October 29, 2008	October 29, 2018
carmatsas.fr	October 29, 2008	October 29, 2018
carmatsas.eu	October 29, 2008	October 31, 2018
carmat.tel	February 20, 2009	March 22, 2018
carmatsa.fr	April 29, 2010	April 29, 2018
carmatsa.com	April 29, 2010	April 30, 2018
carmatsa.eu	April 29, 2010	April 29, 2018

2

RISKS FACTORS

Caution:

Investors are invited to take into consideration all the information appearing in this Registration Document, including the risk factors described in this Chapter.

When preparing this registration document, the Company carried out a review of the risks which might have a significant unfavorable impact on its activity, its financial situation, its performance, its development or its prospects, and it considers that there are no other significant risks than those presented.

However, investors' attention is drawn to the fact that other risks which are unknown or whose materialization is not considered, at the date of filing this registration document, as liable to have a significant unfavorable impact on its activity, its financial situation, its performance, its development or its prospects, might or may exist.

2.1 RISKS RELATING TO THE MARKET IN WHICH THE COMPANY OPERATES

2.1.1 RISKS RELATED TO MARKET SIZE

The Company's bioprosthetic artificial heart aims to be the destination therapy for patients with biventricular end-stage heart failure whose condition is life-threatening in the short term, who have exhausted all therapeutic alternatives and who do not have access to a heart transplant due to their age, comorbidities or the shortage of donor organs.

The scientific community agrees that the prevalence of this indication is increasing significantly due to population ageing and progress made in the treatment of myocardial infarction, which prevents many deaths in the short term, but which substantially increases the absolute number of people living with a compromised cardiac function and with a heart failure in the clinical sense.

However, progress that could be made in the area of prevention of certain risk factors of cardiovascular diseases in general (nicotinism, hypertension, obesity, etc.) or specific therapeutic breakthroughs in the field of heart failure could lead to a reduction in the prevalence of the disease in its advanced stage.

Moreover, the population targeted by the indication is heterogeneous and mostly elderly. It is possible that the Company's bioprosthetic artificial heart may not obtain the indication or adoption by the medical and scientific community for the whole of the population currently targeted (about 0.5% of the total number of heart failure patients).

A significant reduction in the market to which the Company could propose its product, due to a reduction in the prevalence of the disease or a limitation of the indications, whether due to a decision by the regulatory authorities or due to a failure of the scientific community and healthcare professionals to adopt its bioprosthetic artificial heart, could have a significant, unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

2.1.2 RISKS RELATING TO COMPETITION

Potential competition to CARMAT comprises:

- on the one hand, total artificial hearts, whether on sale or still in development, and implantable biventricular assist devices (BIVADs) with a high potential to serve as substitutes for the heart developed by CARMAT;

- In this segment, only the Syncardia® player has a total artificial heart product currently marketed in Europe and the United States. After facing financial difficulties («Chapter 11»), the company received in September 2016 the support of the private equity fund Versa Capital Management, which could stimulate this competitor of CARMAT in a perennial way.

- on the other hand, and to a lesser degree, implantable right/left ventricular assist devices (RVAD/LVAD), which are less apt to serve as substitutes as they only support one ventricle.

- In this other segment, two main players are active:

  - the historical leader, Thoratec®, whose more than 18,000 products were implanted at the end of 2014,

and who was bought by mid-2015 by Saint Jude Medical on the basis of a valuation of $ 3.3 billion, even though HeartMate® products may have resulted in relatively high levels of complications including thrombosis. In April 2016, the Abbott Group and Saint Jude Medical announced their merger, valuing Saint Jude Medical at approximately $ 25.0 billion. The new group created as a result of this merger is positioned as a global leader in medical devices, with applications in the cardiac field, diabetes treatment, or vision disorders. Abbott announced in late August 2017 that it had received FDA approval for its HeartMate® 3 left ventricular support system (LVAD). According to Abbott, this system offers a new option for physicians who manage patients with advanced heart failure requiring short-term hemodynamic support (awaiting transplant).

The system also provides new patients with new devices that embody the evolution of left ventricular assist (LVAD) therapy, such as improving blood flow in a pump that uses a complete magnetic levitation to reduce the trauma of blood passing through the system. However, this system is non-pulsatile and is limited to assistance from the left ventricle.

FDA approval of the HeartMate® 3 system was supported by a clinical study that showed a significant improvement in patients with heart failure, an 83% increase in walking distance, and an improvement of 68% of quality of life to six months. Patients receiving the HeartMate® 3 system also had a survival rate of 86% at six months. During the clinical study, according to Abbott, the HeartMate® 3 system did not have any presumed or established blood coagulation in the pump at six months.

The clinical study included more than 1,000 patients with Class IIIB or IV heart failure in the New York Heart Association (NYHA). Patients were monitored for a six month short-term endpoint and continue to be monitored for a two-year long-term endpoint.

- HeartWare®, the main competitor of Thoratec®, with products such as HVAD®, designed to assist cardiac function but not to substitute for it. This company was acquired by Medtronic in August 2016, for a total valuation of $ 1.0 billion. This acquisition, through the financial support provided by Medtronic, among the world leaders in medical devices, reinforces HeartWare®'s ability to continue its activities and the development of new products competing with the CARMAT artificial heart.

As at the date hereof CARMAT is not currently aware of any existing device or project which involves or plans to involve the use of either biological materials or self-regulation via multiple integrated sensors. These two characteristics are at the core of the technological innovation that CARMAT intends to offer to patients.

Nevertheless, the medical devices market is highly competitive and rapidly evolving. In particular, the Company competes with very larger companies which possess greater industrial and commercial experience and superior resources. Consequently, the Company cannot warrant that its product will:

- obtain the necessary regulatory approvals and reach its intended markets faster than rival products;
- be competitive vis-à-vis other products that have been developed or are in development, which may prove to be cheaper, safer or more efficient;
- adapt rapidly enough to new technological developments and scientific advances;
- be accepted by medical establishments, physicians or patients in place of existing treatments, and;
- compete effectively with other products for treatment of the same pathologies.

Even if the Company's product is marketed successfully, it may be slow to gain acceptance in the market, leaving the Company in a position where its revenues are insufficient to recoup the costs incurred. In order to ensure that its product is accepted by the market ahead of existing products, the Company will have to make significant efforts in terms of both marketing and capital investment. To date, the Company has not undertaken any significant marketing activity since its product is still in clinical development phase.

Lastly, the Company's contracts with its employees do not contain non-competition clauses. The Company therefore does not enjoy the protection afforded by such clauses; however, it intends to maintain and develop a policy of securing staff loyalty by awarding interests in its share capital to its employees.

If all or part of the aforementioned risks materialized, this could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

2.1.3 RISKS OF COMMERCIAL FAILURE

To date, if the Company succeeds in obtaining CE marking in the European Union for the CARMAT bioprosthetic artificial heart and a product marketing authorization from the FDA in the United States enabling it to market its bioprosthetic artificial heart, it may take time to secure the backing of the medical community, especially cardiologists, cardiac surgeons and third-party payers.

Whether or not the market accepts the bioprosthetic artificial heart quickly or not will depend in particular on the following factors:

- the medical profession's perception of the therapeutic benefit of the bioprosthetic artificial heart;
- the medical profession's and patients' perception of the improvement in comfort and quality of life;
- the demonstration of product efficacy and safety;
- the number of establishments likely to carry out artificial heart implants;
- the process and the quality of training of cardiac surgeons in a new surgical technique;
- the cost of the treatment;
- the healthcare payment policies of governments and other third parties;
- the effective implementation of a scientific publicity strategy;
- the possible occurrence of adverse effects in its tests or in the clinical trials of its competitors, once the CE marking has been obtained;
- the support of recognized experts;
- the willingness of targeted patients to try a new product; and
- the willingness of professionals to prescribe the product.

Poor market penetration resulting from any one of these factors could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

2.1.4 RISKS RELATING TO THE ACHIEVEMENT OF NON ORGANIC GROWTH

The Company's commercial activities will in the long term depend partly on its ability to constantly improve and expand its product offerings, and in particular systems relating to the power supply and remote diagnosis of the bioprosthesis, in order to meet constantly changing market requirements, face up to strong competitive and technological pressure and extend its geographic coverage.

To go on that way, the Company might therefore have to consider making selective acquisitions of new or complementary products or technologies. The execution of this strategy partly depends on the Company's ability to identify attractive targets, to acquire them in satisfactory conditions and to integrate the acquired targets successfully into its operations or its technology.

Moreover, the acquisition of products, technologies, teams or companies, and the conclusion of other significant transactions could entail a significant cost burden for the Company. The Company could also have to finance such acquisitions by borrowing or by issuing securities, which could cause it to take financial risks, or have a dilutive impact for its shareholders.

The activity, financial situation, performance, development and prospects of the Company could be significantly affected by the materialization of one or more of these risks.

2.2 RISKS RELATING TO THE COMPANY'S ACTIVITY

2.2.1 RISKS OF DEPENDENCE ON A SINGLE PRODUCT, THE BIOPROSTHETIC ARTIFICIAL HEART, AND THE TECHNOLOGICAL APPROACH ADOPTED BY THE COMPANY

The Company remains dependent on the clinical development and commercial success of its bioprosthetic artificial heart. The development of this complex bioprosthesis, which the Company can not guarantee the outcome, required and still requires significant investments until its commercialization phase in terms of time and financial resources, as well as the involvement of highly qualified staff.

CARMAT's future success and its capacity to generate revenue will thus depend on the technical and commercial success of this medical device, and specifically on a number of conjectural factors, such as:

- the authorization and success of clinical trials necessary for obtaining CE marking for the CARMAT artificial heart in the European Union, being specified that if the results of these studies are not satisfactory or conclusive, the Company may have to choose between abandoning the program, resulting in the loss of the corresponding investment in time and money, or its continuation, without guarantee that the additional expenses thus incurred will lead to success;
- obtaining an HDE (Humanitarian Device Exemption)

or IDE (Investigational Device Exemption) exemption from the FDA, enabling the Company to conduct a trial in the United States, which is necessary in order to obtain HUD (Humanitarian Use Device) or PMA (Premarket Approval) designation prior to introducing the bioprosthesis on the American market, or in accordance with the provisions published by the FDA in April 2015 in its guidance document « Expedite Market Access » (see paragraph 1.5.1 « Regulatory strategy » of the Registration Document);
- the success of the commercial launch; and
- acceptance of the bioprosthetic artificial heart by the medical community, and more particularly by cardiologists and cardiac surgeons, as well as third party payers (e.g. social security systems).

The regulatory barriers to the control, manufacture and marketing of the CARMAT bioprosthetic artificial heart are all stronger as this product constitutes a technological innovation. The combined use of biological materials and a system of self-regulation by means of multiple onboard sensors being unprecedented, the manufacture of a product meeting all the constraints that would be imposed presents a challenge as for its technical development that make it difficult to predict the timing and cost of product development as well as the subsequent requirements of regulatory authorities.

This product requires surgery and the assistance of a seasoned team of surgeon(s), anesthetist(s), perfusionist(s) and nursing staff (at the point of their training, see risk factor 2.2.6 in this registration document), the success of the implementation of the CARMAT bioprosthetic artificial heart also depends on the intervention of third parties that the Company can not control. Surgeons could use the CARMAT bioprosthetic artificial heart inappropriately. Misuse could undermine the Company's image and could in some cases lead to legal action against it. All of these consequences could have adverse effects on the general business of the Company.

If CARMAT does not manage to finalize the clinical and commercial development of its bioprosthetic artificial heart, the Company's activity, its financial situation, its performance, its development and its prospects could be significantly affected.

In the future, capitalizing on the expertise acquired within the framework of its bioprosthetic artificial heart project, CARMAT plans to develop new applications of its expertise in the cardiovascular field or apply this expertise and its intellectual property to other fields of application. However, the development of complementary projects could be delayed insofar as the artificial heart project is at present the Company's priority. Moreover, CARMAT cannot rule out the possibility that it might not manage to have other products enabling it to reduce this dependence. Such a situation would also have a negative impact on its development and its prospects.

The realization of all or part of the aforementioned risks could have a material adverse effect on the Company's business, financial position, results, development or prospects.

2.2.2 RISKS RELATING TO THE FUTURE RESULTS OF CLINICAL STUDIES

As part of its development, the Company will make use of numerous studies to confirm the safety and efficiency of its products. After the successful completion of the feasibility study in early 2016, the Company initiated the pivotal study protocol.The results of clinical studies are in any case uncertain. If the Company were unable to obtain positive results proving the therapeutic breakthrough represented by its products, the Company might not obtain the regulatory approvals required for their marketing. If such a risk were to materialize, the Company's ability to win market share would be negatively affected in a significant manner, and this would have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

If the Company is unable to satisfactorily complete the necessary clinical studies, including obtaining positive results and meeting the other requirements for obtaining a regulatory approval, it is possible that it may never generate revenues with its future products. It could also have to limit or abandon certain development programs.

Lastly, investors could misinterpret the clinical results that the Company might report to the market, partly because it would be hard to establish conclusions in relation to the primary objectives set within the framework of the clinical studies, and partly because the data and analyses provided could be complex to understand.

If one or more of these risks materialized, this could have an unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

2.2.3 RISKS RELATING TO CLINICAL STUDIES IN EUROPE

To obtain the certificate allowing CE marking for its bioprosthetic artificial heart, the Company will have to perform clinical studies on a significant number of patients in several centers in France and abroad. These studies and the publications of the results of these studies should make it possible to rapidly make the products developed by the Company known to important hospital centers and doctors recognized for their expertise in the area of transplantation and circulatory support. However, the quality and relevance of these studies depend on the Company's ability to recruit the planned number of patients within a limited period of time so as to be able to publish the results rapidly. The remoteness or geographic distribution of clinical study centers could give rise to operational and logistic problems, which could cause additional costs and delays.

If the Company were unable to recruit the required number of patients, thereby causing delays in the clinical studies and in the publication of their results, this would postpone the recognition of the Company's products and of its capacity for winning market share, which could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

Moreover, the Company depends and will depend on third-party CROs (Contract Research Organizations) to conduct its clinical studies. Although the Company counts on these organizations to provide a high-quality service relative to the Company's clinical studies, it cannot control all aspects of their activities. If these third parties do not fulfill their contractual duties or obligations, or if they do not meet deadlines, if it is necessary to replace them or if the quality and accuracy of the clinical data that they collect are compromised, the clinical studies planned by the Company could be extended, delayed or canceled. Any extension, delay or cancelation would have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

2.2.4 RISKS RELATING TO CLINICAL STUDIES IN THE UNITED STATES

As stipulated in paragraph 1.5.1 « Regulatory strategy », there are several ways in which the Company can access the American market, but these steps relating to design and setting up clinical studies are costly.

Although the Company has already initiated relations with American opinion leaders and specialists in regulatory matters, it has however never carried out clinical studies in the United States or under the authority of the FDA, and this could have a negative impact on the time and costs involved in such studies. No assurance can be given that the Company will be able to carry out the planned clinical studies in the United States profitably and within a reasonable time frame.
Furthermore, it is possible that the results of these studies will not be positive, that they will cost far more than expected, and that the HUD and/or PMA will never be granted. If one of these events occurred, it could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

2.2.5 OTHER SPECIFIC RISKS CONNECTED WITH CLINICAL TRIALS

The Company is currently in the phase of performing the pivot study required for CE marking. It will then initiate the steps required to obtain authorization for product marketing in the United States, in accordance with the procedures contained in paragraph 1.5.1 « Regulatory strategy ».

For this purpose CARMAT have to perform the industrial assembly of prostheses intended for clinical trials, with higher volumes than in the past.

In a context of validation of an innovative production process involving numerous subcontractors, the planned deadlines may be extended even further for production of the prostheses required for these trials, and then in carrying out the trials themselves. Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

The disclosure of confidential information relating to the performance of clinical trials work in progress, and in particular the disclosure of information making it possible to identify, directly or indirectly, persons taking part in the trials (personal health data) could not only adversely affect the perceptions of the medical community and the general

public regarding the CARMAT product and its prospects, and also expose the Company to a risk of legal action initiated by the persons in question and/or their families.

It should be noted that the Company could decide, or indeed the regulatory bodies could demand, that the Company suspend or put an end to the clinical trials if the patients were exposed to unexpected, serious risks. Deaths and other undesirable events might occur in connection with the trials, thus causing delays or interrupting the trials and thus preventing the Company from pursuing the development of its bioprosthetic artificial heart in the targeted indication or in other indications.

Clinical trials are costly. If the results of these trials are unsatisfactory or inconclusive, the Company may be required to choose between abandoning its program, resulting in the loss of the corresponding investment in time and money, or continuing, with no guarantee that the additional expenses incurred will lead to a successful outcome.

The Company's inability to carry out and complete these clinical trials successfully could have a significant, unfavorable impact on its activity, its prospects, its financial situation, its performance and its development.

2.2.6 RISKS CONNECTED WITH A SLOWDOWN IN THE COMPANY'S EFFORTS TO TRAIN CARDIAC SURGEONS

In order to ensure the success of the Company's marketing efforts, it is essential that a sufficient number of cardiac surgeons are trained by the Company and that they have at their disposal the necessary instructions to implant the bioprosthetic artificial heart.

The Company considers that its methods for training surgeons comply with the relevant legislation in the European Union countries in which it will initially market the bioprosthetic artificial heart, and with FDA regulations. However, these methods for training surgeons may be subject to specific local regulations governing relations between manufacturers of medical devices and health professionals. Thus in France, training programs are subject to the prior approval of the Ordre des Médecins (the French Order of Physicians*), issued at the request of the medical device manufacturer.

This training process could therefore turn out to be longer than predicted and thus affect growth in the Company's sales. If the Company could not adequately train surgeons, the surgeons are at risk of carrying out inappropriate operations or surgical procedures that could delay or stop performance of the clinical trials, or even cause the death of patients.

This type of situation could undermine the image of the Company and possibly lead to legal proceedings being brought against it. Such situations would have unfavorable impacts on the widespread adoption of the bioprosthetic artificial heart and, more generally, on the Company's activity, financial situation, performance, development and prospects.

2.2.7 RISKS RELATING TO THE ADOPTION OF THE CARMAT BIOPROSTHETIC ARTIFICIAL HEART BY CARDIAC SURGEONS, CARDIOLOGISTS, HEALTH CARE PROFESSIONALS, OPINION LEADERS AND PATIENTS

The Company believes that cardiac surgeons, cardiologists and other health professionals will only use its products on a large scale when they have become convinced, through clinical data or scientific publications, that its product offers benefits or is interesting alternative to existing products on the market. These same professionals may be reluctant to change their treatment practices or may reconsider the use of the Company's bioprosthetic artificial heart. In addition, patients themselves will only be interested in the CARMAT bioprosthetic artificial heart if they perceive it as a factor in improving their comfort and quality of life compared to existing treatments.

The development of ventricular assist devices has given rise in recent years to a growing interest in miniature axial or centrifugal pumps with non-pulsatile flow. The CARMAT bioprosthetic artificial heart is intended for different indications and will offer features that these products do not have, such as the use of biological materials and sensors to ensure physiological pulsatile flow according to metabolic demand.

In addition, the lack of accuracy in the media coverage of the Company, including the eventual death of one or more patients, could negatively influence the immediate or term membership of patients with CARMAT bioprosthetic artificial heart. The occurrence of adverse effects on patients with CARMAT bioprosthetic artificial heart, but also on patients with other clinical trials involving artificial hearts, could lead to the requirement of additional regulatory conditions by the authorities, to a perception public delays, delays in granting regulatory authorizations at the testing or approval stage, increased requirements for CE marking, or reduced demand for the product.

Failure of the Company to convince cardiac surgeons, cardiologists and other health professionals of the benefits and benefits of its products would result in poor market penetration that would have a material adverse effect on the Company, its business, its financial position, results, development or prospects.

If the Company was unable to convince cardiac surgeons, cardiologists, other healthcare professionals and patients of the benefits and advantages and the safety of its products, the result would be weak market penetration which would have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

2.2.8 DEPENDENCE RISKS RELATING TO CURRENT AND FUTURE STRATEGIC PARTNERSHIPS AND COLLABORATIONS

As the Company is not involved in producing the various components of the bioprosthetic artificial heart, but rather assembles them in order to create and market this complex bioprosthesis itself, it could be dependent on these partners or other suppliers of raw materials, components, sub-assemblies or essential services.

In particular, the Company cannot control the amount or the timing of the resources which its existing or future partners and suppliers devote and will devote to the bioprosthetic artificial heart. It is possible that these partners or suppliers may not fulfill or may be unable to fulfill their obligations in line with the Company's expectations. As a result, the Company could face development delays which could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects. To limit this risk, the Company carries out risk analysis initiatives in relation to the various subcontractors with a view to implementing replacement solutions where required, and intends to systematically introduce double-sourcing for the mass production phase.

Since its foundation, furthermore, CARMAT has always collaborated with renowned cardiac surgery teams. Three French centers have been selected and trained to participate in the first phase of human clinical trials: the Georges Pompidou European Hospital in Paris, the Marie Lannelongue Surgical Center in Le Plessis-Robinson and the Laënnec Hospital, Nantes.

If the first implants of bioprosthetic artificial hearts are successful, the Company could become dependent on these first French transplantation centers and their cardiac surgery teams. This could slow down the general acceptance of the artificial heart and the transfer of surgical procedure and skills acquired during the first clinical trials to other transplantation centers and, as a result, could have negative consequences on the Company's expansion and development.

In order to limit this risk, the Company has already identified other transplantation centers in Europe and elsewhere with a potential interest in implantation of the Company's artificial heart.

However, if all or part of the aforementioned risks materialized, this could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

2.2.9 RISKS CONNECTED WITH OUTSOURCING THE MANUFACTURE OF THE COMPONENTS OF THE BIOPROSTHETIC ARTIFICIAL HEART

The Company's role is to assemble various components into the bioprosthetic artificial heart, the manufacture of numerous components being outsourced to different suppliers. The Company therefore depends on third parties for the manufacture of most of the components and sub-assemblies forming the bioprosthesis and its power and control systems (see Paragraph 1.5.3 « Industrial strategy »). CARMAT's capacity to market its bioprosthetic artificial heart will partly depend on its capacity to obtain from its suppliers components that have been manufactured in strict compliance with the regulatory provisions and established protocols, in a profitable manner and in the quantities requested.

It is not possible for the Company to control the amount or the timetable of the resources which its suppliers will devote to manufacture of the components of the bioprosthetic artificial heart.

Problems might arise during the manufacturing process for various reasons, such as equipment failure, breach of specific protocols and procedures, or problems with the supply of raw materials.

Certain suppliers may not wish to make commitments beyond the pre-production phase due to specific regulatory or legal risks related to the field of active implantable medical devices.

If relations with its suppliers break down or deteriorate, the Company might find itself unable to form new relations

with other suppliers under commercially acceptable conditions, or even not find equivalent suppliers, which could adversely affect its ability to produce, develop and market its bioprosthetic artificial heart successfully.

If the Company were to change critical suppliers (biological cardiac valves, motor-driven pump unit, long-term implantable PEEK, implantable expanded PTFE, etc.) for its products, it would be asked to perform revalidation of the manufacturing process and procedures in accordance with the standards in force. Obtaining this new CE marking could be costly and time-consuming, and it could require the attention of the Company's most qualified staff. If this new CE marking were to be refused, the Company could be forced to find an alternative supplier, which could delay the production, development and marketing of its products and increase their manufacturing costs.

Moreover, dependence on third-party manufacturers creates additional risks which the Company would not have had to face if it produced the components itself, namely:

- non-compliance of components manufactured by third parties with regulatory provisions and quality control;
- breach of agreements with the Company by third parties; and
- termination or non-renewal of these agreements for reasons outside the Company's control.

If it turns out that products manufactured by third parties do not comply with regulatory provisions, sanctions could be imposed on the Company. These sanctions might include fines, injunctions, claims for damages, the refusal of regulatory authorities to allow it to carry out clinical trials or to grant it CE marking or any other authorization for marketing of its bioprosthetic artificial heart, delays in obtaining authorizations or the suspension or cancelation of authorizations, the revocation of licenses, the seizure or recall of its products, operational restrictions and criminal prosecutions.
These events could have a significant, unfavorable impact on the Company's activity, its prospects, its financial situation, its performance and its development.

Although the Company has always sought to develop sources of procurement from several suppliers and sub-contractors so as to reduce the risks referred to above, CARMAT is still dependent on a single supplier for the provision of the following items:

- Long-term implantable PEEK, for which CARMAT concluded an agreement on August 28, 2012 with Invibio Ltd. (see Paragraph 3.1.10 « Important contracts »), and other implantable polyurethanes;
- Implantable expanded PTFE for which CARMAT obtains supplies from C.R. Bard; and
- Carpentier-Edwards® biological heart valves, for which CARMAT concluded an agreement on November 5, 2010 with Edwards Lifesciences (see Paragraph 3.1.10 « Important contracts »).

Faced with the problem of recurring overloads faced by certain suppliers in the high-tech sector, CARMAT has already begun to identify secondary suppliers for the most critical parts of the prosthesis and external sub-assemblies, in order to ensure the reliability of supplies and thus ensure sufficient production capacity. This selection must be conducted in line with strict criteria for the quality, skills and production facilities of the suppliers. Consequently, CARMAT must undertake surplus production, validate the industrial processes and verify that the products obtained are identical to those from its first procurement source. In some cases, CARMAT will probably have to vertically integrate certain outsourced processes. If the Company were to encounter difficulties in the procurement of these materials, biological products or electronic or electromechanical components, if new standards for the use of these materials were to come into force or if it were unable to keep to these sub-contracting agreements, enter into new agreements or obtain the materials or biological products needed to develop and manufacture its bioprosthetic artificial heart and electric power supply system in the future, its activity, its financial situation, its performance, its prospects and its development might be significantly impacted.

In time, during the marketing phase of the bioprosthetic artificial heart, the Company's gross margin could be affected by fluctuations in the market prices of raw materials such as animal pericardium, expanded PTFE and other implantable polyurethanes and biological valves; these are hard to predict or control and could have an unfavorable impact on the Company's activity, financial situation, performance, development and prospects.

2.2.10 RISKS RELATING TO INDUSTRIAL PROCESS DYSFUNCTION (SUCH AS NON-COMPLIANCE WITH MATERIOVIGILANCE AND PRODUCT TRACEABILITY)

The Company's products are classified as medical devices and, as such, are subject to specific regulations in all the countries in which they are manufactured, tested or marketed. These regulations impose obligations regarding, in particular:

- design;
- product preclinical and clinical trials carried out on humans;
- product manufacturing, quality control and quality assurance;
- product labeling, including user manuals;
- product storage;
- product identification and traceability;
- data storage procedures; and
- supervision after products are put on the market and reporting of incidents related to the use of the products (deaths, serious injuries, dysfunctions, etc.).

These regulations apply to the Company as a manufacturer of these products.

At present, the Company depends on third-party companies to manufacture most of the components and sub-assemblies forming the bioprosthesis and its power and control systems, and this will no doubt continue to be the case in the future. The Company cannot guarantee that its suppliers or subcontractors comply or will comply with the applicable regulations. The notified body, during a certification or monitoring audit, or the regulatory authorities, during an inspection or on the occasion of any other regulatory process, could identify failures to comply with the applicable regulations or standards and request that this be remedied by carrying out corrective actions that could interrupt the manufacture and supply of the Company's products.

The suspension, total stoppage or total or partial prohibition of the activities of the Company's suppliers and subcontractors could adversely affect the Company's reputation and have a significant unfavorable impact on the use or sale of the Company's products.

The Company has established a quality system which is based on procedures aiming, among other things, to detect any nonconforming product internally or externally. This quality system has been certified by a third-party organization in accordance with the regulatory requirements of the applicable European Directive 93/42/EEC and the reference standards (ISO 9001 and ISO 13485). These procedures are included in a compliance defect management system with a view to:

- identifying and recording compliance defects relating to the products or the quality system;
- recording of all investigations and analyses relating to analysis of the causes of these compliance defects and the related risks;
- identifying and implementing corrections or corrective and preventive measures; and
- measuring the efficiency of the actions taken to correct the compliance defects.

The treatment of any incident reporting having consequences for the patients and/or users and/or third parties is defined by the regulations relating to materiovigilance which describes the procedures for reporting incidents to the competent authorities. The Company has an internal procedure for monitoring and analysis of incident reports received and, where applicable, for their reporting by the materiovigilance correspondent to the national regulatory authorities (e.g., the French national agency for medicine and healthcare product safety, ANSM).

Dysfunctions could nevertheless occur, and this could have an unfavorable impact on the Company's activity, financial situation, performance, development and prospects.

2.3 REGULATORY AND LEGAL RISKS

2.3.1 RISKS RELATING TO REGULATIONS AND REGULATORY CHANGE

The control, manufacture and sale of the Company's products are subject to obtaining and maintaining the necessary legal and regulatory authorizations and certifications for the marketing of medical devices. Indeed, the Company's products are covered by strict and constantly changing regulations.

Compliance with this regulatory process may prove long and costly, and no guarantee can be given that the authorizations required for new products or changes to existing

products will be obtained, or obtained within an acceptable period, or that an authorization will not be withdrawn in the future or be subjected to major post-marketing study requirements. Throughout the world, countries have adopted more demanding regulatory conditions than in the past, and this has increased or could increase the time and uncertainty involved in new product launches, and the clinical and regulatory costs involved in these launches. If certification or authorization for marketing the Company's products were refused or removed or subjected to major post-marketing study requirements, their marketing could be delayed or prohibited in the countries in question, or the margins on sales of these products could be negatively affected by the increase in study costs, and each of these risks could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

The clinical and commercial development of the Company's bioprosthetic artificial heart requires everyday working relations with numerous doctors and healthcare professionals who have knowledge and experience essential for its development. These professionals contribute as researchers, consultants, instructors, inventors or speakers. New laws, regulations or other developments could limit the Company's ability to maintain strong links with these professionals or prevent it from receiving their advice and contributions.

In Europe, the United States and in other countries, regulations could:

- delay and/or significantly increase the cost of developing, testing, manufacturing and marketing the Company's bioprosthetic artificial heart;
- limit the pathologies for which CARMAT would be authorized to market its bioprosthetic artificial heart;
- impose new, more stringent requirements;
- suspend the authorization for the bioprosthetic artificial heart;
- require that clinical trials be halted.

The subsequent detection of previously unknown problems could result in fines, delays or suspensions of regulatory authorizations, product seizures or recalls, notifications of doctors or any other action in the field, restrictions concerning operation and/or legal action in the criminal court. Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

2.3.2 RISKS RELATING TO THE REGULATORY ENVIRONMENT IN EUROPE (CE MARKING)

The Company's implantable bioprosthetic artificial heart, but also all the ancillary tools that accompany it and its monitoring consoles, come within the category of medical devices and are governed, in particular, by the provisions of Directive 93/42/EEC which harmonizes the conditions for the sale and free circulation of these products in the European Economic Area.

These products can be placed on the market only after obtaining the certificates permitting CE marking, valid for a period of five years. This CE marking attests the compliance of the medical device in question with the essential health and safety requirements stipulated by the applicable European directive and certifies that it has undergone the appropriate procedures for evaluation of its compliance.

The regulations on medical devices which CARMAT is subject to are complex, and they are becoming increasingly strict. Directive 90/385/EEC of June 20, 1990, as amended by Directive 2007/47/EEC of September 5, 2007, regarding active implantable medical devices for the European Union, transposed into the Public Health Code in France, the Community regulations being prepared to replace these Directives, and similar laws and regulations in other countries worldwide, govern numerous aspects of medical devices, and in particular:

- design, development and manufacture of products;
- product testing and clinical trials carried out on humans;
- product storage;
- product marketing, including advertising and promotion;
- approvals and market authorizations;
- procedures for storing data; and
- supervision after products are put on the market and reporting deaths.

The direct or indirect costs associated with complying with current or future regulations, obligations or directives may rise.

Furthermore, data from clinical trials can produce divergent interpretations, which could delay the obtaining of or restrict the scope of regulatory authorization, or force the Company to repeat trials in order for them to meet the regulator's requirements. Changes to regulations during the development of the bioprosthetic artificial heart and its regulatory review can lead to delays or to the refusal of authorization.

Any change in regulations or any breach of compliance obligations can lead to sanctions, including fines, injunctions, civil sanctions, refusal of CE marking, HUD or PMA, delays, suspension or withdrawal of authorizations, the

seizure or recall of products, restrictions on use or criminal prosecutions. Each of these could significantly increase the costs borne by the Company, delay the development and marketing of its bioprosthetic artificial heart, and thus have a significant unfavorable impact on its activity, its financial situation, its performance, its development and its prospects.

2.3.3 RISKS RELATING TO THE REGULATORY ENVIRONMENT IN THE UNITED STATES

The US market is governed by the regulations established by the FDA which regulate preclinical and clinical trials, the manufacture, labeling, distribution and marketing of medical equipment. The FDA has broad powers to prohibit, isolate and seize medical devices that have been falsified or with labeling not meeting standards, to demand a recall, repairs, a replacement or the reimbursement of such devices, to refuse to grant a product marketing authorization, to suspend studies in progress or to demand export certificates from foreign governments.

The marketing of products such as those manufactured by the Company in the United States market is subject to the PMA procedure, which may be long, complex and costly because it must be based on safety and efficiency data, coming in particular from large-scale clinical trials, sometimes randomized where a similar product exists.

In the case of CE marking, the choice between the "Bridge To Transplant" indication, i.e. waiting for a transplant, or "Destination Therapy", i.e. definitive treatment, is left to the judgment of the medical personnel. In the United States, the FDA demands a clinical safety and efficiency study for each indication, starting with the shortest, i.e. waiting for a transplant. No equivalent device (ventricular assist device or artificial heart) has so far submitted an IDE and then a PMA for the "destination therapy" indication without having first obtained a PMA for the "waiting for transplant" indication (see Paragraph 1.2.2 « Technologies and market players »).

There is an alternative to the conventional IDE and PMA process concerning compassionate indications (see Paragraph 1.5.1 « Regulatory strategy »). In light of the population targeted by the CARMAT bioprosthetic heart (patients whose condition is life threatening in the short term) and its specific features notably with regard to the use of biological materials (making it possible to address a sub-population of patients for which anticoagulation would be harmful), CARMAT could, initially, aim at a HUD designation. This process is based on safety data collected during a study involving a small number of patients without randomization, and is therefore less expensive and faster. On the other hand, the US product marketing authorization is limited to 4,000 devices per year. This approach could enable the Company to develop gradually and at a lower cost the skills and partnerships necessary for the establishment of an IDE. In addition to this process, CARMAT could also benefit from the new provisions issued by the FDA in April 2015 in a guidance document entitled "Expedite Market Access". This alternative approach is reserved for products meeting medical needs which are not covered by existing treatments. Applications are dealt with on a priority basis by the FDA with a reply in less than the 120 days currently required. CARMAT meets the two principal criteria required for eligibility under these provisions, either on the basis of medical urgency "e.g. intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition" or of medical need e.g. "address an unmet need". The number of treatable patients does not seem to be limited in "expedite market access" cases.

While an HDE or an IDE would allow the Company to start clinical studies, there is no guarantee that the Company would subsequently obtain an HUD or a PMA, or obtain it within reasonable deadlines. If the Company were unable to obtain an HUD or a PMA, it could not sell its products in the US market.

Even when products have received an HUD or a PMA, the product marketing authorizations granted by the FDA can be withdrawn following failure to comply with regulatory standards or the occurrence of unexpected problems after the authorization has been granted.

Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

2.3.4 RISKS CONNECTED WITH CHANGES IN REIMBURSEMENT POLICIES FOR MEDICAL DEVICES

The Company's capacity to generate revenues with the bioprosthetic artificial heart and the associated systems and services that it could develop, the degree of success of these products and their performance, partly depend on the conditions of compensation and reimbursement in those countries where it plans to market its products.

Many patients will not be capable of paying themselves to obtain access to a product that the Company could

develop. The Company's ability to obtain acceptable levels of reimbursement from government authorities, private health insurers and any other organization will therefore have an impact on its capacity for marketing its products successfully. Reimbursability affects customers' choices concerning the products that they buy and the prices that they are prepared to pay. Reimbursement varies from one country to another and can have a significant impact on the acceptance of new products and services. The Company cannot be certain of obtaining an optimal reimbursement in Europe, the United States or elsewhere for the products that the Company has developed or might develop, and any reimbursement granted could be reduced or canceled in the future.

In Europe, in the United States and in the other main markets in which the Company could sell its products, there is constant economic, regulatory and political pressure to limit the cost of procedures involving medical devices. Third-party paying organizations are increasingly questioning the prices of medical devices, and many third-party paying organizations could refuse to reimburse or could increase the proportion paid by patients for certain devices.

New legislative or administrative reforms to reimbursement systems in Europe, the United States or other countries which could substantially reduce the reimbursement of operations using the Company's medical devices or which could refuse coverage for these operations, for example by price regulation, competitive pricing, coverage and payment policies, the comparative efficiency of therapies, technological assessments and managed healthcare systems, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

2.3.5 RISKS RELATING TO PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

The Company is the owner of patents and a know-how that is specific to it, as well as other intellectual property rights (such as, in particular, copyright, marks and domain names).

It is important for the success of the Company's activity that it is able to obtain, maintain and ensure respect for its patents and other intellectual property rights and thus protect its technologies against possible unlawful use by third parties.

Given the importance of patents in its industry, in 2008 the Company commissioned a study by a specialized firm to confirm its freedom to operate, both in the United States and in Europe, as to the corresponding US and European patents bearing claims on any device, system and method relating to the bioprosthetic artificial heart. According to the findings of the study, the relevant patents of the Company did not infringe on that date the US and European patents found in the research carried out.

An update of this study was commissioned by the Company in the fourth quarter of 2017, by researching and analyzing patent applications and patents filed with the European Patent Office (EPO) and the United States Patent Office (USPTO) bearing claims on any device, system and method pertaining to the bioprosthetic artificial heart that were made public after January 2008. The research firm in charge of this study concluded under the terms of this study that the CARMAT heart does not counterfeit the claims of granted patents - and claims as written in patent applications - for all patents and patent applications found in the search performed.

In addition, CARMAT implements a policy of applying for patents at an early stage in order to optimize priority rights.

However, the Company's patents and other intellectual property rights may offer only limited protection and may not prevent any unlawful use of its technologies. Regarding this, the unauthorized exploitation of the Company's technologies by third parties could, in particular, deprive CARMAT of its competitive advantage.

Despite the efforts made by CARMAT to protect its technologies, its assets and its know-how, there is a risk regarding the validity and/or the value of the intellectual property rights pertaining thereto.

Indeed, the possibility cannot be excluded that:

- the Company's granted patents and more generally its intellectual property rights may be disputed or invalidated at a subsequent stage or that the Company may not be able to enforce them;
- patents for which applications are being considered, including certain important patents in several jurisdictions, or any other claim to a deed pertaining to an intellectual property right, might ultimately not be granted;
- the extent of the protection conferred by a patent or an intellectual property deed might be insufficient to provide effective protection from competitors;
- the Company's products will not infringe, or be accused of infringing, patents or other intellectual property rights belonging to third parties;
- third parties might claim rights over patents or other intellectual property rights that the Company owns directly or that it exploits.

It is precised that there is great disparity between the national legislations applicable in the various countries

where the Company registers or protects its intellectual property rights.

Until now, no uniform global policy has emerged on the content of patents granted in the area of medical devices and the scope of the claims allowed.

Lastly, the protection and enforcement of the Company's intellectual property rights will require legal action where necessary, the costs and contingencies of which may have an impact on the Company's activities. In this sense, apart from the expenses that these legal actions entail, they could have the effect of diverting the management team from its priorities and reducing the Company's profits.

If one of these factors concerning one of the patents or intellectual property rights occurs, it could have an unfavorable impact on the activity, prospects, financial situation, performance and development of the Company.

2.3.6 RISKS RELATING TO THE CONFIDENTIALITY OF THE COMPANY'S INFORMATION AND KNOW-HOW

The Company may be required to provide public or private bodies with sensitive proprietary information notably in order to conduct certain tests for the purposes of researching or validating its commercial projects. The Company also relies on its own technologies, methods, processes, know-how and data that are not patented and which it considers to be industrial and technical secrets. In both cases, their protection is specifically insured by confidentiality agreements between the Company and its employees, consultants and relevant third parties.

However, these agreements and other methods of protecting commercial and technical secrets are not always effective and cannot protect with any certainty the confidentiality of said industrial and technical information and secrets, because any breach of the aforementioned contractual agreements, including through disclosure to competitors, would potentially entail imminent damage for the Company without it having any really appropriate measure for obtaining compensation.

Furthermore, the dissemination, notably via the media or by third parties, of confidential or even non-confidential information concerning the Company or its activities, with or without its authorization, and the dissemination of false or inaccurate information by third parties could also have unfavorable consequences for the Company's activity, financial situation, performance, development and prospects.

2.3.7 RISKS CONNECTED WITH PRODUCT LIABILITY

All cardiac surgery involves significant risks of serious complications that can have mortal consequences. The clinical trials and marketing of the bioprosthetic artificial heart involve a risk of incurring the manufacturer's liability for defective goods. If CARMAT were faced with a liability claim for defective goods, and if it did not manage to defend that claim successfully, its liability could be significant.

As the Company has not entered the sales phase for the bioprosthetic artificial heart, it has not taken out insurance against liability for defective products. However, the Company has already taken out insurance policies in relation to the clinical trials phase as a result of which it possesses the level of insurance cover required under current regulations in France (in accordance with the French Public Health Code and the provisions arising from the Huriet Act of December 20, 1988) and in other countries. If necessary, it will take out other insurance policies as its clinical trials program is extended (see Paragraph 2.4 « Insurance and cover for risks » below).

However, the Company cannot guarantee that its insurance cover will be sufficient to meet liability suits that may be filed against it. If CARMAT were held liable and were unable to obtain and maintain appropriate insurance cover at an acceptable cost, or to protect itself in any way against liability suits arising out of defective goods, this would have a serious impact on the marketing of the bioprosthetic artificial heart and more generally it would damage the Company's reputation, its activities, its financial situation, its performance, its development and its prospects.

2.4 INSURANCE AND COVER FOR RISKS

The Company has adopted a policy for covering the main insurable risks with cover limits that it considers compatible with the nature of its activity. The premiums paid by the Company for all insurance policies amounted to €69,088 for the 2017 reporting period, compared with €19,186 for the 2016 period.

As the Company has not entered the sales phase for the bioprosthetic artificial heart, it has not yet taken out insurance against liability for defective products.

2.5 FINANCIAL RISKS

2.5.1 HISTORY OF OPERATIONAL LOSSES – RISKS CONNECTED WITH FORECAST LOSSES

The Company was established in June 2008. As at December 31, 2017, accumulated losses stood at €145,751,009. This loss comes from research costs and the costs of developing the CARMAT bioprosthetic artificial heart; such costs cannot be capitalized as intangible assets under French accounting rules.

The Company will incur further significant operational losses in the course of the next few years, particularly due to:

- the completion of research and clinical trials on the bioprosthetic artificial heart in Europe and then the United States in order to obtain sales authorizations;
- the extension of production capabilities of the bioprosthetic artificial heart CARMAT;
- costs connected with marketing the CARMAT bioprosthetic artificial heart;
- the expansion of its portfolio of products through the future implementation of projects to develop new breakthrough medical devices using skills and know-how developed by CARMAT for bioprosthetic artificial hearts; and
- payment of additional milestones, royalties or payments for licenses or partnerships.

As of the date of this registration document, the bioprosthetic artificial heart has not generated any operational revenue. The Company's profitability will be dependent on the results of its clinical trials and on sales of the bioprosthetic artificial heart, which could be commenced once CE marking has been obtained. The Company considers that before revenues are generated from sales of the bioprosthetic artificial heart, its only sources of financing will come from funds raised on the Euronext Alternext market in Paris, state grants, research tax credits (CIR) and, to a lesser extent, income from cash investments and current financial instruments, and that this will enable it to deal with short and medium term liquidity risks (see Paragraph 2.5.5 « Liquidity Risks »).

In addition to the funding provided in December 2017 for €52.9 million, additional financing, particularly in the form of new capital increases, will be required for the Company to be able to finance, in particular, the marketing of the artificial bioprosthetic heart (see paragraph 2.5.3 « Dilution risk connected with issuing shares giving immediate or future access to the Company's capital »).

The increase in expenses, particularly in the event of a lack or suspension of revenue sources, could have a significant unfavorable impact on the Company's business, financial situation, performance, development and its prospects.

2.5.2 UNRELIABLE CAPITAL RESOURCES AND UNRELIABLE ADDITIONAL FUNDING

The Company has made significant investments in research and development since it began its operations in 2008. The total cost of developing the bioprosthetic artificial heart (i.e. excluding expenses related to preparations for its marketing and industrial production) represents as of today a total amount of €185.5 million for the Company since it was founded.

The Company expects to have significant financing requirements in particular to prepare for and then begin marketing the bioprosthetic artificial heart once CE marking

has been obtained. In particular, the Company will have to finance its current operations and research and development during the initial commercial launch phase, the working capital requirement related to sales development and investments intended to increase production capacity and automate production processes.

The future capital needs of CARMAT remain dependent on a number of factors, such as:

- higher costs and slower progress than expected for its program to develop the bioprosthetic artificial heart;
- higher costs and longer delays than expected in obtaining regulatory authorizations, including time required to conduct additional tests for the purpose of obtaining such authorizations or the preparation time for application dossiers submitted to regulatory bodies;
- higher costs and longer delays than expected in obtaining monies, such as reimbursements, for the Company's devices and services from the relevant public or private bodies in European or other countries, including the time required to conduct additional tests for the purpose of obtaining such funding or the preparation time for application dossiers submitted to the bodies concerned;
- the costs of preparing, lodging, defending and maintaining patents and other intellectual property rights;
- the ability of the Company to establish or maintain collaborative arrangements within the time frame contemplated;
- new opportunities to develop new promising products or acquire new technologies, products or companies or other activities; and
- the date of the commercial launch of the total heart of the Company, currently scheduled for 2019.

The Company estimates that based on its current cash position, all of its additional financial requirements until it can generate positive cash flows could be as high as €100 million in total (part of which may be covered by the line of Kepler equity financing, with a balance of €29.9 million as of December 31, 2017).

As a result, fundraising will be required, beyond using the available balance of Kepler equity lines. The sizing and sequencing of these surveys will depend, in particular, on (i) the opportunities that will arise as clinical trial progresses and (ii) the ability to carry out, in parallel, the steps usually deployed sequentially. such as clinical studies in Europe and the United States, or the expansion of production capacity.

The Company might fail to raise sufficient funds on favorable terms or fail to raise any funds at all when it needs to. If the necessary funds are not available, the Company may have to:

- delay or scale down its development or marketing program;
- cut staff;
- obtain funds through partnership agreements which could force it to give up rights over certain technologies, rights which it would not have given up in different circumstances;
- grant licenses on its technologies to partners or third parties or conclude collaboration agreements that might be less attractive than those which it would have been possible to obtain in different circumstances; or
- consider hiving off assets, or even approaching another company.

In addition, if the Company raises capital by issuing new shares, the participation of its shareholders could be diluted. Indebtedness financing, to the extent that it would be available, could also include restrictive conditions for the Company and its shareholders. In addition, seeking additional financing could distract management from its day-to-day operations, which could limit its ability to develop and market its product.

If one or more of these risks materialized, this could have a significant negative impact on the Company's business, financial situation, performance, development and its prospects.

2.5.3 DILUTION RISK CONNECTED WITH ISSUING SECURITIES GIVING IMMEDIATE OR FUTURE ACCESS TO THE COMPANY'S CAPITAL

As mentioned in Paragraph 2.5.2 « Unreliable capital resources and unreliable additional funding » of this registration document, the Company could issue shares or new financial instruments giving access to its capital to finance its expansion, which may lead to a certain dilution for the shareholders of the Company.

In addition to the financing operations, since its creation the Company has also allocated or issued BCE warrants, BSA share subscription warrants and preferential shares free of charges convertible in ordinary shares as part of its incentive policy for its executives and employees. The Company could in the future allocate or issue new instruments giving access to its capital to employees and/or consultants.

As at December 31, 2017, the exercise or the conversion of all securities giving access to capital would allow the subscription of 943,025 new ordinary shares representing 10.46% of the current issued share capital and 9.47% of share capital after issue of these new ordinary shares.

It should be noted that within this envelope, 365,400 new

Type of security	Number of new ordinary shares that may be created (as at December 31, 2017)
Incentive instruments for the management and board members	
- BCE-2009-2	65,075
- BCE-2012-1	34,000
- BCE-2012-2	6,700
- BSA-2009-1	38,850
- BSA-2017-Board members	12,000
- Preferential shares	421,000
Total incentive instruments	577,625
Financing tool	
- BSA Kepler Cheuvreux Tranche 1	194,900
- BSA Kepler Cheuvreux Tranche 2	170,500
Total financing instruments	365,400

ordinary shares (38.75% of the dilution potential) are likely to result from the exercise of BSA Kepler, a financing tool put in place by the Company at the end of 2015.

The exercise or the conversion of the issued instruments giving access to capital and all new allocations or issuances would lead to a potential significant dilution for the shareholders.

2.5.4 RISKS CONNECTED WITH STATE SUBSIDIES AND RESEARCH TAX CREDITS

If the Company were to breach the terms of its agreements with Bpifrance for subsidies and repayable advances totaling €31.6 million (see Paragraph 3.1.10 « Important contracts »), it might not receive the expected aid. (Balance to be collected by the Company as of December 31, 2017: €1,450,732)

If the Company were to breach the terms of its agreements with Bpifrance, it could also be required to repay the sums advanced. These situations could deprive the Company of the financial means to complete its research and development.

In addition, to finance its activities, the Company also opted to take the research tax credit («CIR») for the financial periods from 2009 to 2017. This mechanism involves offering a tax credit to enterprises which invest significantly in research and development.

Research expenditure eligible for the CIR specifically includes wages and salaries, services sub-contracted to approved research organizations (public or private) and intellectual property costs.

The CIR relating to the 2017 period was recorded under Income taxes in the income statement and appears under Other accounts receivable in the balance sheet. The income statement for the period from January 1, 2017 to December 31, 2017 shows a research tax credit of €2,334,690.

The Research Tax Credit is an important source of financing. It could be jeopardized by a change in regulations or by an objection from the tax authorities, even though the Company complies with the requirements concerning documentation and the eligibility of costs.

If one or more of these risks materialized, this could have a significant negative impact on the Company's business, financial situation, performance, development and its prospects.

2.5.5 LIQUIDITY RISKS

In 2017, the Company consumed €28.0 million in cash. The Company finances its growth through equity increases made by way of capital increases.

At the date of this registration document, the Company has no bank debts and it is therefore not exposed to any liquidity risks from the enforcement of clauses on the early repayment of bank loans.

Owing to its historic loss-making situation, which results from the fact that it is still in a development phase during which it is incurring expenditure on (mainly clinical) research and development without earning regular revenues, the Company faces a funding risk.

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

- cash and available cash instruments totaling €60,722,988 as at December 31, 2017;
- the payment of repayable advances (€1,450,732) still to be claimed between now and the end of the Bpifrance aid program signed in 2009, corresponding to milestone 7 (CE marking expected in 2019);
- the research tax credit of €2.3 million generated in the 2017 fiscal year period;
- the possibility of using the balance of the equity financing line set up in January 2015 with Kepler Cheuvreux, exercised on the initiative of the latter, subject in particular to certain price and liquidity assumptions, for a total amount, on which Kepler Cheuvreux is engaged under these same assumptions, of €29.9 million as of December 31, 2017 (balance of Tranche 1 of €8.0 million, Tranche 2 balance of €6.9 million and Tranche 3 of €15.0 million).

The Company's industrial and commercial development after it has obtained CE marking will give rise to further financial requirements: financing for ongoing operations and R&D during the initial commercial launch phase, need for working capital in relation to sales development, investment for the purpose of increasing production capacity and automating production processes. The Company currently estimates that these additional requirements could reach €100 million. Extra funds will need to be raised in addition to the exploitation of the remaining Kepler equity financing lines.

These funds will be needed in particular to:

- finance the training of additional surgical centers in addition to those trained for the clinical trials of the feasibility study;
- develop and run a direct or indirect sales force, and to provide technical and clinical support to implant centers and their patients;
- carry out clinical activities such as implant registries or comparative or medico-economic studies, upon request by regulatory authorities or voluntarily for marketing purposes;
- implement improvements to the systems or pursue activities necessary to secure the willingness of healthcare providers to pay for the bioprosthetic artificial heart, its external systems and ancillary services in various countries;
- to initiate and finalize a multi-center study (IDE) in the United States, in order to obtain from the FDA the authorization to market the prosthesis there;
- ramp up industrial production by developing automated production processes, securing alternative suppliers for critical supplies and by setting up additional production capacity.

2.5.6 EQUITY RISK

At the time of registration of this registration document, the Company has no shareholdings in third-party listed companies and is therefore not exposed to risks in relation to third-party shares.

The Company entered into a liquidity contract with an independent financial services provider, initially Dexia Securities France (now DSF Markets) in 2010 and subsequently Tradition Securities and Futures as of 2014, and today with Gilbert Dupont, the purpose of which is 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 an amount of €300,000 available to this service provider. Treasury shares acquired through the implementation of this liquidity agreement are recorded under financial assets at their purchase price.

Where appropriate, a valuation allowance is recorded with reference to the average official stock market price for the month preceding the end of the period (see Paragraph 3.2.2.4 « Supplementary information on balance sheet »).

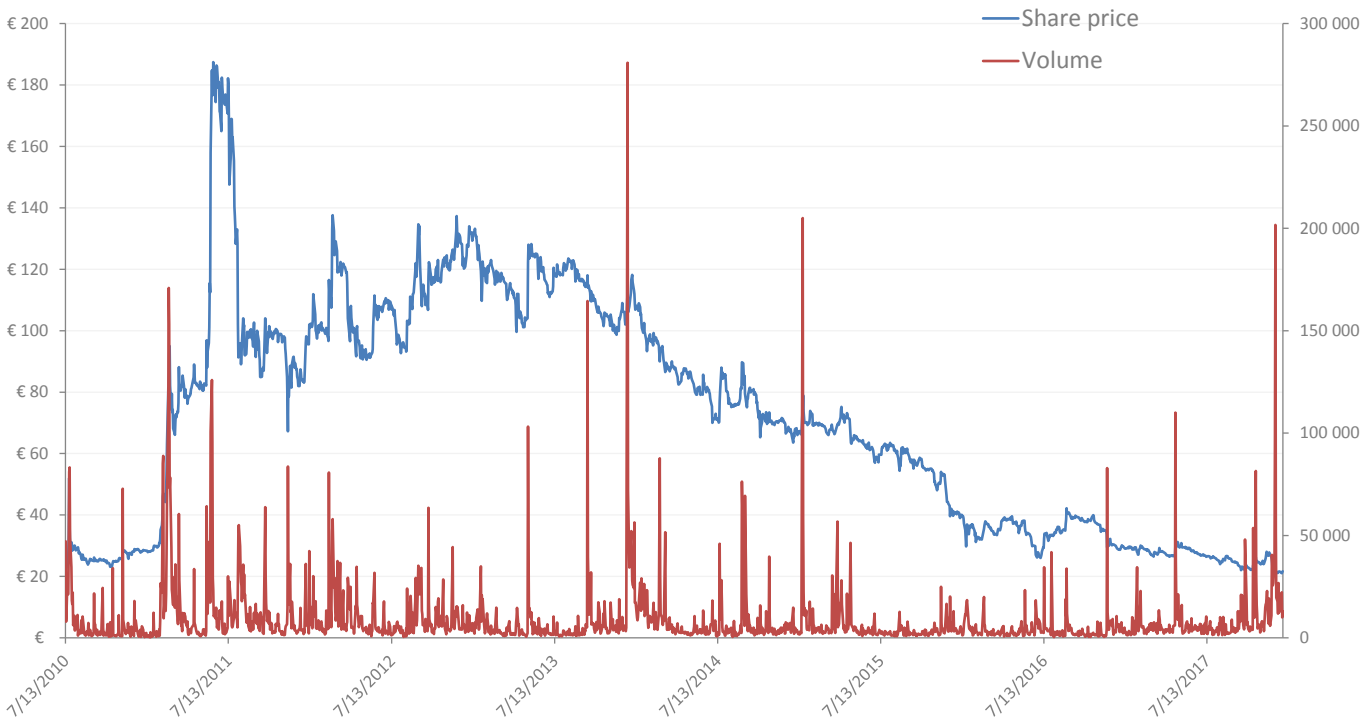
2.5.7 RISK RELATED TO CHANGES IN THE STOCK PRICE AND MARKET VALUATION OF THE COMPANY

The share price of the Company is subject to the volatility of the financial markets and may be significantly affected by events such as changes in market conditions specific to the Company's business sector, announcements by the Company, the realization or not, or the late performance by the Company of scientific or regulatory steps in the development of the total artificial heart project of CARMAT.

In recent years, the financial markets have also experienced significant variations that may not reflect the operational or financial performance of listed companies.

In this respect, the market price of the CARMAT share has changed a lot since its IPO in July 2010, as evidenced by the following graph.

Fluctuations in the stock markets, the economic situation or any failure or delay by the Company in achieving new scientific or regulatory milestones could have a material adverse effect on the Company's share price and market valuation.



2.5.8 RISK OF SHARE PRICE VOLATILITY AND MARKET VALUATION OF THE COMPANY LINKED TO THE PROFILE OF THE PATIENTS AND PATHOLOGY TARGETED

CARMAT's bioprosthetic heart project aims to be the destination therapy for patients with biventricular end-stage heart failure (NYHA class IV - Intermacs classes 1-4), i.e. patients whose illness is at a very advanced stage and whose life expectancy is short. The current standard treatment for this pathology is heart transplantation.

In France, heart transplants have a one-month survival rate of 84.8% for «young» patients aged 18-60 and 79.3% for patients aged over 60. The one-year survival rate is 75.8% for the first category and 67% for the second (see paragraph 1.1.4 « Available treatments » - Transplantation and the 2013 annual report of the Biomedicine Agency referred to therein). This relative performance must also be appreciated with regard to the profile of the population eligible for transplantation, i.e. patients whose general health is good enough for the transplanted organs to have the best chance of success, given that they are in short supply. The patients in CARMAT's current trials are not eligible for transplants due to comorbidities or their age, and they are therefore even more fragile than patients who are eligible for or have received transplants.

At present, no treatment available or in clinical trials for the targeted pathology has a one-year survival rate of 100%. While the Company's object is to put forward a credible alternative to heart transplantation and achieve a comparable or better survival rate, it does not hope to obtain a 100% survival rate over any period.

With the feasibility study carried out on four patients, the CARMAT system has gained clinical experience of 21 months of operation. The last two patients died due to medical complications unrelated to the prosthesis. Notwithstanding this encouraging outcome at a clinical and scientific level, the issue of survival rate is complex and highly emotive. It remains poorly understood by the media and, consequently, by the public.

Other deaths during future clinical studies are to be expected and are an inherent factor in the profile of the targeted patients and pathology. Taken individually, one death will not jeopardize the project if the overall survival rate set down in the study protocols is achieved or exceeded. Nevertheless, any death that attracts negative coverage in the media in spite of the efforts – part reserve, part education – made by the Company, could have a significant unfavorable effect on the Company's share price and market capitalization, as well as on its net assets and its ability to raise new capital.

2.5.9 RISKS RELATED TO FUTURE USE OF TAX LOSS CARRY FORWARDS

At December 31, 2017, after taking into account the net loss generated in the first half of the year, the Company has a carry forwards deficit of €177,648,794. To date, this deficit can be indefinetely carried forward to future profits. In France, for the years ended December 31, 2012 onwards, the allocation of these deficits is capped at 1 million euros, plus 50% of the fraction of profits exceeding this ceiling. The unused balance of the deficit can be carried forward to subsequent years, and is chargeable under the same conditions without limitation in time.

It can not be ruled out that future tax developments in the area of corporate taxation will call into question all or part of the allocation of these previous deficits to future profits or to limit it in time.

2.6 RISKS RELATING TO THE COMPANY'S ORGANIZATION

2.6.1 RISKS RELATING TO THE LACK OF SALES RESOURCES AND MEANS OF DISTRIBUTION

Given its stage of development, the Company still has only limited experience in the sales, marketing and distribution areas. In order to ensure the large-scale success of sales of the bioprosthetic artificial heart, the Company will have to adapt its organization, expand in global markets, set up a distribution network and recruit dedicated, qualified staff (especially to provide technical and clinical support for implant centers and their patients). It is in this perspective that CARMAT announced on September 1, 2016 the arrival of Stéphane Piat as chief executive officer, replacing Marcello Conviti. With his experience in the commercialization of medical devices, particularly at Johnson & Johnson Cordis or Abbott, Stéphane Piat intends to implement a strategy aimed at executing the commercialization through a direct sales force in the principal European countries, at least during the initial phase. In other countries such as the United States, indirect forms of distribution could be considered. The Company cannot nevertheless guarantee that it will be able to keep its distributors or sign new distribution agreements, nor that these distributors will devote the necessary resources to the commercial success of its products.

Moreover, the Company will have to provide training for doctors in the countries in which it wants to operate, and therefore have "ambassadors" and training centers (see Paragraph 1.5.2 « Marketing strategy »).

The Company might not be able to establish an appropriate structure or it could experience a delay in the organization of marketing and distribution resources, in the recruitment and training of sales staff or in setting up its distribution network.

Any of these events could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

2.6.2 RISKS RELATING TO THE NEED TO KEEP, ATTRACT AND RETAIN KEY PERSONNEL AND SCIENTIFIC ADVISORS

The Company's success depends largely on the work and expertise of the members of its board of directors and its key scientific personnel, in particular Stéphane Piat, chief executive, Dr. Piet Jansen, medical director, Éric Richez, development director and Marc Grimmé, technical director. To date the Company has not taken out any so-called «key person» insurance (insurance policies to cover permanent incapacity/death) and the loss of their skills would affect its capacity for attaining its goals. Although the Company has for several years conducted management and knowledge transfer programs, thereby creating a know-how base which is not confined to specific individuals, the simultaneous departure of several important employees from its executive management or its research and development activities would significantly affect the Company's capacity to attain its goals.

Furthermore, the Company will need to recruit new executives and highly qualified scientific personnel in order to develop its activities as and when it expands into areas which require supplementary skills such as manufacturing, marketing, clinical support, reimbursement and regulatory affairs.

The Company is competing with other companies, research bodies and academic institutions in order to recruit and retain highly qualified scientific, technical and management personnel. As this competition is very intense, the Company may not be able to attract or retain key personnel in conditions that are acceptable from an economic point of view.

Faced with this risk, the Company has established systems for motivating its personnel and strengthening its loyalty, in the form of variable remuneration based on performance and the allocation of securities giving access to the Company's capital and preferential shares free of charges convertible to ordinary shares, although there is nothing to ensure that these systems will be sufficient to enable the Company to retain or recruit the necessary personnel. See section 5.2.1 « Share capital and security classes » of this registration document.

The Company's inability to attract and retain this key personnel would prevent it from attaining its overall objectives, and would thus have a significant unfavorable impact on its activity, its financial situation, its performance, its development and its prospects.

2.6.3 RISKS CONNECTED WITH GROWTH MANAGEMENT

The Company expects to grow significantly and to extend its field of activity to designing and producing medical devices other than the bioprosthetic artificial heart. It will therefore need to adapt its organizational structure and employ new skills, and it will therefore need to recruit personnel and extend its operational capacities; this could place significant demands on its internal resources.

To this end, the Company will have to:

- train, manage, motivate and hold on to a growing number of qualified staff and/or distributors;
- anticipate the expenses connected with this growth and the associated financing needs;
- anticipate demand for its products and the revenues they might generate; and
- increase the capacity of its existing operational, financial and management computer systems.

The Company's inability to manage growth or unexpected difficulties encountered during its expansion could have a significant unfavorable impact on its activity, its financial situation, its performance, its development and its prospects.

2.7 SPECIAL CIRCUMSTANCES AND DISPUTES

There are no administrative, judicial or arbitration proceedings, including any proceedings the Company is aware of which are pending or which are being threatened, which are capable of having or which in the course of the last 12 months have had a significant impact on the financial situation or the profitability of the Company and/or group.

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3

FINANCIAL INFORMATIONS

3.1 NOTES ON ACTIVITY IN THE 2017 REPORTING PERIOD

3.1.1 SELECTED FINANCIAL INFORMATIONS

Income statement (simplified) (in thousands of euros)	12 months 2017	12 months 2016	12 months 2015
Net revenue	0	0	0
Other revenues	28	263	14
Operating expenses	31,063	24,842	19,782
OPERATING RESULT	**-31,035**	**-24,579**	**-19,767**
Financial result	-472	-1,143	-838
EARNINGS BEFORE INTEREST AND TAX	**-31,507**	**-25,722**	**-20,605**
Extraordinary result	-56	-75	-89
Research tax credit	2,335	2,817	3,149
PROFIT OR LOSS	**-29,228**	**-17,546**	**-17,546**

Cash flow statement (simplified) (in thousands of euros)	12 months 2017	12 months 2016	12 months 2015
NET RESULT	-29,228	-22,980	-17,546
Self financing capacity	-27,227	-21,573	-16,206
Cash flow from operations	-24,279	-21,254	-17,187
Cash flow from investment operations	-3,709	-1,040	-205
Cash flow from financing operations	57,547	50,117	11,185
Change in cash and cash equivalents	29,560	28,171	-6,207
OPENING CASH AND CASH EQUIVALENTS	**31,163**	**3,012**	**9,219**
CLOSING CASH AND CASH EQUIVALENTS	**60,723**	**31,163**	**3,012**

The activity of the Company is exclusively focused on the research and development of an innovative product in the medical sector. No sales activities are envisaged in the immediate short term.

CHANGE IN THE COMPANY'S ACTIVITY IN THE COURSE OF THE REPORTING PERIOD

CARMAT recorded no revenue in 2017, as its total artificial heart is still in clinical development. The CE marking process, which is a prerequisite to marketing the product in Europe, is progressing in line with the Company's expectations.

Operating expenses totaled €31.1 million in 2017, a 25% increase on 2016 due to:

- the continuation of the CE marking process undertaken with DEKRA materialized by the completion of the majority of the technical dossier;

- the ramping up of the Company's industrial development with a view to opening a new manufacturing site in the first quarter of 2018;

- the analyses and actions undertaken by the Company enabling it to be granted approval to resume the pivotal study during the first half of the year;

- the internationalization of the pivotal study, notably with the training of the teams from the investigation centers involved in the study and the performing of the first implantations in Kazakhstan and the Czech Republic.

Once a financial loss (-€472.3 thousand), exceptional items (-€55.6 thousand) and Research Tax Credit (€2.3 million) are taken into account, the net loss at December 31, 2017 was of €29.2 million, versus a loss of €23.0 million at December 31, 2016.

- Clinical development

During 2017 fiscal year, CARMAT made significant advances:

- on May 2, 2017, the ANSM (French national agency for the safety of medicines and health products) granted CARMAT the approval to resume the pivotal study in France.

- during the second half of 2017, CARMAT internationalized the pivotal study by performing the first human

implantations of its bioprosthesis in Kazakhstan and the Czech Republic, in compliance with the protocol approved by the ANSM and the authorizations received from those countries' respective health authorities.

- in accordance with its clinical strategy, the Company is pursuing its efforts aimed at expanding the pivotal study to four other European countries (including Denmark as announced on February 20, 2018) and initiating a clinical study in the United States in 2018.

- Industrial production and production

- During the second half of 2017, work on the new automated assembly plant entered its final phase, and the site should become fully operational during the first quarter of 2018. It will allow manufacturing on a larger scale with a higher yield to meet the requirements of the pivotal phase and the commercial launch.

- In November 2017, CARMAT signed a partnership agreement with AddUp, the Michelin and Fives Joint Venture, regarding a unique collaboration in the medical sector that will eventually lead to the 3D printing of certain components and the production acceleration in the commercial phase.

- Governance and management

The year 2017 was marked by:

- the cooptation of 2 cardiology experts as independent Board members:

  Mr. Jean-Luc Lemercier, Corporate Vice-President EMEA, Canada & Latin America at Edwards Lifesciences;

  Dr. Michael Mack, a US cardiac surgeon and Director of Cardiovascular Research at the Baylor Scott & White Health group in Dallas (Texas).

- the appointment of 2 managers with substantial industrial and marketing experience:

  Mr. Wenzel Hurtak, previously Business Director New Products at Contract Medical International GmbH, as Director of Manufacturing;

  Mr. Francesco Arecchi, previously Product Manager EMEA Structural Heart at Abbott, as Marketing Manager.

Thanks to these strategic appointments, CARMAT has an enhanced expertise to obtain CE marking, complete the ongoing industrial transformation and successfully develop and deploy its European and American market access strategy.

STRENGTHENED FINANCIAL STRUCTURE

At December 31, 2017, cash and marketable cash instruments of €60.7 million, a substantial increase compared to December 31, 2016 (€31.2 million) due to:

- the completion of a €52.9 million capital increase in December 2017;

- drawdowns on the second tranche of the contingent equity line subscribed to with Kepler Cheuvreux for a gross total of €8.0 million. Within the framework of this financing, CARMAT has access to an additional €29.9 million of financing that may be exercised depending on its requirements and on market conditions.

These financial resources will allow the Company to continue its industrial and clinical development until it receives CE marking, which is expected in 2019.

3.1.2 INVESTISMENTS MADE AND ENVISAGED

PRINCIPAL INVESTMENTS MADE IN THE LAST THREE FINANCIAL PERIODS

In the year ended December 31, 2017, the Company increased its capital expenditure in the sum of €3,558,636, representing:

- property, plant and equipment of €3,528,393, primarily for the purchase of measuring and control equipment and industrial tools, and linked to the ongoing development of the new Bois d'Arcy production site, for an amount of €2,760,389;
- intangible assets of €30,243, representing the acquisition of licenses and computer software.

In the year ended December 31, 2016, the Company incurred new capital expenditure in the sum of €1,096,157, representing:

- property, plant and equipment of €977,980, primarily for the purchase of measuring and control equipment and industrial tools, premises refurbishment and the acquisition of computer hardware;
- intangible assets of €118,177, representing the acquisition of licenses and computer software.

In the year ended December 31, 2015, the Company incurred new capital expenditure in the sum of €292,393, representing:

- property, plant and equipment of €221,655, primarily for the purchase of measuring and control equipment

and industrial tools, premises refurbishment and the acquisition of computer hardware;
- intangible assets of €70,738, representing the acquisition of licenses and computer software.

PRINCIPAL CAPITAL EXPENDITURE UNDERWAY AND METHOD OF FINANCING

Assets in the process of being acquired at the end of 2017 amounted to € 2.8 million, financed on the basis of available cash, and relate to the ongoing development of the new Bois d'Arcy production site.

MAIN INVESTMENTS ENVISAGED

The main investments expected in the short term relate to production equipment to improve processes or streamline production.

3.1.3 PROGRESS MADE AND DIFFICULTIES ENCOUNTERED DURING THE REPORTING PERIOD

As a reminder, the clinical feasibility study, finalized at the beginning of the 2016 financial year, allowed to combine a 21month experience of the CARMAT system and to provide the necessary lessons for preparing the pivotal study.

The latter began in the summer of 2016, in accordance with the authorizations of ANSM and the Patient Protection Committee (PPC). Unfortunately, the pivotal study was suspended by CARMAT following the death of the first patient in the study, implanted at the end of August 2016. The analyzes carried out showed that the prosthesis had functioned correctly and that the death was related to a bad handling of the batteries by the patient. The ANSM requested additional elements, and on the basis of the answers given by CARMAT, it authorized the Company on May 2, 2017 to resume the pivotal study in France.

3.1.4 ANTICIPATED DEVELOPMENTS, OUTLOOK AND SIGNIFICANT EVENTS AFTER THE END OF THE REPORTING PERIOD

In accordance with its clinical strategy, CARMAT confirms that it is working on expanding the pivotal study to other European countries, in addition to France, Kazakhstan, Czech Republic and Denmark. The aim is to accelerate enrolment in the study and, more importantly, to optimize the selection of patient profiles in order to maximize the study's chances of success.

Furthermore, CARMAT is still studying development opportunities on the US market and has been in contact with the FDA (Food and Drug Administration), the American market having the greatest potential for mechanical circulatory support systems.

The fundraising operation carried out last December 2017 also enabled securizing investments already launched in the development of new manufacturing capabilities (new Bois d'Arcy production site).

TRENDS SINCE THE YEAR END

There have been no significant changes to the financial or commercial situation since the financial year ended on December 31, 2017.

The Company devotes itself exclusively to the clinical trials required to advance the artificial bioprosthetic heart project and to prepare the CE marking application, with a view to marketing the product.

PROFIT FORECASTS OR ESTIMATES

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

3.1.5 STATEMENT OF RESULTS FOR THE PAST FIVE PERIODS

STATEMENT OF RESULTS FOR THE PAST FIVE PERIODS

(in euros)	Dec. 31, 2017	Dec. 31, 2017	Dec. 31, 2015	Dec. 31, 2014	Dec. 31, 2013
Capital at the end of the period					
Share capital	360,661.76	241,277.76	183,117.40	175,200.80	171,338.80
Number of existing ordinary shares	9,016,544	6,031,944	4,577,935	4,380,020	4,283,470
Number of existing preference shares	-	-	-	-	-
Maximum number of future shares to be created					
- by conversion of bonds	-	-	-	-	-
- by exercise of subscription rights	943,025	852,140	466,610	640,875	348,125
Opérations and results					
Revenue excluding VAT	0	0	0	0	0
Profit before tax, profit sharing, depreciation and amortization, and increases in provisions	-30,020,856	-25,378,370	-20,229,406	-19,975,189	-15,395,852
Corporation taxes	2,334,690	2,817,116	3,148,534	2,209,185	1,770,114
Profit sharing for the period	-	-	-	-	-
Profit after tax, profit sharing, depreciation and amortization and increases in provisions	-29,227,910	-22,980,178	-17,545,761	-18,263,056	-14,644,902
Distributed profit	-	-	-	-	-
Profit per share					
Profit after tax and profit sharing, but before depreciation and provisions	-3.07	-3.74	-3.73	-4.06	-3.18
Profit after tax, profit sharing, depreciation and amortization, and increases to provisions	-3.24	-3.81	-3.83	-4.17	-3.42
Dividend paid per share	-	-	-	-	-
Staff					
Average workforce employed during the period	70	56	48	47	40
Wage bill for the period	5,220,243	4,371,200	4,069,741	3,792,937	3,283,217
Value of social benefits paid during the period	2,163,452	1,803,184	1,611,888	1,272,566	1,127,202

3.1.6 PROPOSED APPROPRIATION OF THE RESULT

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

These financial statements show a net loss of €29,227,910.

We propose appropriation of this loss to Losses carried forward, taking the balance of that item from €-116,523,099 to €-145,751,009.

3.1.7 PARTICULARS OF DIVIDENDS

In accordance with the provisions of Article 243 of the General Tax Code, it is recalled that no distribution of dividends has taken place for the last three fiscal 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

SIGNIFICANT EXISTING OR PLANNED PROPERTY, PLANT AND EQUIPMENT

The Company performs its activities in premises that it leases on the basis of a lease agreements concluded in accordance with market prices and conditions with companies which have no direct or indirect ties to Company directors. CARMAT does not own any real estate.

For the financial year in course at the date of this registration document, the Company considers that it has suitable premises that will be adequate for its projected growth and employees.

As a reminder, during the second half of 2017, work on the new automated assembly plant entered its final phase, and the new Bois d'Arcy site should become fully operational during the first quarter of 2018.

It will allow manufacturing on a larger scale with a higher yield to meet the requirements of the pivotal phase and the commercial launch.

ENVIRONMENTAL ISSUES

In connection with search for non-thrombogenic* material, CARMAT decided to follow a path originally opened by Professor Alain Carpentier's work on biological valves, which uses animal pericardium that has been chemically treated to render it inert and biologically stable, so that rejection by the body is avoided.

In designing and manufacturing the bioprosthetic artificial heart, the Company is therefore subject to chemical and biological risks, obliging it to put in place preventative and protective measures for the benefit of its operators and for waste management in line with current environmental and safety regulations governing the use, storage, handling and disposal of hazardous materials. The Company believes that it complies with these regulations.

In particular, the Company has entrusted two specialized subcontractors to manage its waste products. It undertakes an annual evaluation of the risks by work unit. This involves analyzing each hazardous situation, quantifying the risks by severity and occurrence and describing preventive measures. Generally, all operations in which there is the possibility of substance evaporation are performed under hoods or in chambers with activated carbon filters.

Lessee	Address	Nature of premises	Surface area	Lease start date	Lease expiry date	2017 rental cost (including charges)
CARMAT SA	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy-Villacoublay FRANCE	Business premises	1,053 m²	February 1, 2009	January 31, 2027	€ 321,981.31
CARMAT SA	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy-Villacoublay FRANCE	Business premises	595 m²	October 1, 2010	September 30, 2019	€ 157,251.72
CARMAT SA	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy-Villacoublay FRANCE	Business premises	595 m²	July 1, 2011	September 30, 2018	€ 109,792.88
CARMAT SA	9, rue René Clair Batiment G Sis parc Spirit Meliers III 78390 Bois d'Arcy FRANCE	Business premises	1 558 m²	December 7, 2017	December 6, 2028	€ 12,732.82

3.1.9 PARTICULARS OF PAYMENT PERIODS

PARTICULARS OF SUPPLIER PAYMENT PERIODS

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 details concerning supplier payment periods:

As at December 31, 2017, trade accounts payable totaled €3,680,392. A comparison of the figures from the financial statements is set out below:

(in euros)	December 31, 2017	December 31, 2016
Trade accounts payable and related payables shown under liabilities	5,825,388	3,588,737
Less: amounts receivable from suppliers shown under assets in balance sheet	-13,342	-1,914
Less: accrued charges included under this heading	-2,131,654	-1,778,506
Liabilities related to fixed assets and similar liabilities	0	0
Less: accrued charges included under this heading	0	0
TOTAL	**3,680,392**	**1,808,317**

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

(in euros)	December 31, 2017	December 31, 2016
Due (including amounts receivable from suppliers)	606,658	119,957
Falling due on January 31	3,073,734	1,688,360
Falling due on February 28	0	0
Falling due on or after March 31	0	0

Detail of debts due at the end of the financial year:

Article D.441 I.-1 °: Invoices received not settled on the closing date of the financial year whose term has expired

(in euros)	0 day	1 to 30 days	31 to 60 days	61 to 90 days	> 90 days	Total
		(A) Late payment part				
Number of invoices concerned	35					
Total amount of invoices concerned (includ. VAT)	460,764	0	0	0	0	0
Percentage of the total amount of purchases for the year (includ. VAT)	1.75%	0	0	0	0	0
		(B) Invoices excluded from (A) relating to disputed				
Number of invoices concerned		1 invoice for an amount of €145,894 includ. VAT				

PARTICULARS OF TRADE RECEIVABLES PAYMENT PERIODS

Non applicable.

3.1.10 IMPORTANT CONTRACTS

The important 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 Paragraph 5.6 « Regulated agreements »;
- an exclusive license agreement with the Pierre and Marie Curie University relating to patent no 8800381: please refer to Paragraph 1.5.4 « Innovation and management of the R&D »;

- an exclusive license agreement with the Centre Technique des Industries Mécaniques relating to patent no 2760973: please refer to Paragraph 1.5.4 «Innovation and management of the R&D »;

- 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 granted by Bpifrance of €33 million.

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 CARMAT Industrial 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 last one being the achievement of CE marking.

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 in the project: Dedienne Santé, PaxiTech, Vignal Artru Industries (Pack'Aero Group) and Iréis (formerly HEF R&D).

Relationships with the partners

- PaxiTech is responsible for the work relating to development of a portable fuel cell. This agreement was entered into for a term of two years with effect from July 7, 2009. If PaxiTech wishes to use the results in any area outside the medical domain, it will have to obtain the prior authorization of CARMAT, which may not be refused without good reason. Note that at the end of the aforementioned agreement, a new agreement was reached between CARMAT and PaxiTech outside of the Bpifrance framework on September 13, 2011, in light of the progress realized in the first two years that allowed for the possibility of creating the first industrial prototypes.

- Dedienne Santé is responsible for the work relating to manufacture of parts in implantable PEEK. This agreement, initially made for a four-year period from July 7, 2009, has been extended to June 1, 2017. If Dedienne Santé wishes to use the results in any area outside the medical domain, it will have to obtain the prior authorization of CARMAT, which may not be refused without good reason.

- Iréis (formerly HEF R&D) is responsible for the work relating to qualification of the motor pump unit. This agreement was entered into for a term of six years with effect from July 7, 2009. In return for ownership of the results of the work attributable to CARMAT, the latter undertakes to grant HEF R&D an exclusive and transferable usage right, free of charge and without time limit, to these results for application outside of the medical devices domain.

- Vignal Artru Industries (Pack'Aero Group) is responsible for the work relating to construction of the motor pump unit. This agreement, initially made for a four-year period from July 7, 2009, has been extended to June 1, 2017. If Vignal Artru Industries wishes to use the results in any area outside the medical domain, it will have to obtain the prior authorization of CARMAT, which may not be refused without good reason.

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 executed.

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 « 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 financial debts » line.

By addendum to initial contract, signed in September 16, 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 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 sales exceeding 20% of the updated forecasts (in 2013), as defined in the table below, these amounts would be capped as follows:

- for year 2: at 0.5% of yearly sales of the reference products and services in the previous year;
- for years 3 and 4: at 1% of yearly sales of the reference products and services in the previous year;
- for years 5 and 6: at 2% of yearly sales of the reference products and services in the previous year.

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 €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 sales, subject to a maximum financial return of €50 million at nominal value, if achieved before the end of 8 years.

Amounts received and still to be received at December 31,2017

The Bpifrance agreements provides for the payment of a total of € 17.4 million in grants, all of which was received at the end of the 2017 financial year.

It also provides for the payment of a total sum of € 14.5 million for repayable advances, of which € 1.5 million remains to be collected by the end of the program (after obtaining the CE marking).

OTHER IMPORTANT CONTRACTS

Edwards Lifesciences

An agreement with an initial term of one year, automatically renewable annually, was entered into in the final quarter of 2010 by CARMAT and Edwards Lifesciences, the world leader in the heart valves sector and in hemodynamic monitoring, for the use and supply of Carpentier-Edwards bioprosthetic heart valves for the CARMAT total artificial heart.

Invibio Limited

An agreement with a term of 12 years was concluded during the third quarter of 2012 between CARMAT and Invibio Limited, for the supply and use of PEEK-OPTIMA polymer materials®. This material is used by CARMAT owing to its biocompatibility characteristics, its certified long-term implantability and its mechanical properties. The structural sub-assemblies of the prosthesis are manufactured out of this material.

3.2 FINANCIAL STATEMENTS AS AT DECEMBER 31, 2017

3.2.1 2017 ANNUAL STATEMENTS

INCOME STATEMENT

Income statement	December 31, 2017			December 31, 2016
(in euros)	France	Export	Total	Total
OPERATING INCOME				
Sales of merchandise				
Sales of finished goods				
Sales of finished services				
NET REVENUE				
Production left in stock				
Fixed asset production				
Subsidies (note 3.2.2.5)			28,000	173,167
Write-backs of amortization/depreciation and provisions, and transfers of expenditure				89,827
Other revenues				
TOTAL OPERATING INCOME (I)			28,000	262,994
OPERATING EXPENSES				
Purchases of merchandise				
Change in inventory (merchandise)				
Purchases of raw materials and other supplies			2,410,973	2,888,925
Change in inventory (raw materials and other supplies)				
Other purchases and external expenditure			19,478,803	15,023,260
Taxes, fees and similar payments			185,402	218,404
Wages and salaries			5,220,243	4,371,200
Social security costs			2,163,452	1,803,184
Amortization/depreciation and impairments				
- of fixed assets: amortization/depreciation (note 3.2.2.4)			751,822	503,809
- of fixed assets: impairments				
- of current assets: impairments				
Provisions (note 3.2.2.4)			789,922	4,942
Other expenses			61,980	28,479
TOTAL OPERATING EXPENSES (II)			31,062,596	24,842,202
1 - OPERATING RESULT (I - II)			-31,034,596	-24,579,208
SHARES IN RESULTS OF JOINT OPERATIONS				
Profits allocated or loss transferred (III)				
Loss or profit transferred (IV)				
FINANCIAL INCOME				
Financial income from equity interests				
Income from other securities and fixed asset receivables				
Other interest receivable and similar income			707	5,246
Write-backs of impairments and provisions, transfers of expenditure				
Positive exchange differences			73,797	5,940
Net proceeds from sales of marketable securities				1,337
TOTAL (V)			74,504	12,523

Income statement (in euros)	December 31, 2017			December 31, 2016
	France	Export	Total	Total
FINANCIAL EXPENSES				
Amortization/depreciation, impairments and provisions				
Interest expenses and similar charges			503,724	1,133,976
Negative exchange differences			43,143	21,264
Net expenses from sales of marketable securities				
TOTAL (VI)			546,867	1,155,239
2 - FINANCIAL RESULT (V-VI)			-472,363	-1,142,716
3 - EARNINGS BEFORE INTEREST AND TAX (I-II+III-IV+V-VI)			-31,506,958	-25,721,924
EXTRAORDINARY INCOME (NOTE 3.2.2.5)				
Extraordinary income from management operations				
Extraordinary income from capital operations			59,740	41,415
Write-backs of impairments and provisions, transfers of expenditure				
TOTAL (VII)			59,740	41,415
EXTRAORDINARY EXPENSES (NOTE 3.2.2.5)				
Extraordinary expenses from management operations			9,869	2,064
Extraordinary expenses from capital operations			105,513	114,721
Amortization/depreciation, impairments and provisions				
TOTAL (VIII)			115,382	116,785
4 - EXTRAORDINARY RESULT (VII-VIII)			-55,642	-75,370
Employee profit-sharing (IX)				
Income taxes (X) (note 3.2.2.4)			-2,334,690	-2,817,116
TOTAL INCOME (I+III+V+VII)			162,244	316,932
TOTAL EXPENSES (II+IV+VI+VIII+IX+X)			29,390,154	23,297,110
5 - LOSS (total income – total expenses)			-29,227,910	-22,980,178

BALANCE SHEET

Assets (in euros)	December 31, 2017 Gross	Amortization and depreciation	Net	December 31, 2016 Net
UNCALLED SHARE CAPITAL (TOTAL I)				
Fixed assets				
Intangible fixed assets (note 3.2.2.4)				
- Start-up costs				
- Development costs				
- Licenses, patents and similar rights	1,861,904	1,789,832	72,072	196,486
- Goodwill *				
- Assets under construction				
- Advances and payments on account				
Property, plant and equipment (note 3.2.2.4)				
- Land				
- Buildings				
- Technical plant, equipment and tooling	6,328,506	5,116,826	1,211,681	200,735
- Other property, plant and equipment	1,216,287	981,277	235,010	349,794
- Assets under construction	2,760,389		2,760,389	682,475
- Advances and payments on account				
Financial assets ** (note 3.2.2.4)				
- Holdings accounted for on an equity basis				
- Other holdings				
- Other equity investments				
- Loans				
- Other financial assets	472,542		472,542	321,999
TOTAL II	12,639,629	7,887,935	4,751,694	1,751,490
Current assets				
Stocks and work in progress				
- Raw materials, supplies				
- Work in progress – goods				
- Work in progress – services				
- Semi-finished and finished products				
- Merchandise				
Advances and prepayments on orders	181,706		181,706	15,145
Debtors ***				
- Trade accounts receivable				
- Other accounts receivable (note 3.2.2.4)	3,825,641		3,825,641	4,228,308
- Subscribed capital – called, not paid up				
Marketable securities				
Cash instruments (note 3.2.2.4)				4,003,356
Cash	60,722,988		60,722,988	27,159,992
Deferred charges *** (note 3.2.2.4)	367,492		367,492	331,082
TOTAL III	65,097,827		65,097,827	35,737,884
ADJUSTMENT ACCOUNTS				
Bond issuance costs to be amortized (IV)				
Bond redemption premiums (V)				
Unrealized foreign exchange losses (VI)				
GRAND TOTAL (I+II+III+IV+V+VI)	77,737,456	7,887,935	69,849,521	37,489,373
* including lease rights.				
** of which less than one year.			139,725	185,497
*** of which more than one year.				

Liabilities (in euros)	December 31, 2017	December 31, 2016
EQUITY		
Capital (of which, paid in: 360,662) (note 3.2.2.4)	360,662	241,278
Issue, merger and acquisition premiums (notes 3.2.2.3 and 3.2.2.4)	189,541,644	132,113,544
Excess of restated assets		
Reserves		
- Legal reserve		
- Statutory or contractual reserves		
- Regulatory reserves		
- Other reserves		
Losses brought forward	-116,523,099	-93,542,921
Result for the period (profit or loss)	-29,227,910	-22,980,178
Capital grants		
Regulatory provisions		
TOTAL 1	44,151,297	15,831,723
OTHER EQUITY		
Proceeds of issues of participating stock		
Conditional advances (note 3.2.2.4)	13,056,577	13,056,577
TOTAL II	13,056,577	13,056,577
PROVISIONS		
Provisions for risks		
Provisions for charges (notes 3.2.2.4 and 3.2.2.5)	983,135	193,213
TOTAL III	983,135	193,213
DEBTS *		
Financial debts		
- Convertible bonds		
- Other bonds		
- Loans from credit institutions		
- Bank overdrafts		
- Sundry loans and financial debts (note 3.2.2.4)	3,714,150	3,212,500
Advances and payments on account received for current orders		
Accounts payable (note 3.2.2.4)		
- Trade accounts payable and related payables	5,825,388	3,588,737
- Tax and social liabilities	2,118,974	1,606,623
Liabilities secured to property and related liabilities (note 3.2.2.4)		
Other debts (note 3.2.2.4)		
ADJUSTMENT ACCOUNTS		
Deferred income * (note 3.2.2.4)		
TOTAL IV	11,658,512	8,407,860
Unrealized foreign exchange gains		
TOTAL V		
GRAND TOTAL (I+II+III+IV+V)	69,849,521	37,489,373
* debts and deferred income of less than one year.	7,944,362	5,195,360

CASH FLOW STATEMENT

Cash flow statement (in euros)	December 31, 2017	December 31, 2016
Net result	-29,227,910	-22,980,178
Amortization/depreciation and provisions	1,541,744	508,751
Write-backs of amortization/depreciation and provisions	-42,847	-89,827
Gains or losses on asset sales		
Investment subsidies transferred to income		
Other income and expenses with no impact on cash flow	501,650	988,703
SELF-FINANCING CAPACITY	-27,227,364	-21,572,551
Tax and social liabilities	512,352	-106,942
Trade accounts payable	2,236,651	579,955
Other debts		-22,263
Deferred income		
Stocks and work in progress		
Advances and prepayments on orders	-166,561	171,095
Other accounts receivable	402,667	-179,240
Trade receivables		
Deferred charges	-36,410	-143,928
CHANGES IN CASH POSITION (CHANGE IN WORKING CAPITAL)	2,948,699	298,677
CASH FLOW FROM OPERATIONS	-24,278,664	-21,254,095
Acquisition of property, plant and equipment	-3,528,393	-977,981
Acquisition of intangible fixed assets	-30,243	-118,178
Acquisition of financial fixed assets	-150,543	55,970
Proceeds from financial fixed asset disposals		
CASH FLOW FROM INVESTMENT OPERATIONS	-3,709,179	-1,040,189
Increase in capital	119,384	58,161
ORA/BSA		
Issue premium	57,418,100	50,116,638
Capitalization of current accounts		
Loans and conditional advances		
CASH FLOW FROM FINANCING OPERATIONS	57,547,484	50,465,284
CHANGE IN CASH AND CASH EQUIVALENTS	29,559,640	28,171,000
OPENING CASH AND CASH EQUIVALENTS (NOTE 3.2.2.4)	31,163,348	3,012,127
CLOSING CASH AND CASH EQUIVALENTS (NOTE 3.2.2.4)	60,722,988	31,163,348

3.2.2 ANNEX TO THE FINANCIAL STATEMENTS

Annex to the balance sheet for the year ended December 31, 2017, totaling €69,849,521, and to the income statement for the year ended December 31, 2017, presented in list form and showing zero revenue resulting in a loss of €29,227,910.

The financial year commenced on January 1, 2017 and ended on December 31, 2017, a duration of 12 months which is identical to that of the comparative period.

The notes and tables presented in the following are an integral part of the financial statements for the period ended on December 31, 2017 as approved by the board of directors on February 12, 2018. They are presented in euros unless otherwise stated.

3.2.2.1 FEATURES OF THE YEAR

The Company's activity 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 following a protocol approved by the ANSM.

- During the year, the Company carried out a fundraising decided by the Board of Directors on December 12, 2017, with the delegation of authority of the Combined General Meeting of April 27, 2017. This operation was realized by a capital increase of € 105,800.00, with a gross issue premium of € 52,794,200, representing a total amount of issue proceeds of € 52,900,000.

  This capital increase resulted in the creation of 2,645,000 new shares, with a par value of € 0.04. Taking into account the costs related to the capital increase, amounting to € 3,320,008, which are deducted from the issue premium under the preferential accounting method, the net issue premium in respect of the capital increase is € 49,474,192.

Otherwise :

- Under the terms of the equity financing agreement with Kepler Cheuvreux on January 20, 2015, thirty-four subscriptions were made between January and October for a total of 324,500 stock warrants, enabling the capital to be increased by € 12,980.00, by issuing 324,500 ordinary shares with a par value of € 0.04, issued at an average unit price of € 24.64, with a gross issue premium of € 7,982,735. Taking into account the costs related to the capital increase of € 149,023, which are deducted from the issue premium under the preferential accounting method, the net issue premium in respect of this capital increase is € 7,833,712.

- Fifteen BCE exercises were executed between January and September for a total of 604 BCE 2009-2, increasing the capital by an amount of € 604.00 by issuing 15,100 ordinary shares with a par value of € 0.04, issued at a unit price of € 8 per share, ie with an issue premium of € 7.96 per share.

All of the capital increases carried out during the financial year increased the share capital by an amount of € 119,384 by creating 2,984,600 new ordinary shares. The share capital of the company was thus increased from € 241,277.76 to € 360,661.76. The total amount of issue premiums was increased from € 132,113,544 to € 189,541,644.

The Company maintains the option for the Research Tax Credit for the year 2017. The first option was exercised in respect of the 2009 calendar year and renewed each year until 2017. The Research Tax Credit For the year 2017 has been recorded in the income statement (€ 2,334,690) (see note 3.2.2.5 in the notes to the financial statements) and shown in 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 « Comments on the Company's business during the year » of this document.

3.2.2.2 SIGNIFICANT EVENTS AFTER THE END OF THE REPORTING PERIOD

No event occurring after the end of the financial year is liable to alter the presentation or the valuation of the accounts as decided by the Board of Directors.

3.2.2.3 ACCOUNTING RULES AND METHODS

The valuation methods for this period have not been changed from those used in the previous financial year.

General principles and conventions

The accounts for the period have been prepared and presented in accordance with the accounting regulations and the principles laid down in Articles 120-1 et seq. of the

General Chart of Accounts 2005.

The basic valuation method for the items shown in the accounts is that of historical cost.

The accounting conventions have been applied in accordance with the provisions of the French Commercial Code, the Accounting Decree of November 29, 1983 and the CRC regulations concerning the redrafting of the General Accounting Plan 2005 applicable as at the end of the period.

The general accounting conventions have been applied in accordance with the prudent person rule, on the basis of the following assumptions:
- the business is a going concern;
- the accounting methods are consistent from one year to the next;
- there is a clear cut-off between accounting periods.

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

- the level of cash and cash equivalents available as of December 31, 2017, for a total amount of € 60,722,988;

- the payment of repayable advances (€ 1,450,732) still to be collected by the end of the Bpifrance aid program signed in 2009, corresponding to key step 7;

- The possibility of using the flexible equity financing set up in January 2015 with Kepler Cheuvreux for a total amout of € 29.9 million as at December 31, 2017 (Tranche 1 balance of € 8.0 million, Tranche 2 balance of € 6.9 million and Tranche 3 balance for € 15.0 million, representing a total of € 29.9 million).

The Company's industrial and commercial development after it has obtained CE marking will give rise to further financial requirements: financing for ongoing operations and R&D during the initial commercial launch phase, need for working capital in relation to sales development, investment for the purpose of increasing production capacity and automating production processes. The Company currently estimates that these additional requirements could reach €150 million. Funds will need to be raised in addition to the exploitation of the Kepler equity financing lines. The extent and timing of such fund-raising will depend in particular on (i) the opportunities that arise as clinical trials progress and (ii) the ability of the Company to carry out various steps simultaneously that normally occur in sequence, such as e.g. clinical studies in Europe and the US, and extending production capacity.

Supplementary information

- Applied research and development costs

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

- Intangible fixed assets

Patents, licenses and other intangible fixed assets have been valued at their cost of acquisition, excluding the expenses incurred in acquiring them.

The methods and periods of amortization used are as follows:

Category	Mode	Term
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	Mode	Term
Fixtures and fittings	Straight line	9 à 10 years
Technical plant	Straight line	3 years
Equipment and tooling	Straight line	2 to 6 years
Furniture	Straight line	8 years
IT equipment	Straight line	3 years

- Financial assets

OTHER SECURITIES CLASSIFIED AS FIXED ASSETS

In 2010, the Company entered into a liquidity contract, the purpose of which is 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 an amount of €300,000 available.

On May 19, 2016, the Company transferred the liquidity contract 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, a provision is made for impairments 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 own shares.

- Receivables and liabilities

Receivables and payables are shown at face value. If necessary, impairments are recorded against receivables to take account of difficulties with recovery that are likely to occur. Any provisions for impairments are determined by comparison between the acquisition value and the likely realization value.

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

- Stocks

The equipment in stock is not valued at the end of the financial year as these are intended to be integrated into the prostheses used for the pivotal study, their 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 to euros at the exchange rate ruling on the balance sheet date. Gains and losses on conversion are recognized immediately in the profit or loss for the period as exchange gains and losses.

- Cash instruments

These comprise time deposit accounts, shown under assets at their acquisition cost, plus accrued interest at the closing date of the reporting period.

- 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 on hand » items under the assets, 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 at the foot 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 financial debts.

- 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. Subsidies are recorded under income taking account, if necessary, of the corresponding rate of expenditure in order to adhere to the principle of matching of expenses with revenue.

- Retirement indemnities

Future payments for benefits to members of staff are valued 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 commitments are the subject of 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 charges.

- Share issue costs

In accordance with the preferential method, share issue costs are recorded in the balance sheet as deductions from the issue premium.

3.2.2.4 SUPPLEMENTARY INFORMATION ON THE BALANCE SHEET

- Schedule of fixed assets

(in euros)	Gross value at start of period	Additions	
		Line to line transfers	Acquisitions
Licenses, patents and similar rights *	1,831,661		30,243
Assets under construction			
TOTAL	1,831,661		30,243
Technical plant, equipment and industrial tooling **	4,884,489		1,486,865
General plant, sundry fixtures and fittings	869,619		
Office and IT equipment, furniture	340,206		6,461
Assets under construction ***	682,475		2,077,914
TOTAL	6,776,790		3,571,241
Other financial fixed assets ****	321,999		3,949,098
TOTAL	321,999		3,949,098
GRAND TOTAL	8,930,450		7,550,582

(in euros)	Reductions		Gross value at end of period	Revaluation of original value at end of period
	Line to line transfers	Disposals		
Licenses, patents and similar rights *			1,861,904	
Assets under construction			0	
TOTAL			1,861,904	
Technical plant, equipment and industrial tooling **		42,847	6,328,507	
General plant, sundry fixtures and fittings			869,619	
Office and IT equipment, furniture			346,667	
Assets under construction			2,760,389	
TOTAL		42,847	10,305,183	
Other financial fixed assets ***		3,798,555	472,542	
TOTAL		3,798,555	472,542	
GRAND TOTAL		3,841,402	12,639,629	

* This item includes a sum of €411,284, accounted for as the share of the contribution in kind made on September 30, 2008, with a total value of €960,000, relating to the contribution of patents.

** 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 representing the proportion of the contribution in kind of €960,000 made on September 30, 2008 that related to the contribution of equipment and tooling.

*** This item includes the development of the new Bois d'Arcy production site, for an amount of €2,760,389.

**** This item includes the 2,206 own shares held in connection with the liquidity contract, valued at €43,670, and (i) the liquidities not invested in own shares as at the end of the period under the liquidity contract of €96,055 and (ii) guarantee deposits of €332,818, mainly comprising deposits under premises lease contracts.

- Schedule of depreciation and amortization

Statements and movements for the period (in euros)	Value at start of period	Allowances for the period	Reductions Write-backs	Value at end of period
Licenses, patents and similar rights	1,635,176	154,657		1,789,832
TOTAL	1,635,176	154,657	0	1,789,832
Technical plant, equipment and industrial tooling	4,683,754	476,327	42,847	5,117,234
General plant, sundry fixtures and fittings	593,036	88,237		681,273
Office and IT equipment, furniture	266,995	32,601		299,596
TOTAL	5,543,785	597 165	42,847	6,098,103
GRAND TOTAL	7,178,960	751,822	42,847	7,887,935

- Schedule of provisions

Provisions (in euros)	Value at start of period	Increases Allowances	Reductions Amounts used	Reductions Amounts not used	Value at end of period
Sundry risks					
Pensions and similar commitments *	193,213	81,441			274,654
Social charges on free preferential shares **		708,481			708,481
TOTAL	193,213	789,922			983,135
Impairment of other equity investments					
TOTAL	0	0			0
GRAND TOTAL	193,213	789,922			983,135
Including operational allowances and write-backs		789,922			
Including financial allowances and write-backs					

* See note 3.2.2.6

** See following note Provision for expenses

- Schedule of maturities of receivables and liabilities

Schedule of receivables (in euros)	Gross amount	Up to 1 year	More than 1 year
Staff-related receivables	809	809	
Social security and other social bodies	16,462	16,462	
Income taxes *	2,371,986	2,371,986	
Value added tax	1,388,042	1,388,042	
Sundry debtors	48,342	48,342	
TOTAL	3,825,641	3,825,641	

* The receivable corresponds to:
- the CIR for the year 2017 for an amount of €2,334,690
- and the CICE for the year 2017 for an amount of €37,296.

Schedule of liabilities (in euros)	Gross amount	Up to 1 year	1 to 5 years	More than 5 years
Sundry loans and financial debts	3,714,150		3,714,150	
Trade accounts payable and related payables	5,825,388	5,825,388		
Staff-related liabilities	1,173,013	1,173,013		
Social security and other social bodies	932,377	932,377		
Other taxes, duties and similar	13,584	13,584		
TOTAL	11,658,512	7,944,362	3,714,150	

- Capital

Composition of the share capital

Categories of shares	Nominal value in euros	Number of shares			
		Opening	Created	Redeemed	Closing
Ordinary shares	0.04	6,031,944	2,984,600		9,016,544
TOTAL		6,031,944	2,984,600		9,016,544

The capital increase, through the exercise of Kepler BSA, during the financial year 2017 resulted in the creation of 324,500 ordinary shares with a par value of € 0.04 .

The capital increase resulting from the placement carried out in December 2017 resulted in the creation of 2,645,000 ordinary shares with a par value of € 0.04 per share.

The capital increase through the exercise of BCE during the financial year 2017 resulted in the creation of 15,100 ordinary shares with a par value of € 0.04 per share.

Changes in equity

EQUITY AT THE START OF THE PERIOD	15,831,723
Increase in capital through exercising of BCE warrants	120,800
Increase in capital through exercising of Kepler BSA warrants	7,846,692
Increase in capital through placement realized	49,579,992
Result for the period	-29,227,910
EQUITY AT THE END OF THE PERIOD	44,151,297

Preferential shares

On the authorization of the combined general meeting of April 27, 2017, the board of directors' meeting decided, on May 15, 2017, to allocate provisionally 5,250 preferential shares, distributed 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 preferential shares, distributed as follows: 50 AGAP 2017- 01, 200 AGAP 2017-02, 310 AGAP 2017-03.

These preferential 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.

Stock warrants

BSA 2009-1

At the general meeting and the meeting of the board of directors of July 8, 2009 and following the board of directors' meeting of September 8, 2011, 3,096 BSA 2009-1 warrants were issued; of these 556 were canceled following the resignation of one of the directors and 986 have been exercised. As at December 31, 2017, there remained 1,554 BSA 2009-1 warrants conferring rights to subscribe for 38,850 new shares, representing 0.43% of the existing capital as at December 31, 2017, at a unit price of €8.

BSA KEPLER CHEUVREUX (TRANCHE 1)

In accordance with the board of directors' decision of December 9, 2014, as authorized by the combined general meeting of April 2, 2014, 400,000 BSA warrants were issued, 205,100 of which had been exercised as at December 31, 2017. The 194,900 BSA warrants not exercised as at that date confer subscription rights to 194,900 new shares, representing 2.16% of the existing capital as at December 31, 2017, at a unit price 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 KEPLER CHEUVREUX (TRANCHE 2)

In accordance with the board of directors' decision of December 12, 2016, as authorized by the combined general meeting of June 28, 2016, 500,000 BSA warrants were issued, 329,500 of which had been exercised as at December 31, 2017. The 170,500 BSA warrants not exercised as at that date confer subscription rights to 170,500 new shares, representing 1.89% of the existing capital as at December 31, 2017, at a unit price 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 warrants were issued pursuant to a delegation of authority granted by the combined general meeting of April 27, 2017, none of which had been exercised as at December 31, 2017. 12,000 warrants not exercised on the same date entitle them to subscribe for 12,000 new shares, representing 0.13% of the existing capital as at December 31, 2017, at a unit price of 30.10 euros.

SUMMARY TABLE OF BSA WARRANTS

	Issued	Subscribed	Lapsed	Reserve	Exercised	Balance	Lapsing on
BSA 2009-1 GM of July 8, 2009	3,096	3,096	556	0	986	1,554	July 8, 2019
BSA Kepler Chevreux Tranche 1	400,000	400,000	0	0	205,100	194,900	Jan 23, 2016 *
BSA Kepler Cheuvreux Tranche 2	500,000	500,000	0	0	132,500	367,500	Dec. 13, 2017
BSA 2017	12,000	12,000	0	0	0	12,000	May 15, 2027

* : date extended by tacit agreement between the parties

Start-up company stock warrants (BCE)

BCE 2009-1

At the general 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 warrants were issued, exercised.

BCE 2009-2

At the general 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 warrants were issued, 3,185 of which have been exercised and 1,778 of which have lapsed and been canceled. The 2,603 BCE-2009-2 warrants subscribed and not exercised as at December 31, 2017 confer the right to subscribe to 65,075 new shares, representing 0.72% of the existing capital as at December 31, 2017, at a unit price of €8.

BCE 2012-1

In accordance with the board of directors' decision of June 27, 2012, as authorized by the combined general meeting of April 26, 2012, 56,500 fully assigned and subscribed BCE-2012-1 warrants were issued, of which 22,500 have lapsed and been canceled. The 34,000 BCE-2012-1 warrants subscribed and not exercised as at December 31, 2017 confer subscription rights to 34,000 new shares, representing 0.38% of the existing capital as at December 31, 2017, at a unit price of €108.483.

BCE 2012-2

In accordance with the board of directors' decision of November 8, 2012, as authorized by the combined general meeting of April 26, 2012, 6,700 fully assigned and subscribed BCE-2012-2 warrants have been issued. The 6,700 BCE-2012-2 warrants subscribed and not exercised as at December 31, 2017 confer subscription rights to 6,700 new shares, representing 0.07% of the existing capital as at December 31, 2017, at a unit price of €122.00279.

SUMMARY TABLE OF BCE WARRANTS

	Issued	Subscribed	Lapsed	Exercized	Balance	Lapsing on
BCE 2009-1 GM of July 8, 2009	3,108	3,108	0	3,108	0	Sept. 9, 2019
BCE 2009-2 GM of July 8, 2009	7,566	7,566	1,778	3,185	2,603	July 8, 2019
BCE 2012-1 GM of April 26, 2012	56,500	56,500	22,500	0	34,000	June 27, 2022
BCE 2012-2 GM of April 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 €13,056,577 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 €3,714,150 at the year end and appears in liabilities under Sundry loans and financial debts.

Accrued interest was calculated using the capitalization method until June 30, 2017. The calculation method was revised taking into account exchanges with Bpifrance concerning the interpretation of the clauses relating to the calculation of interest. The change in method leads to reducing the amount of interest provisioned by €629,000 at the end of the financial year.

Accrued income

Value of accrued income included in the following balance sheet items	Value
Other debtors	15,962
Total	**15,962**

Accrued charges

Value of accrued charges included in the following balance sheet items	Value
Sundry loans and financial debts	3,714,150
Trade accounts payable and related payables	2,131,655
Tax and social liabilities	1,821,930
Total	**7,667,734**

Deferred income and charges

Deferred charges	Value
Operating expenses	367,492
Total	**367,492**

Deferred charges comprises the following:

- the share of rent for the first quarter of 2018 billed in December 2017, totaling €181,697;

- the share of subscriptions, software license royalties and insurance premiums for the period after December 31, 2017, totaling €185,795.

Deferred income	Value
Operating income	None
Total	**None**

Information on related enterprises

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

Trade accounts payable and related payables	464,318

Provision for expenses

Two preferential share allocation plans, as at May 15, 2017 and September 25, 2017, allowed for the provisional allocation of 5,810 preferential shares, which can be converted based on the achievement of the performance criteria to a maximum of 421,000 ordinary shares. The definitive vesting date for these preferential shares is fixed at May 15, 2018 for the preferential shares issued on May 15, 2017 and on September 25, 2018 for preferential shares issued on September 25, 2017. At the end of the year, the Company booked a provision for expenses corresponding to the amount of the employer contributions of 30% to be due in June 2018 and October 2018 respectively, on a porata 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 €22;
- Employer contribution rate of 30%.

3.2.2.5 SUPPLEMENTARY INFORMATION ON THE INCOME STATEMENT

- Operating subsidies

The Company received the sum of €28,000 as an operating subsidy from the Association nationale de la recherche et de la technologie (national research and technology association) for employment of 2 PhD student.

The Company did not receive any Bpifrance grants.

- Applied research and development costs

Research and development costs are accounted for under expenses. They amounted to €17,051,032 in 2017, compared to €14,245,621 in the previous year.

- Research tax credit

The income statement for the year shows a research tax credit amounting to €2,334,690, corresponding to the amount calculated for the year 2017.

- Auditors' fees

The total amount of auditors' fees paid over the year is €168,600 excluding taxes and disbursements and breaks down as follows:
- fees for the statutory audit of the financial statements and the services provided for by law: €68,600;
- fees for consultancy and services other than the certification of accounts: €100,000. These services concerned exclusively the issuance of two reports as part of the capital increase of December 2017.

Type	December 31, 2017	December 31, 2016
Extraordinary income		
- Property disposal		
- Disposal of own shares	59,740	41,415
Total	59,740	41,415
Extraordinary expenses		
- Property disposal		
- Disposal of own shares	105,513	114,721
- Fines and penalties	9,869	2,064
Total	**115,382**	**116,785**

The extraordinary income results mainly from the sale of own shares under the liquidity contract.

- Information on associates

The following income statement items include sums in connection with associates:

Other purchases and external expenditure	765,373

3.2.2.6 FINANCIAL COMMITMENTS AND OTHER INFORMATION

- Financial commitments

Commitments made

The total value of orders signed by the Company as at the end of the period for items not yet delivered or built came to €14,331,617.

Repayable advances totaling €13,056,577 have been received at the end of the fiscal 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 held shareholdings of 6.08% and 14.79% respectively as at December 31, 2017. 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 and ending upon expiry of the patents shown in Annex 1 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 Indice du Prix à la Production de l'Industrie des Services aux Entreprises - Matériel médicochirurgical et d'orthopédie-exportation zone euro [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, 2017, since the marketing of the CARMAT Artificial Heart had not started, no royalty had been paid by the Company under the agreement.

Commitments received

The Bpifrance agreement provides for payment of a total sum of €17,442,639 by way of subsidies, all of which were received at the end of the financial year

The agreement also provides for payment of a total sum of €14,507,324 by way of repayable advances, of which €1,450,732 remains to be paid between now and the end of the program.

Pension and retirement commitments

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

In accordance with the preferential method, the provision for retirement commitments has been booked as at December 31, 2017.

The calculation assumptions made were as follows:
- time-apportioned rights method in accordance with Regulation 2003 R-01 of the CNC;
- 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 1.30% per annum (as against the rate of 1.31% used as at December 31, 2016 and 1.67% as at June 30, 2017).

The overall amount of the provision was €274,654 at the end of the period, an increase of €81,441 on the previous period.

- Other information

Information on the management

ADVANCES AND LOANS TO MANAGEMENT

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

MANAGEMENT REMUNERATION

The total remuneration paid to directors in the form of directors' fees amounted to €61,972 for the year (sums recorded in the income statement under Other expenses).

The total remuneration allocated to members of the management bodies was €625,375 for the year and breaks down as follows:

Type	2017	2016
Gross salaries	460,314	764,079
Benefits in kind	9,062	123,970
Bonuses	156,000	257,748
Total remuneration	**625,375**	**1,145,797**

Increases and reductions in future tax liabilities

Type of temporary differences	Value
Allowable loss carry-forwards	177,648,794

This amount comprises:

- the tax loss carried forward made during previous periods and available as at January 1, 2017, in the sum of €142,746,916;

- the tax loss made in the 2017 fiscal year in the sum of €34,901,878.

Average staffing levels

Salaried staff	2017	2016
Managers	48	42
Supervisors and technicians	13 **	6
Employees	9 *	8 *
Total	**70**	**56**

* : including two trainees

** : including five trainees

3.3 AUDITORS' REPORT ON THE 2017 FINANCIAL STATEMENTS

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

OPINION

In execution of the mission entrusted to us by your general meeting, we have audited the financial statements of CARMAT for the year ended December 31, 2017, as attached to this report.

We certify that the annual accounts are, in the light of French accounting rules and principles, fair and accurate and give a true and fair view of the results of the operations of the past financial year and the financial position and assets of the company at the end of the year.

FOUNDATION OF THE OPINION

Auditing framework

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

Our responsibilities under these standards are set out in the «Auditors' Responsibilities for Auditing the Annual Accounts» section of this report.

Independence

We carried out our audit mission in accordance with the independence rules applicable to us, from January 1, 2017 to the date of our report, and in particular we did not provide services prohibited by the code of ethics of the profession of auditor.

JUSTIFICATION OF OUR ASSESSMENTS

Pursuant to the provisions of Articles L. 823-9 and R.823-7 of the French Commercial Code relating to the justification of our assessments, we inform you that the most important assessments that we have made, in our professional judgment, have the appropriateness of the accounting principles applied and the reasonableness of the significant estimates used and the overall presentation of the accounts.

The assessments thus made fall within the context of the audit of the annual financial statements taken as a whole and the formation of our opinion expressed above. We do not express an opinion on items in these separate annual accounts.

VERIFICATION OF THE MANAGEMENT REPORT AND OTHER DOCUMENTS ADDRESSED TO SHAREHOLDERS

In accordance with the professional standards applicable in France, we have also performed the specific verifications required by law.

Information provided in the management report and other documents sent to shareholders on the financial position and the annual accounts

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

Corporate governance information

We certify the existence, in the section of the management report of the Board of Directors devoted to corporate governance, of the information required by Article L.225-37-4 of the French Commercial Code.

Other information

In application of the law, we made sure that the various information relating to the identity of the owners of the capital or the voting rights were communicated to you in the report of management.

RESPONSIBILITIES OF THE MANAGEMENT AND THE PERSONS CONSTITUTING CORPORATE GOVERNANCE RELATING TO THE ANNUAL ACCOUNTS

It is the responsibility of the Management to prepare annual accounts presenting a true and fair view in accordance with French accounting rules and principles and to set up the internal control that it deems necessary for the preparation of annual accounts that do not contain any significant anomalies, that they come from fraud or result from errors.

When preparing the annual accounts, it is the responsibility of Management to evaluate the ability of the Company to continue operating, to present in these accounts, as the case may be, the necessary information relating to the continuity of operations and operations. apply the going concern accounting policy unless it is intended to wind up the company or cease its business.

The annual accounts have been adopted by the Board of Directors.

RESPONSIBILITIES OF THE AUDITORS RELATING TO THE AUDIT OF THE ANNUAL ACCOUNTS

It is our responsibility to prepare a report on the annual accounts. Our objective is to obtain reasonable assurance that the financial statements taken as a whole do not contain any material misstatements. Reasonable assurance corresponds to a high level of assurance, but does not guarantee that an audit performed in accordance with the standards of professional practice can systematically detect any significant anomaly. Anomalies may arise from fraud or error and are considered significant where it can reasonably be expected that they, taken individually or cumulatively, may influence the economic decisions that account users take in their business. based on these.

As specified by Article L.823-10-1 of the French Commercial Code, our mission of certification of accounts is not to guarantee the viability or the quality of the management of your company.

As part of an audit conducted in accordance with the professional standards applicable in France, the statutory auditor exercises his professional judgment throughout this audit.

In addition :

- it identifies and assesses the risks that the annual accounts contain material misstatements, whether due to fraud or error, defines and implements audit procedures to address such risks, and collects considers it sufficient and appropriate to base its opinion. The risk of not detecting a significant anomaly from fraud is higher than that of a significant misstatement resulting from an error, as the fraud may involve collusion, falsification, voluntary omissions, misrepresentation or circumventing internal control;

- it becomes aware of the internal control relevant to the audit in order to define appropriate audit procedures in the circumstances, and not to express an opinion on the effectiveness of the internal control;

- it assesses the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as the information concerning them provided in the annual accounts;

- it assesses the appropriateness of management's application of the going concern accounting policy and, depending on the elements collected, the existence or otherwise of significant uncertainty related to events or circumstances likely to causes the company's ability to continue as a going concern. This assessment is based on the information gathered up to the date of its report, but it is recalled that subsequent circumstances or events could jeopardize the continuity of operations. If it concludes that there is significant uncertainty, it draws the attention of the readers of its report to the information provided in the annual accounts about this uncertainty or, if this information is not provided or is not relevant, it formulates a qualified certification or a refusal to certify;

- it assesses the overall presentation of the annual accounts and assesses whether the annual accounts reflect the underlying transactions and events so as to give a true and fair view.

Signed in Neuilly-sur-Seine and Paris,
Tuesday, March 20, 2018,

The statutory auditors

PRICEWATERHOUSCOOPERS AUDIT	LISON CHOURAKI AUDIT
THIERRY CHARRON	LISON CHOURAKI

4

CORPORATE GOVERNANCE

4.1 COMPOSITION OF THE COMPANY'S ADMINISTRATIVE AND MANAGEMENT BODIES

4.1.1 COMPOSITION OF THE BOARD OF DIRECTORS

The shareholders' meeting of April 27, 2017 approved the cooptation of two cardiology experts as independent board members:

- Mr. Jean-Luc Lemercier, Vice-President Transcatheter Heart Valve EMEA with US group Edwards Lifesciences;
- Dr. Michael Mack, an internationally recognized US cardiac surgeon and current Director of Cardiovascular Research at the Baylor Scott & White Health group in Dallas (Texas).

In addition, the same general meeting decided to appoint Stéphane Piat, Chief Executive Officer of CARMAT since August 29, 2016, as a director.

The board of directors now consists of 9 members, 4 of them being independent.

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

Full name or registered name of the member	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Other positions and functions in other companies over the last five years, but not exercised at the date of this registration document
Mr. Jean-Claude Cadudal	First appointed (under SA form): May 7, 2010 Term of office: Until GM to approve the accounts for year ending December 31, 2021	Chairman of the board of directors	- Chairman of Kardiozis SAS - Chairman of Holding Incubatrice Medical Devices - Chairman of Epigon SAS	None
Mr. Stéphane Piat	First appointed: April 27, 2017 Term of office: Until GM to approve the accounts for year ending December 31, 2021	Chief Executive Officer Member of the Board of Directors	Board member of Triflo Cardiovascular Inc.	Division vice-president, Global Market Development, at Structural Heart Division - Abbott Vascular - San Francisco
Matra Défense **Represented by Ms Anne-Pascale Guédon**	First appointed (under SA form): March 20, 2015 Term of office: Until GM to approve the accounts for year ending December 31, 2021	Director	None	None

Full name or registered name of the member	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Other positions and functions in other companies over the last five years, but not exercised at the date of this registration document
Professor Alain Carpentier	First appointed (under SA form): May 7, 2010 Term of office: Until GM to approve the accounts for year ending December 31, 2021	Director	- Chairman of the Scientific Council of the Fondation Lefoulon-Delalande (Institut de France) - Member of the board of directors of the Fondation Singer Polignac - Director of the Scientific Research Association of the Alain Carpentier Foundation (ARSFAC)	- Former chairman of the Academy of Sciences
Mr. Henri Lachmann	First appointed (under SA form): December 23, 2010 Term of office: Until GM to approve the accounts for year ending December 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) (an association under the law of 1901) - Chairman of the Institut Télémaque (an association under the law of 1901) - Director of the Fondation Entreprendre - Chairman of the campaign committee of the Strasbourg University Foundation	- Chairman of the supervisory board of Schneider Electric SA* - 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 (an association under the law of 1901)
Truffle Capital **Represented by Dr Philippe Pouletty**	First appointed (under SA form): May 7, 2010 Term of office: Until GM to approve the accounts for year ending December 31, 2021	Director	<u>In a personal capacity:</u> - Chairman of the board of directors of Abivax SA* - Director at Deinove SA* - Manager at Nakostech SARL - Chief executive and director of Truffle Capital - Honorary chairman and director of France Biotech (an association under the law of 1901) <u>As representative of Truffle Capital:</u> - Director at Vexim SA* - Director at Biokinesis SAS - Director at Pharnext SAS - Director at Myopowers SA (Switzerland)	- Chairman of the board of directors from November 2010 to May 2012: Theradiag SA* - Chairman from 2001 to 2009 of France Biotech - Director of Neovacs SA* until 2014 - Chairman and director of Splicos SAS until 2013 - Director of Wittycell SAS until 2013 - Director at Plasmaprime SAS until 2015 - Director at Immune Targeting Systems Ltd (UK) until 2015 - Director at Altimmune, Inc. (United States) until December 2016
Santé Holdings SRL **Represented by Mr. Antonino Ligresti**	First appointed: April 12, 2016 Term of office: Until GM to approve the accounts for year ending December 31, 2021	Director	- Sole shareholder of Immobiliare Cosio SRL, Iniziative Immobiliari Due SRL and Iniziative Immobiliari Tre SRL	None

Full name or registered name of the member	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Other positions and functions in other companies over the last five years, but not exercised at the date of this registration document
Mr. Jean-Luc Lemercier	First appointed: January 2, 2017 Term of office: Until GM to approve the accounts for year ending December 31, 2021	Independent director	Corporate officer Edwards Lifesciences	None
Dr Michael Mack	First appointed: January 2, 2017 Term of office: Until GM to approve the accounts for year ending December 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 years;
- 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.

4.1.2 BACKGROUNDS OF THE MEMBERS OF THE BOARD OF DIRECTORS

ANNE-PASCALE GUEDON

Anne-Pascale Guédon has more than 25 years' experience in investment and M&A. She held a number of executive positions at leading French companies such as Bouygues, Loxam and Crédit Agricole and international firms including GE Capital and Man Group before joining Airbus. Since 2008, she has been Vice President Financial Engineering at Airbus Group, where she is responsible for managing funds to invest worldwide through joint ventures and acquisitions.

Ms Guédon graduated from HEC business school and the French society of financial analysts (SFAF). She is also an auditor of the 64th national session of the National Institute for Defence Studies (IHEDN) and is a colonel in the French Air Force reserves.

JEAN-CLAUDE CADUDAL

Jean-Claude Cadudal began his career in the design and development departments of nuclear power stations before switching to industrial management at ITT, where he received the Production & Inventory Control Worldwide Award in 1979.

After a spell in the Operations Department at Revlon Europe, he returned to Matra in 1983, where he handled Matra's main mergers & acquisitions. He later served as Director of International Operations at the EADS Group (now Airbus) until early 2008. Mr Cadudal was also Chairman of Matra Défense, Financial Controller at MBDA and was the Carmat programme director.

PROFESSOR ALAIN CARPENTIER

Professor Emeritus at Descartes University in Paris and adjunct professor at Mount Sinai Medical School in New York, Alain Carpentier has made decisive contributions to

the field of surgery for heart valves and heart failure. He is considered by many in the international community to be the founding father of modern valve surgery, after breaking with the traditional use of mechanical prostheses to develop biological and physiological solutions to problems related to heart valve replacement.

He was awarded the Grand Prize by the French Foundation for Medical Research and in 2007 received the prestigious Albert Lasker Medical Research Award for the invention of bioprostheses and the development of plastic/reconstructive surgery for heart valves.

Professor Carpentier also holds a range of responsibilities as Chairman of the Scientific Committee at Fondation Lefoulon-Delalande Institut de France, Member of the Board at Fondation Singer Polignac, and Director of the Alain Carpentier Foundation Scientific Research Association (ARSFAC).

DR PHILIPPE POULETTY

Dr Philippe Pouletty is a pioneer in biotechnology and medical devices. He founded SangStat in 1988, a company specialising in organ transplant therapy, listed on the NASDAQ, then Conjuchem in 1993, a biotech firm specialised 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 specialising 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 has been Chairman of Schneider's Supervisory Board since 2006.

Mr Lachmann graduated from HEC business school and is a qualified chartered accountant. He sits on the board at a number of companies, including responsibilities as Vice Chairman of the Supervisory Board at Vivendi, member of the Supervisory Board at Norbert Dentressangle, member of the board at AXA Mutuelles, Chairman of the Board at Centre Chirurgical Marie Lannelongue, Chairman of the Foundation for Continental Law, Chairman of Institut Télémaque, non-voting Director at Fimalac, member of the board at Fondation Entreprendre, Chairman of the Advisory Board of Campus d'Excellence at the Commissariat Général à l'Investissement (Grand Emprunt), Vice Chairman and Treasurer for Institut Montaigne, and member of the Steering Committee for Institut de l'Entreprise.

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, specialising in cardiology and internal medicine.

JEAN-LUC LEMERCIER

Jean-Luc Lemercier draws on more than 20 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 2008, 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 cardiac surgeon with extensive experience in the introduction of medical devices and innovative procedures for cardiovascular disease. He has authored more than 500 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.

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.

BENOÎT DE LA MOTTE

Benoît de la Motte has a broad experience in financial management of mid-sized industrial companies, and leadership of financing, strategic and transformation projects. He joined Carmat as Chief Financial Officer in April 2015.

Benoît de la Motte started his career as an auditor at pwc in 1989. He became Finance Manager for mid-sized subsidiaries and divisions of large European and American companies (Thales / Daimler Benz Aerospace – Thales / Siemens, and Diebold). He was then appointed CFO of Nexeya in 2008, a highly entrepreneurial public company in the engineering industry, leading several build up, strategic and transformation projects.

Benoît de la Motte is a graduate of EM Lyon business school, he holds an MBA in Corporate Financial Management from Pace University in New York and is a French certified public accountant.

MARC GRIMME

Since 1996, Marc Grimmé has been the technical lead on the programme 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).

JOËLLE MONNIER

Joëlle Monnier-Roulé joined Carmat in April 2009 after 20 years in the medical device industry.

She began her career in 1987 as a medical representative for the French pharma company Synthélabo. She was appointed Product Manager at Laboratoires Sérozym two years later, and in 1991 became Marketing Coordinator for DePuy Synthes, a Johnson & Johnson company specialising in medical device industry, where she was responsible for clinical trials and regulatory matters. In 1998, she joined Implants Service Orthopédie, where she worked for nine years and held a number of positions including Site Manager, Quality Manager and R&D Manager. In 2008, she became a consultant for Iris Conseil Santé, part of the IMPE Group.

Ms Monnier-Roulé graduated General medical practice from Rennes University and in Epidemiology from Pierre & Marie Curie University (UPMC) in Paris.

WENZEL HURTAK

Wenzel Hurtak is a seasoned medical device professional with a strong and broad expertise in R&D and manufacturing. engineering Graduate in Physics and Materials Science from the University of Groningen (The Netherlands), he has spent most of his career in Life Sciences companies such as Cordis / Johnson & Johnson where he held several management positions in manufacturing and process engineering as well as Advanced R&D. In 2004, he joined Integra LifeSciences Corporation, a world leader in Neurosurgery and Orthopaedics, where he became Vice President of European Operations. In that role, he was responsible for 5 manufacturing facilities across Europe and contributed to the development of over 10 products.

Prior to joining CARMAT, Wenzel Hurtak was Business Director for new products at Contract Medical International GmbH, a leader in product development for minimally invasive devices in cardiology and various other applications.

FRANCESCO ARECCHI

A marketing professional with strong experience in global leading companies within the healthcare industry, Francesco Arecchi joins Carmat in September 2017. Francesco Arecchi spent most of his career in Life Sciences companies such as Johnson & Johnson and Abbott, where he holds a number of positions from sales to marketing in Cardiology breakthrough technology products such as Cypher and MitraClip.

Prior to joining Carmat, he stood as Product Manager EMEA Structural Heart at Abbott. Francesco Arecchi is a biomedical engineer and graduated from Politecnico di Milano (Italy) with an MBA from Rotterdam School of Management (Netherlands).

RAOUIA BOUYANZER

Raouia dispose de près de 16 ans d'expérience dans le domaine de la paie et des ressources humaines. Elle a débuté sa carrière dans un cabinet d'expertise comptable en 1998. En 2001, Raouia intègre Morgan Stanley, où elle occupera pendant plus de 9 ans plusieurs positions dans le contrôle de gestion sociale, la paie et les ressources humaines. Raouia a rejoint CARMAT au stade de "développement" de la société en février 2011 sur un poste de Responsable Administratif et Financier, et a mis en œuvre dès 2012 une politique de ressources humaines.

Raouia est titulaire d'un Master RH de l'ESSEC Business School et détient un diplôme d'expertise comptable et financière (2001).

4.2 CONFLICTS OF INTEREST IN THE GOVERNING, MANAGEMENT AND SUPERVISORY BODIES AND THE EXECUTIVE BOARD

4.2.1 POTENTIAL CONFLICTS OF INTEREST

At the date of this 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 members of the board of directors of the Company 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 towards the Company and their private interests and/or other duties.

As at the date of this registration document, there were no service contracts linking the members of the board of

directors and the general management of the Company.

4.2.2 COMMITMENTS OF THE DIRECTORS AND EXECUTIVE MEMBERS TO PRESERVE SHAREHOLDINGS

Historically, there was no commitment of the directors and executive members to preserve shareholdings.

As part of the investment protocol signed on February 26, 2016, in connection with the Company's €50 million private placement, investors (ALIAD (Air Liquide), Cornovum, Babalia and Santé Holdings SRL) and shareholders (Matra Défense (Airbus Group), the funds managed by Truffle Capital, Professor Alain Carpentier and the Scientific Research Association of the Alain Carpentier Foundation) have undertaken not to sell their shares of the Company (shares held on that date as well as those subscribed in the context of the private placement), directly or indirectly, except with the prior consent of the investors and historical shareholders, until the earliest of the following two dates: (i) 2 years from the settlement-delivery of the reserved capital increase (ie April 28, 2018) and (ii) the date of the CE marking of the CARMAT heart.

It should nevertheless be noted that this commitment does not apply to the investment funds FCPI UFF Innovation 5 and FCPI Europe Innovation 2006 managed by Truffle Capital, whose sale of CARMAT securities would be necessary to enable them to meet their regulatory liquidity obligations (these funds hold respectively 35,318 shares and 175,272 shares as at December 31, 2017).

4.3 SPECIALIZED COMMITTEES

As at the date of this registration document, the Company had set up the following committees:

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. As at the date of this registration document, the audit committee comprises three members:

- Jean-Claude Cadudal, chairman of the board of directors and member of the audit committee;
- Henri Lachmann, independent director and member of the audit committee;
- Matra Defense, represented by Ms Anne-Pascale Guédon, director and member of the audit committee.

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 assume the 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:

  - reviewing the assumptions used for the preparation of the annual financial statements of the Company and the half-yearly and, where applicable, quarterly accounts before their examination by the Board of Directors, 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 accounts, the adequacy of the accounting principles and methods used, the effectiveness of the accounting control procedures and any other appropriate matters;

- issuing a recommendation on the auditors proposed for appointment by the shareholders' meeting and to review the terms of their remuneration;

- 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 its proper application;
  - authorize the use of auditors for work other than auditing;

  - examine the conditions of use of derivatives;

  - execute periodic review of the status of significant litigation;

- review the Company's procedures for the receipt, retention and treatment of claims relating to internal accounting and accounting 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 financial year 2017, the Audit Committee met twice, in particular to review the financial statements prepared for the financial year 2016 and to review the semi annual financial statements for HY 2017. The Committee also met on February 5, 2018 to review the annual accounts prepared for the 2017 financial year.

4.3.2 APPOINTMENTS AND COMPENSATION COMMITTEE

The Company has established an appointments and compensation committee which as at the date of this registration document is comprised of two members, appointed by the board of directors at its meeting on April 22, 2009 for an unlimited term:

- Truffle Capital, represented by Dr Philippe Pouletty, director and chairman of the appointment and compensation committee;
- Matra Defense, represented by Ms Anne-Pascale Guédon, director and member of the appointment and compensation committee.

The main objectives of the appointments and compensation committee are:

- to recommend to the Board of Directors the persons who should be appointed to the general management, the board of directors and the main functions of the Company, as the case may be;
- review the remuneration policies for managers and high-potential staff within CARMAT, propose the remuneration of the officers 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 BOARDS OF OBSERVERS

Article 17-VI of the Articles of Association gives the ordinary general 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 general meeting of shareholders called to decide on the accounts 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 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 duty within the Company ofadvice and monitoring. 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 registration document, no observer has been appointed.

4.4 STATEMENT ON CORPORATE GOVERNANCE

4.4.1 CORPORATE GOVERNANCE

The Company is refering to the recommendations of the code of corporate governance for quoted companies issued by the AFEP-MEDEF in December 2008, 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 code of corporate governance for quoted companies issued by the AFEP-MEDEF. The principal recommendations not applied are as follows:

Exclusions	Reasons
Assessment of the board of directors	There is no formal system to measure the individual contribution of each director. 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.
Term of office of directors	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. Reason: When the Company was established, it was deemed that a longer term would ensure the stability of the Company's governance.
Composition of the appointments and compensation committee	There are no independent directors on the compensation committee. Reason: Taking into account the size of the Company, the number of compensation committee members has been capped at two.
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 of feminization.
Conclusion of a non-competition agreement with corporate officers	To the extent that the contracts concluded between the Company and its employees do not include non-competition 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.

Apart from setting up the board of auditors, the appointments and compensation committee and the scientific committees mentioned in Paragraph 4.3 « Specialized committees », and in order to meet the standards of corporate governance that the Company has set itself, the elements described below have now been put in place.

4.4.2 BYLAWS

In 2011, the board of directors adopted bylaws, 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 rules were reviewed during 2016 year.

In addition to respecting the legal, regulatory and statutory provisions applicable to the Board, the Board of Directors:

- determine the orientations of the Company's activity and ensure their implementation. Subject to the capabilities expressly granted by shareholders' meetings and within the scope of the Company's purpose, it shall consider any matter affecting the proper functioning of the Company and shall, by its deliberations, resolve matters affecting it,
- appoint the chairman of the Board, the chief executive officer and the deputy chief executive officers, determine their duties and determine their remuneration,
- authorize the agreements and commitments referred to in Articles L.225-38 and followings of the Commercial Code,
- authorize the decisions and commitments listed in the Annex to the Rules of Procedure. It ensures the quality of information provided to shareholders and the markets.

4.4.3 SEPARATION OF THE MANDATES OF THE CHAIRMAN OF THE BOARD OF DIRECTORS AND THE CHIEF EXECUTIVE

When the Company converted to a société anonyme, the board of directors opted for a dissociation of the mandates of the chairman of the board of directors and of the chief executive.

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) defining the strategic, economic, social, financial and scientific orientations of 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 merger 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;

(l) the hiring, firing and alteration of employment contracts

(including the remuneration) of any employee who has an executive function (ie medical director, director of operations, sales manager and administrative director and financial director);

(m) selection of advisers and intermediaries in strategic decision-making and remuneration;

C. Regulated agreements and related party agreements (approval and annual review of contracts in progress);

D. Titles:

(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 general meeting of shareholders 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. Remuneration and profit-sharing of officers in respect of their mandate or employment contract (including any stock option plans, bonus shares or other similar arrangements) on the proposal of the appointments and compensation committee;

I. Appointment and dismissal of the officers, the administrative and financial director, the scientific director and the medical director;

J. Decision of commitment or transaction relating to a dispute of more than two hundred and fifty thousand euros (250,000 €);

K. Site closure; adoption of a plan to safeguard employment;

L. Appointment of statutory auditors and substitutes;

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; and

N. Granting of guarantees, endorsements or guarantees for the benefit of third parties (including for the benefit of a subsidiary) or granting of security rights to guarantee debts of the Company,

being specified that:

- one of the aforementioned decisions that would have been foreseen within the annual budget in a precise manner will not have to be approved again when it is implemented; and

- decisions A to E shall be adopted by a majority of (i) half of the directors on first notice and (ii) one - 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 the general management, please refer to Paragraph 5.4.2 « Provisions of the articles, a charter or a regulation of the Company regarding members of the board of directors and of the general management ».

4.4.4 INDEPENDENT DIRECTORS

The Company has four independent directors: Henri Lachmann, Jean-Luc Lemercier and Michael Mack, and the company Santé Holding 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 2013), that is:

- not be or have been in the past five years:

  - employee or director of the Company (the chairman of the Board may be considered as independent if the Company justifies it) or of a group company,

  - director of another company in which the Company directly or indirectly holds a mandate or in which an employee or a director of the Company (present or having been less than five years) holds a mandate;

- 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 twelve years;

- not to be a reference shareholder of the Company or of its parent company exercising control or 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.

4.4.5 INTERNAL CONTROL

At the date of this registration document, the Company had internal control procedures, in particular in the administrative, accounting, and financial areas, with a view to implementing its strategic policies. The Company's audit committee reviews all the procedures annually.

Following the new 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 now, like companies listed on a regulated market, establish and maintain the list of persons who have access to privileged information concerning them.

CARMAT has therefore put in place a code of ethics in order to sensitize all the company's managers and employees, third parties having access to privileged information as well as the persons with whom they are in 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 was previously revised by the Audit Committee.

4.5 COMPENSATION AND BENEFITS OF DIRECTORS AND MANAGEMENT

4.5.1 COMPENSATION AND BENEFITS IN KIND GRANTED TO MANAGERS AND DIRECTORS

Summary table of compensation and options, warrants and bonus shares awarded to each executive officer (in euros):

As a reminder, at the Board meeting of August 29, 2016, due to the evolution of the CARMAT's development period, with a new phase of development, notably with a view to commercializing its bioprosthesis, the Board of Directors decided to appoint Stéphane Piat as chief executive officer to replace Marcello Conviti, who in this context left office.

Jean Claude Cadudal - Chairman of the Board of Directors	FY 2016	FY 2017
Annual compensation	123,318	63,001
Value of options and warrants awarded during the FY	-	-
Value of bonus shares awarded for the FY	-	-
TOTAL	123,318	63,001

Marcello Conviti - Chief executive officer	FY 2016	FY 2017
Annual compensation *	655,752	-
Value of options and warrants awarded during the FY	-	-
Value of bonus shares awarded for the FY	-	-
TOTAL	655,752	-

* : Excluding benefits in kind

Stéphane Piat - Chief executive officer	FY 2016	FY 2017
Annual compensation *	136,857	553,313
Value of options and warrants awarded during the FY	-	-
Value of bonus shares awarded for the FY **	-	2,316,313
TOTAL	136,857	2,869,626

* : excluding benefits in kind
** : free shares granted during the financial year are subject to performance conditions. Their value as at December 31, 2017 corresponds to the estimate done by the company, given the probability of the criteria being met. The valuation assumptions are specified in the note Provision for expenses in the annex to the annual accounts

Summary table of the compensation of each executive officer (in euros):

Jean Claude Cadudal - Chairman of the Board of Directors	FY 2016		FY 2017	
	Amounts due *	Amounts paid **	Amounts due *	Amounts paid **
Fixed remuneration	-	-	-	-
Variable remuneration	-	-	-	-
Special remuneration	60,000	60,000	-	-
Directors' fees	63,318 ***	63,318 ***	63,001 ***	63,001 ***
Benefits in kind	-	-	-	-
TOTAL	123,318	123,318	63,001	63,001

* : For the financial year.
** : During the financial year, in respect of the previous year.
*** : At the meeting of December 19, 2013, the board decided that, to comply with the applicable regulations, the remuneration of its chairman would be treated for tax and social security purposes as wages. This amount was raised to €63,318 in 2016 and to €63,001 in 2017.

Marcello Conviti - Chief executive officer until August 29, 2016	FY 2016		FY 2017	
	Amounts due *	Amounts paid **	Amounts due *	Amounts paid **
Fixed remuneration	240,676	240,676	-	-
Variable remuneration	157,519	157,519	-	-
Special remuneration	257,557	257,557	-	-
Directors' fees	-	-	-	-
Benefits in kind	52,035	52,035	-	-
TOTAL	707,787	707,787	-	-

* : For the financial year.
** : During the financial year, in respect of the previous year.

Stéphane Piat - Chief executive officer from August 29, 2016	FY 2016		FY 2017	
	Amounts due *	Amounts paid **	Amounts due *	Amounts paid **
Fixed remuneration	136,857	136,857	397,313	397,313
Variable remuneration	58,500	-	179,888	156,000
Special remuneration	-	-	-	-
Directors' fees	-	-	-	-
Benefits in kind	70,903	70,903	9,062	9,062
TOTAL	266,260	207,759	586,263	562,375

* : For the financial year.
** : During the financial year, in respect of the previous year.

Directors' fees and other compensation allocated to non-executive officers during the years ended December 31, 2016 and 2017

	FY 2016	FY 2017
Professor Alain Carpentier - Director *		
Director's fees	5,000	5,000
Other compensation	-	-
Philippe Pouletty, representing Truffle Capital - Director *		
Director's fees	5,000	5,000
Other compensation	-	-
Anne Pascale Guedon, representing Airbus Group - Director		
Director's fees	5,000	5,000
Other compensation	-	-
Stéphane Piat - Director		
Director's fees	-	-
Other compensation	-	-
Jean Claude Cadudal - Chairman of the board		
Director's fees	63,318	63,001
Other compensation	-	-
Henri Lachmann - Director **		
Director's fees	10,000	7,500
Other compensation	-	-
Antonino Ligresti, representing Santé Holding SRL - Director		
Director's fees	3,500	5,000
Other compensation	-	-
Jean Luc Lemercier - Director		
Director's fees	-	10,000
Other compensation	-	-
Michael Mack - Director		
Director's fees	-	24,960
Other compensation	-	-

* : At the board meeting of February 28, 2013, the remuneration of Mr Carpentier and Truffle Capital, equivalent to that for the 2011 financial year, was confirmed for the 2012 financial year and is maintained for the following financial years until the board decides otherwise.

** : At the board meeting of February 28, 2013, the remuneration of Messrs. Ballester, Finance and Lachmann, equivalent to that for the 2011 financial year, was confirmed for the 2012 financial year and is maintained for the following financial years until the board decides otherwise.

Share subscription or share purchase options awarded to each executive officer during the years ended December 31, 2015 and 2016

Not applicable (the Company has never awarded options).

However, the Company has awarded share subscription warrants and start-up company stock warrants (see Paragraph 5.2.5).

Share subscription or share purchase options exercised by each executive officer during the years ended December 31, 2015 and 2016

The Company has never awarded options.

Free shares awarded to each executive officer during the years ended December 31, 2016 and 2017

As detailed in Section 5.2.1 of this registration document, the general meeting of April 27, 2017 decided to introduce within Article 12.2 of the Articles of Association of the Company three new preferential share classes respectively named « AGAP 2017-01 », « AGAP 2017-02 » and « AGAP 2017-03 » (hereinafter together referred to as the « Preferential Shares »), the board of directors of the Company, making use of the delegations of authority approved at the general meeting of April 27, 2017, awarded free of charge on May 15, 2017:

- 270 AGAP 2017-01, including 180 AGAP 2017-01 to Stéphane Piat (Managing Director and Director),
- 1,800 AGAP 2017-02, including 1,000 AGAP 2017-02 to Stéphane Piat (Managing Director and Director), and
- 3,180 AGAP 2017-03, including 1,720 AGAP 2017-03 to Stéphane Piat (Managing Director and Director).

If all the performance criteria are met, the beneficiaries of the aforementioned allocation of 5,250 Preferential Shares could convert them into a maximum of 381,000 ordinary shares, including 2,900 Preferential Shares convertible into a maximum of 210,000 ordinary shares held by Stéphane Piat, CEO. For information, the value of these shares, based on the closing price of the ordinary share on May 15, 2017 (ie €29.96), would be €11,414,760 and €6,291,600 respectively.

Free shares awarded to each executive officer which became freely disposable during the years ended December 31, 2015 and 2016

None.

See section 5.4.3 « Rights, privileges and restrictions attaching to shares (Articles 9 to 14 of the Articles of Association) » of the registration document, relative to the conversion rights of preferential shares into ordinary shares.

Historic table of share subscription or share purchase options awarded to executive officers

The Company has never awarded options. However, it has awarded share subscription warrants and start-up company stock warrants (see Paragraph 5.2.5).

History of options to subscribe or purchase shares granted to the top ten employees who are not officers, and options exercised by them

The Company has never awarded options. However, it has awarded share warrants and start-up company stock warrants (see Paragraph 5.2.5).

History of bonus shares awarded

The general meeting of April 27, 2017 decided to introduce within Article 12.2 of the Articles of Association of the Company three new preferential share classes respectively named « AGAP 2017-01 », « AGAP 2017-02 » and « AGAP 2017-03 », the board of directors of the Company, making use of the delegations of authority approved at the general meeting of April 27, 2017, awarded free of charge on May 15, 2017:

- 270 AGAP 2017-01, including 70 AGAP 2017-01 to Marc Grimmé (R&D Director) and 180 AGAP 2017-01 to Stéphane Piat (Managing Director and Director),
- 1,800 AGAP 2017-02, including 200 AGAP 2017-02 to Marc Grimmé (R&D Director), 400 AGAP 2017-02 to Dr. Piet Jansen (Medical Director), 1,000 AGAP 2017-02 to Stéphane Piat (Managing Director and Director) and 200 AGAP 2017-02 to Eric Richez (Director of Development), and
- 3,180 AGAP 2017-03, including 180 AGAP 2017-03 to Benoît de la Motte (Administrative and Financial Director), 280 AGAP 2017-03 to Marc Grimmé (R&D Director), 310 AGAP 2017-03 to Dr. Piet Jansen (Medical Director), 90 AGAP 2017-03 to Joëlle Monnier (Quality Director), 1,720 AGAP 2017-03 to Stéphane Piat (Managing Director and Director), 140 AGAP 2017-03 to Eric Richez (Director of Development) and 60 AGAP 2017-03 to Raouia Bouyanzer (Human Resources Manager).

The board of directors of the Company, once again making use of the delegations of authority approved at the general meeting of April 27, 2017, awarded free of charge on September 25, 2017:

- 50 AGAP 2017-01 and 200 AGAP 2017-02 to Wenzel Hurtak (Manufacturing Director), and
- 310 AGAP 2017-03, including 190 AGAP 2017-03 to Wenzel Hurtak (Manufacturing Director) and 120 AGAP

2017-03 to Francesco Arecchi (Marketing Manager).

Preferential Shares are subject to vesting and holding periods and performance criteria to enable their conversion into ordinary shares, as described in section 5.2.6 of the registration document.

Clarification regarding the terms of compensation and other benefits granted to executive officers:

The chief executive and the directors do not enjoy any particular retirement benefits, severance payments due when they leave office, or non-competition payments.

Executive officers	Employment contract		Supplementary pension scheme		Allowances or benefits due or likely to be due upon severance or change in role		Allowances connected to a non-competition clause	
	Yes	No	Yes	No	Yes	No	Yes	No
Jean-Claude Cadudal, chairman of the Board of Directors		X		X		X		X
Start date of office	May 7, 2010 (first term since conversion to a société anonyme)							
End date of office	At the end of the annual general meeting approving the financial statements for the year ending December 31, 2021							
Marcello Conviti, chief executive officer		X		X		X		X
Start date of office	May 7, 2010 (first term since conversion to a société anonyme)							
End date of office	August 29, 2016							
Stéphane Piat, chief executive officer		X		X		X		X
Start date of office	August 29, 2016							
End date of office	Indefinite period							

4.5.2 SUMS SET ASIDE OR DETERMINED BY THE COMPANY FOR THE PAYMENT OF PENSIONS, RETIREMENT OR OTHER BENEFITS FOR THE MANAGEMENT AND DIRECTORS

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

In accordance with the preferential method, the provision for retirement commitments has been accounted for as at December 31, 2017.

The calculation assumptions made were as follows:

- time-apportioned rights method in accordance with Regulation 2003 R-01 of the CNC;
- 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 1.30% per annum (as against the rate of 1.31% used as at December 31, 2016 and 1.67% as at June 30, 2017).

The overall provision for managers stands at €33,313 at the end of the period.

4.5.3 SHARE SUBSCRIPTION WARRANTS (BSA) OR START-UP COMPANY STOCK WARRANTS (BCE) ASSIGNED TO MANAGEMENT AND DIRECTORS

The following table shows all non-lapsed share subscription warrants (BSA) or start-up company stock warrants (BCE) issued by the Company to its corporate officers and managers and not exercised by the beneficiaries as at the date of this registration document: (next page)

André-Michel Ballester exercised the 468 BSA-2009-1 warrants held by him on November 8, 2016. These warrants gave rise to the issue of 11,700 new shares. Likewise, Marcello Conviti exercised the 2,800 BCE-2009-1 he held on December 12, 2016. These BCE-2009-1 resulted in the issuance of 70,000 new shares. No BSA or BCE exercise was recorded at the initiative of a director or an officer during the 2017 financial year.

Holder	BSA-2009-1	BCE-2009-1	BCE-2012-1
Jean Claude Cadudal Chairman of the Board of Directors	1,554	-	-
Marcello Conviti Chief executive officer till August 29, 2016	-	0	4,000

The exercise of each BSA-2009-1 or BCE-2009-1 entitles the holder to 25 new shares in CARMAT. The exercise of each BCE-2012-1 entitles the holder to one new share in CARMAT.

For a detailed description of BSA-2009-1, BCE-2009-1 and BCE-2012-1, please refer to Paragraph 5.2.5 « Other securities giving access to capital ».

4.5.4 STATEMENT ON SERVICE CONTRACTS

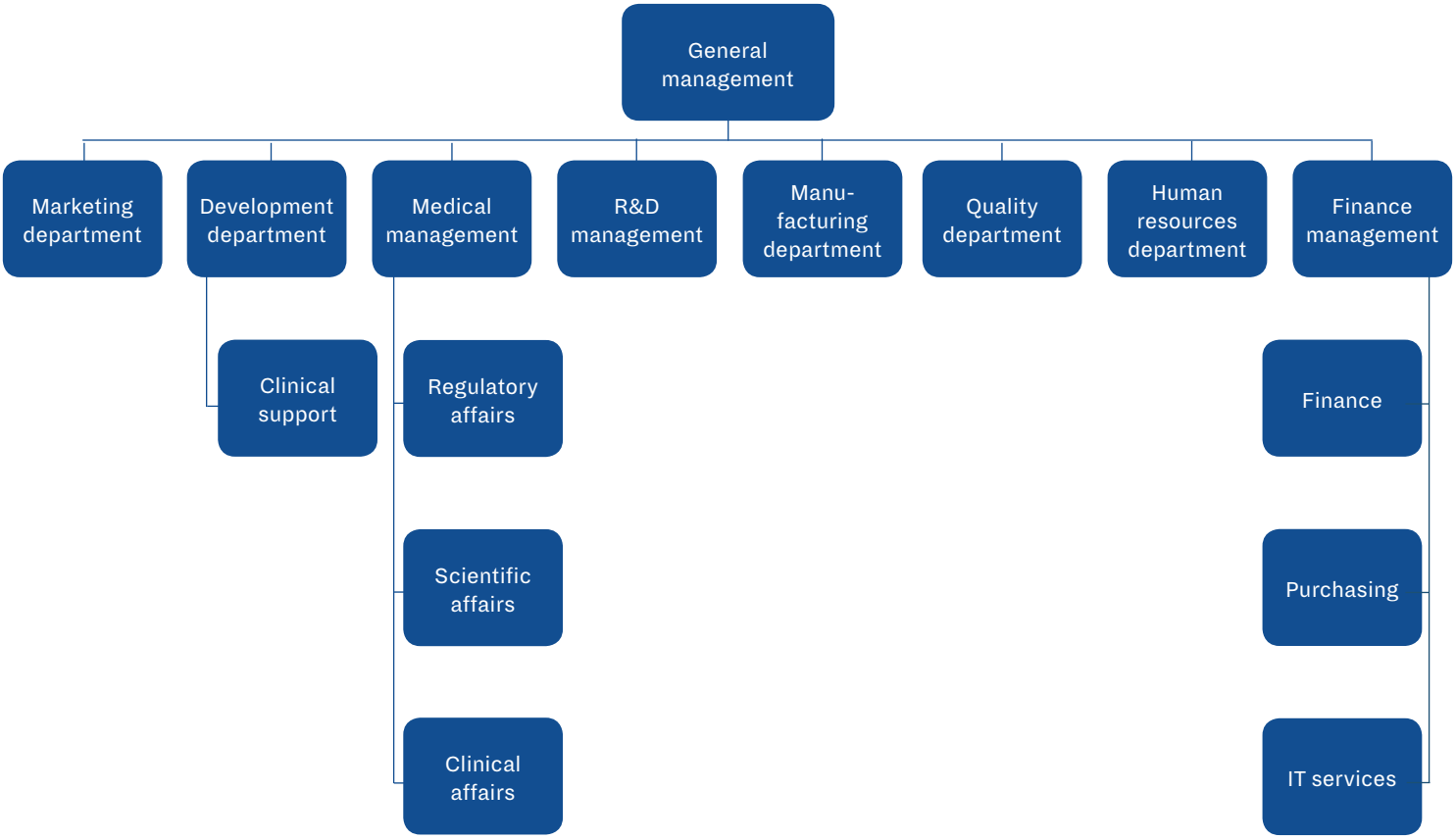
There is no service contract binding the members of the Board of Directors or management of the Company and providing for the granting of benefits under such a contract.

4.6 STAFF AND ORGANIZATION

4.6.1 HUMAN RESOURCES

OPERATIONAL STRUCTURE

As at December 31, 2017, the operational structure of the Company was as follows:



For certain stages of the development of the bioprosthetic artificial heart project, the Company uses a number of outside providers of specific services. At at December 31, 2017, 68 outside service providers work for CARMAT and are divided up as follows:

- R&D department: 33 providers;
- medical department: 7 providers;
- quality department: 12 providers;
- manufacturing department: 11 providers;
- support: 5 providers.

NUMBER AND BREAKDOWN OF STAFF

At at December 31, 2017, the Company's workforce numbered 70 people, including 7 temporary workers.

Changes in workforce at	December 31, 2017	December 31, 2016	December 31, 2015	December 31, 2014	December 31, 2013	December 31, 2012	December 31, 2011	December 31, 2010
Managers	48	42	35	35	29	30	29	25
Non-management	15	12	10	9	9	7	7	7
Trainies	7	2	3	3	2	5	-	-
TOTAL	70	56	48	47	40	42	36	32

At at December 31, 2017, all members of staff were employed under permanent employment contracts, except 7 staff under temporary employment contracts and 7 trainees. One employee is employed part-time.

HUMAN RESOURCES POLICY

Staff management is of considerable importance to the company. In fact, the Company must have qualified employees available with strong skill sets since the business of CARMAT relies to a significant extent on the quality and effectiveness of its members of staff. The company believes that it has good staff relations.

The workforce at December 31, 2017 was made up of 24 women and 39 men and included 2 doctors, 35 engineers and 7 senior graduate technicians. The average age of the salaried workforce was 40. Around 19% of the staff are aged under 30. During the 2017 fiscal year, the Company financed approximately 320 hours of training.

The company applies the National Collective Agreements of the "Metallurgical Industries: workers, employees, technicians, and supervisors" and the "Metallurgical Industries: engineers and managers", as well as the Regional Collective Agreement of the "Metallurgical Industries: workers, employees, technicians, and supervisors of the Paris Region". There are no company agreements other than the rules of procedure.

Standard contracts of employment contain no clauses relating to breach of the contract of employment or to undertakings relating to non-competition and non-solicitation (staff and/or customers).

All members of staff of the Company benefit, in addition to their basic salary, from a potential annual bonus subject to achieving quantitative and qualitative targets set in advance by the board of directors of the Company and individual targets agreed in advance with the line manager. The amount of this bonus is limited to a percentage of the gross annual salary (between 5% and 45% of the gross annual salary according to the staff or managers concerned).

The working week at the company is 35 hours for non-managers with a fixed number of days per year for managers of 218. There is no agreement on work time within the Company, but an internal memorandum concerning work time and working hour arrangements was issued on July 1, 2016 (over and above the provisions of the collective agreement applicable within the company). This memorandum in particular specifies the length of the working day (7.30 am - 8.30 pm) and sets core hours (9.15 am - 11.45 am and 1.45 pm - 4.45 pm).

The Company's workforce increased by 14 employees with 70 employees as of December 31, 2017 (including 4 temporary employees in production positions), compared to 56 (including 2 temporary employees) as at December 31, 2016. 14 hirings have been carried out since December 31, 2016, including a Manufacturing Director (Wenzel Hurtak), a Marketing Manager (Francesco Arecchi), a Clinical Affairs Manager, a Regulatory Affairs Officer, a Clinical Research Associate, two R&D Project Leaders, a Quality Engineer, a Purchasing projects and two technicians to strengthen the manufacturing management.

4.6.2 INTERESTS AND SHARE OPTIONS HELD BY MEMBERS OF THE MANAGEMENT AND SUPERVISORY BODIES, AND BY EMPLOYEES

All the share subscription warrants (BSA) and founders' stock warrants (BCE) not yet exercised or expired issued by the Company for the benefit of its corporate officers and employees are presented in the tables in section 5.2.5 « Other securities giving access to the capital » of the registration document. It is specified that the top ten non-corporate officers hold BCEs that entitle them to subscribe for a total 73,925 shares of the Company (of which 23,500 for BCE-2012-1 and 50,425 for BCE-2009-2).

In addition, the board of directors of the Company, making use of the delegations of authority approved at the general meeting of April 27, 2017, awarded free of charge on May 15, 2017 and on September 25, 2017, preferential shares for the benefit of several corporate officers and employees as detailed in section 4.5.1 « Compensation and benefits in kind of officers and directors » of the registration document.

4.6.3 EMPLOYEE OWNERSHIP AND PROFIT SHARING SCHEMES

As at the date of this registration document, the Company had not set up any employee ownership or profit sharing schemes.

5

INFORMATION ON THE COMPANY AND ITS CAPITAL

5.1 LEGAL STRUCTURE

5.1.1 REGISTERED NAME

The Company's registered name is: "CARMAT".

5.1.2 PLACE AND NUMBER OF THE COMPANY'S REGISTRATION

The Company is registered in the Versailles Trade and Companies Register under number 504 937 905.

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, subject to any extension or early dissolution.

5.1.4 REGISTERED ADDRESS, 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. The Company is a corporation (société anonyme) under French law with a single board of directors, and is governed especially by the provisions of Book II of the French Commercial Code.

5.1.5 ORGANIZATION OF THE GROUP

The Company is not part of a group.

5.1.6 SUBSIDIARIES AND SHAREHOLDINGS

The Company has no subsidiaries or shareholdings.

5.2 SHARE CAPITAL

5.2.1 VALUE OF THE SHARE CAPITAL

As at December 31, 2017, the fully paid-up share capital amounted to €360,661.76, divided into 9,016,544 shares with a par value of €0.04 each (hereinafter referred to as the « Ordinary Shares »).

The general meeting of 27 April 2017 decided (i) to delete within article 12.2 of the Company's Articles of Association two categories of preferential shares convertible into ordinary shares governed by articles L. 228-11 et seq. Code of Commerce which were known as « AGAP 2016-01 » and « AGAP 2016-02 » (it being recalled that these two categories of preferential shares were not awarded free of charge to employees and corporate officers of the Company, there has therefore been no effective issue of AGAP 2016-01 and / or AGAP 2016-02), and (ii) to introduce within Article 12.2 of the Company's Articles of Association three new classes of preferential shares respectively named « AGAP 2017-01 », « AGAP 2017-02 » and « AGAP 2017-03 » (hereinafter together referred to as the « Preferential Shares »).

On May 15, 2017, the board of directors of the Company, making use of the delegations of authority approved at the general meeting of April 27, 2017, awarded free of charge:

- 270 AGAP 2017-01,
- 1,800 AGAP 2017-02, and
- 3,180 AGAP 2017-03.

On September 25, 2017, the board of directors of the Company, making use of the delegations of authority approved at the general meeting of April 27, 2017, awarded free:

- 50 AGAP 2017-01,
- 200 AGAP 2017-02, and
- 310 AGAP 2017-03.

Preferential Shares are subject to vesting and holding periods and performance criteria to enable their conversion into Ordinary Shares, as described in section 5.2.6 of the registration document.

5.2.2 SECURITIES NOT REPRESENTING CAPITAL

As at the date of this registration document, there were no securities not representing capital.

5.2.3 PLEDGES, GUARANTEES AND COLLATERAL

As at the date of this registration document, and to the best of the Company's knowledge, there exist no pledges, guarantees or collateral taken on the Company's equity.

5.2.4 ACQUISITION BY THE COMPANY OF ITS OWN SHARES

As at December 31, 2017, the Company held 2,206 treasury shares, representing 0.02% of its share capital.

The combined general meeting of April 27, 2017, authorized the implementation by the board of directors of an 18-month program to buy back company shares, starting from 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 (AMF). The main terms of this authorization are the following:

Number of shares that can be purchased: 10% of the share capital on the date of the buyback. When shares are acquired in order to promote the trading and liquidity of shares, the number of shares taken into account to determine the 10% limit referred to above corresponds to the number of shares purchased, less the number of shares sold during the period of authorization.

Objectives of the share buyback program:

- to ensure the liquidity of the shares of the Company as part of a liquidity contract to be signed with an investment services provider, in accordance with a code of ethics recognized by the French Financial Markets Authority;
- to honor the obligations linked to stock option purchase programs, bonus share allocations, employee savings or other allocations of shares to employees and managers of the Company or affiliated companies;
- to deliver shares when the rights attached to securities giving access to capital are exercised;
- to purchase shares for keeping and later delivery or exchange or payment as part of possible acquisitions;
- more generally, to operate for any objective that would be authorized by law or any market practice that would be authorized by market authorities, with the understanding that in such an event, the Company would inform its shareholders in a press release.

Maximum purchase price: €240, excluding any fees and commissions and adjustments in order to account for capital transactions.

It is specified that the number of shares acquired by the Company to keep and later deliver as payment or in exchange as part of a merger, demerger or contribution transaction cannot exceed 5% of its capital.

Maximum amount of funds that can be used to buy back shares: €5,000,000

The shares bought back can be canceled up to a limit of 10% of the share capital every 24 month period.

5.2.5 OTHER SECURITIES GIVING ACCESS TO CAPITAL

As at December 31, 2017, the exercise or the conversion of all securities giving access to capital would allow the subscription of 943,025 new ordinary shares representing 10.46% of the current issued share capital and 9.47% of share capital after issue of these new ordinary shares.

Thus, the size of the holding of a shareholder holding 1% of the current share capital would reduce to 0.91% if the rights to all these securities were exercised.

Refer to the table below:

Type of security	Number of new ordinary shares that may be created (as at December 31, 2017)
Incentive instruments for the management and board members	
- BCE-2009-2	65,075
- BCE-2012-1	34,000
- BCE-2012-2	6,700
- BSA-2009-1	38,850
- BSA-2017-Board members	12,000
- Preferential shares	421,000
Total incentive instruments	577,525
Financing tool	
- BSA Kepler Cheuvreux Tranche 1	194,900
- BSA Kepler Cheuvreux Tranche 2	170,500
Total financing instruments	365,400

The tables below detail all the securities giving access to the issued capital of the Company, granted and in effect as at December 31, 2017, allowing the subscription of 943,025 new Ordinary Shares.

START-UP COMPANY STOCK WARRANTS (BCE)

Type of security	BCE-2009-2
Number of BCE warrants issued and allocated	7,566 *
Number of BCE warrants lapsed	1,778 *
Number of BCE warrants exercised	3,145 *
Balance of BCE warrants to be exercised	2,603 *
Date of the general meeting	July 8, 2009
Date of the meeting of the board of directors	July 8, 2009
Exercise price per new share subscribed	€8
BCE warrant exercise deadline	Ten years from the date of the allocation of the BCE warrants
Ratio	1 BCE-2009-2 warrant for 25 new CARMAT shares
General conditions of exercise	- 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/her actual and continued presence within the Company at that date; - 40% of the BCE-2009-2 warrants may be exercised per completed monthly period in tranches of 1/48th from the date of the first anniversary of the beneficiary joining the Company; - 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 on 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; - 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; - 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 heart (report from the scientific advisory committee), subject to his/her actual and continued presence within the Company at that date; - 6.5% of the BCE-2009-2 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; - 7% of the BCE-2009-2 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 the general 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	65,075

* : after adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011.

Type of security	BCE-2012-1
Number of BCE warrants issued and allocated	56,500
Number of BCE warrants lapsed	22,500
Number of BCE warrants exercised	0
Balance of BCE warrants to be exercised	34,000
Date of the general meeting	April 26, 2012
Date of the meeting of the board of directors	June 27, 2012
Exercise price per new share subscribed	€108,483
BCE warrant exercise deadline	Ten years from the date of allocation of the BCE warrants
Ratio	One BCE-2012-1 warrant for 1 new CARMAT share
General conditions of exercise	- 50% of BCE-2012-1 warrants may be exercised on the basis of monthly periods in tranches of 1/48th for a period of four years 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; - 16.25% of 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; - 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 the general 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	34,000

Type of security	BCE-2012-2
Number of BCE warrants issued and allocated	6,700
Number of BCE warrants lapsed	0
Number of BCE warrants exercised	0
Balance of BCE warrants to be exercised	6,700
Date of the general meeting	April 26, 2012
Date of the meeting of the board of directors	November 8, 2012
Exercise price per new share subscribed	€122.003
BCE warrant exercise deadline	Ten years from the date of allocation of the BCE warrants
Ratio	One BCE-2012-2 warrant for 1 new CARMAT share
General conditions of exercise	- 50% of BCE-2012-2 warrants may be exercised on the basis of monthly periods in tranches of 1/48th for a period of four years 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; - 16.25% of 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; - 16.25% of the BCE-2012-2 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-2012-2 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 the general 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	6,700

SHARE SUBSCRIPTION WARRANTS (BSA)

Type of security	BSA-2009-1
Number of BSA warrants issued and allocated	3,096 *
Number of BSA warrants lapsed	556 *
Number of BSA warrants exercised	986 *
Balance of BSA warrants to be exercised	1,554 *
Date of the general meeting	July 8, 2009
Date of the meeting of the board of directors	July 8, 2009
Exercise price per new share	€8
BSA warrant exercise deadline	Ten years from the date of allocation of the BSA warrants
Ratio	One BSA-2009-1 warrant for 25 new CARMAT shares
General conditions of exercise	- 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; - 75% of BSA-2009-1 warrants may be exercised on the basis of monthly periods in tranches of 1/36th from the date of the first anniversary of the beneficiary joining the Company over a period of three years, subject to his/her actual and continued presence within the Company at that date. 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 of 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	38,850

* : after adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011.

Type of security	BSA Kepler Cheuvreux - Tranche 1 (all exercisable by Kepler Cheuvreux)
Number of BSA warrants issued and allocated	400,000
Number of BSA warrants lapsed	0
Number of BSA warrants exercised	205,100
Balance of BSA warrants to be exercised	194,900
Date of the general meeting	April 2, 2014
Date of CEO's decision	January 23, 2015
Exercise price per new share	94% of the average volume-weighted trading price
BSA warrant exercise deadline	January 23, 2016, date extended by tacit agreement
Ratio	One Kepler BSA warrant for one new CARMAT share
Number of new shares that may be subscribed	194,900

Type of security	BSA Kepler Cheuvreux - Tranche 2 (all exercisable by Kepler Cheuvreux)
Number of BSA warrants issued and allocated	500,000
Number of BSA warrants lapsed	0
Number of BSA warrants exercised	329,500
Balance of BSA warrants to be exercised	170,500
Date of the general meeting	June 28, 2016
Date of CEO's decision	December 13, 2016
Exercise price per new share	94% of the average volume-weighted trading price
BSA warrant exercise deadline	December 13, 2017
Ratio	One Kepler BSA warrant for one new CARMAT share
Number of new shares that may be subscribed	170,500

Type of security	BSA-2017-Board members
Number of BSA warrants issued and allocated for free	12,000
Number of BSA warrants lapsed	0
Number of BSA warrants exercised	0
Balance of BSA warrants to be exercised	12,000
Date of the general meeting	April 27, 2017
Date of the meeting of the board of directors	May 15, 2017
Exercise price per new share	€30.10
BSA warrant exercise deadline	May 15, 2027
Ratio	One BSA-2017-Board members warrant for one new CARMAT share
General conditions of exercise	- up to 1,500 warrants will be exercisable from January 2, 2018; - up to 94 additional warrants will be exercisable from each month starting on January 2, 2018, ie 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

PREFERENTIAL SHARES (FREE PREFERENTIAL SHARES SUBJECT TO PERFORMANCE CRITERIA OVER A 3 YEARS PERIOD)

(see section 5.4.3 « Rights, privileges and restrictions attaching to shares (Articles 9 to 14 of the Articles of Association) » of the registration document, specifying the characteristics of Preferential Shares and conversion ratios into Ordinary Shares).

Preferential shares classes	Performance criteria	Number of preferential shares issued	Maximum conversion ratio applicable for each performance criteria	Number of common shares issuable
Class 1	Definition of the Company's industrial development plan	320	100	32,000
Class 2	Successful implantation of the bioprosthesis evaluated on 10 patients in total in the world	2,000	20	40,000
Class 3	Filing of the clinical module of the CE marking of the bioprosthesis	3,490	15	52,350
	CE marking of the bioprosthesis		20	69,800
	Obtaining additional financing for the Company for an aggregate amount, between the grant date and the convertibility date, of €100 million		25	87,250
	Implementation of a production process meeting certain criteria		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 in the world		10	34,900
	Positive development of the ordinary share price according to specific criteria		10	34,900
	Maximum number of ordinary shares that may be created, regardless of the number of performance achieved		100	349,000
	TOTAL	5,810		421,000

5.2.6 SHARE CAPITAL AUTHORIZED BUT NOT ISSUED

Shareholders' meeting of April 27, 2017

On the date of filing of this registration document, the board of directors made use of the delegations of authority voted at the general meeting of shareholders of the Company of April 27, 2017 detailed below, as follows: :

- the board of directors, making use of the delegations of authority approved at the general meeting of April 27, 2017, proceeded on May 15, 2017 to the free allocation of:

- 270 AGAP 2017-01,
- 1.800 AGAP 2017-02, and
- 3.180 AGAP 2017-03.

This same board of directors decided to issue 12,000 BSA - 2017 under the 24th resolution voted at the general meeting of April 27, 2017.
- the board of directors, again using the delegations of authority approved at the general meeting of April 27, 2017, proceeded on September 25, 2017 to the free allocation of:

- 50 AGAP 2017-01,
- 200 AGAP 2017-02, and
- 310 AGAP 2017-03.

- the board of directors, making use of the 16th resolution approved at the general meeting of April 27, 2017, decided on December 12, 2017 the issue of 2,645,000 new shares at the issue price of €20.00 each.

Resolution	Subject matter of the resolution	Maximum nominal amount in euros	Maximum nominal amount in euros	Period of authorization and expiry
15th 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 securites, with retention of preferential subscription rights	Nominal value of increases in capital: €160,000 (1) Face value of bonds and other debt instruments giving access to capital: €120,000,000 (1)	N / A	June 27, 2019 (26 months)
16th 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 capital or giving right to the allocation of debt securities, with removal of the preferential subscription right by way of a public offer (Article L.225-136)	Nominal value of increases in capital: €160,000 (1) Nominal amount of bonds and other debt instruments giving access to capital: €120,000,000 (1)	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%)	June 27, 2019 (26 months)
17th 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 capital or giving right to the allocation of debt securites, with removal of the preferential subscription rights, by offering to qualified investors or to a limited circle of investors in 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: €160,000 (1) Nominal amount of bonds and other debt instruments giving access to capital: €120,000,000 (1)	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%)	June 27, 2019 (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 15 to 19 is set at €160,000. The maximum nominal amount of debt securities which can be issued under the above delegations is set at €120,000,000.

Resolution	Subject matter of the resolution	Maximum nominal amount in euros	Maximum nominal amount in euros	Period of authorization and expiry
18th 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 preferential subscription right to categories of beneficiaries (TEPA)	Nominal value of increases in capital: €160,000 (1) Face value of bonds and other debt instruments giving access to capital: €120,000,000 (1)	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%)	October 27, 2018 (18 months)
19th 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 preferential subscription right of shareholders for the benefit of a category of beneficiaries (Article L.225-138) via an equity line financing plan	Nominal value of increases in capital: €160,000 (1) Nominal amount of bonds and other debt instruments giving access to capital: €120,000,000 (1)	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%)	October 27, 2018 (18 months)
20th 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 preferential subscription right, to set the issue price at a maximum of 10% of the share capital and within the limits determined by the board of directors	Limited to 10% of the Company's 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%)	June 27, 2019 (26 months)
21st resolution	Delegation of authority allowing the board of directors to increase the amount of each of the issues with or without preferential subscription right which would be decided under resolutions 15 to 19.	Limited to 15% of the initial issue	Price identical to that of the initial issue	June 27, 2019 (26 months)
23rd resolution	Delegation of authority allowing the board of directors to increase capital by incorporation of premiums, reserves, profits or other	Nominal value of increases in capital: €160,000 (2)	N / A	June 27, 2019 (26 months)
25th resolution	Authorization granted to the board of directors to award options for the subscription or purchasing of shares.	€2,412 (corresponding to 60,300 shares) (3)	(4)	June 27, 2020 (38 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 15 to 19 is set at €160,000. The maximum nominal amount of debt securities which can be issued under the above delegations is set at €120,000,000.
(2) Separate limit to the limit for resolutions 15 to 19 above.
(3) These amounts are not cumulative. The overall maximum nominal amount of capital increases that can be carried out under the delegations granted under resolutions 24 and 25 is set at €2,412.
(4) 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;
- 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 dow to the nearest euro, nor, for the bonds, to 80% of the average salesprice of the bonus shares of the Company, rounded down to the nearest euro.

Ordinary shares warrants issue:

Resolution	Subject matter of the resolution	Maximum nominal amount in euros	Method of determining the issue price	Method of determining the exercise price	Period of authorization and expiry
24th resolution	Delegation of authority allowing the board of directors to issue warrants dedicated to board members (not having the quality of employees or managers), persons bound by a contract of services or members of Committees set up by the board of directors	€2,412 (corresponding to 60,300 shares) (3)	To be fixed 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	October 27, 2018 (18 months)

(3) These amounts are not cumulative. The overall maximum nominal amount of capital increases that can be carried out under the delegations granted under resolutions 24 and 25 is set at €2,412.

Free allocation of preferential shares:

Resolution	Subject matter of the resolution	Maximum nominal amount in euros	Acquisition period for the preferred shares	Lockup period applicable to the preferred shares	Exercise period of the conversion option into ordinary shares	Period of authorization and expiry
28th resolution	Delegation of authority allowing the board of directors to allocate free preferential shares convertible into ordinary shares «AGAP 2017-01» dedicated to employees and / or corporate officers	€1,280 (corresponding to 32,000 ordinary shares)	1 year	2 years minimum	5 years and 3 months from the end of the lock-up period	June 27, 2020 (38 months)
29th resolution	Delegation of authority allowing the board of directors to allocate free preferential shares convertible into ordinary shares «AGAP 2017-02» dedicated to employees 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	June 27, 2020 (38 months)
30th resolution	Delegation of authority allowing the board of directors to allocate free preferential shares convertible into ordinary shares «AGAP 2017-03» dedicated to employees and / or corporate officers	€21,120 (corresponding to 528,000 ordinary shares)	1 year	2 years minimum	5 years and 3 months from the end of the lock-up period	June 27, 2020 (38 months)

Performance criteria to be met in order to make the preferential shares AGAP 2017-01, AGAP 2017-02 and AGAP 2017-03 convertible into ordinary shares:

- For AGAP 2017-01:

- the definition of the Company's industrial development plan, which will give the right to convert each AGAP 2017-01 preferential share into 100 ordinary shares.

- For AGAP 2017-02:

- the successful implementation of the bioprosthesis evaluated on a total of 10 patients worldwide, which will give the right to convert each AGAP 2017-02 preferential share into 20 ordinary shares.

- For AGAP 2017-03:

- the filing of the clinical module of the CE marking of the bioprosthesis, which will give the right to convert each AGAP 2017-03 preferential share into 15 ordinary shares;

- the CE marking of the bioprosthesis, which will give the right to convert each AGAP 2017-03 preferential share into 20 ordinary shares;

- obtaining additional financing for the Company for a cumulative amount of € 100 million between the grant date and the convertibility date, giving the right to convert each AGAP 2017-03 preferential share into 25 ordinary shares;

- the implementation of a production process meeting certain criteria, which will give the right to convert each AGAP 2017-03 preferential share into 15 ordinary shares;

- the effective commercialization of the bioprosthesis at 15 European centers, which will give the right to convert each AGAP 2017-03 preferential share into 10 ordinary shares;

- the successful implementation of the bioprosthesis evaluated on 10 patients in the United States, which will give the right to convert each AGAP 2017-03 preferential share into 10 ordinary shares;

- the successful implementation of the bioprosthesis evaluated in 100 patients worldwide, which will give the right to convert each AGAP 2017-03 preferential share into 10 ordinary shares;

- a favorable change in the price of the ordinary share according to specific criteria will give the right to convert each AGAP 2017-03 preferential share into a maximum of 10 ordinary shares.

At the date of filing of this Update, the Company made use of the delegations of authority voted at the general meeting of April 27, 2017 and proceeded to:

(i) May 15, 2017, at the free allocation of:

- 270 AGAP 2017-01;
- 1,800 AGAP 2017-02; and
- 3,180 AGAP 2017-03.

(ii) on September 25, 2017, at the free allocation of:

- 50 AGAP 2017-01;
- 200 AGAP 2017-02; and
- 310 AGAP 2017-03.

5.2.7 DETAILS OF THE COMPANY'S SHARE CAPITAL SUBJECT TO AN OPTION OR A CONDITIONAL OR UNCONDITIONAL AGREEMENT MAKING THEM SUBJECT TO AN OPTION

None.

5.2.6 TABLE OF CHANGES IN THE COMPANY'S SHARE CAPITAL

The Company was registered in the Versailles Trade and Companies Register on June 30, 2008 with an initial share capital of €40,000. The table below shows a summary of the changes in share capital during the last 3 years.

Date of realization of the operation	Type of operation	Increase in capital (in euros)	Issue premium or contribution (in euros)	Number of shares created	Nominal value of shares (in euros)	Cumulative number of shares	Share capital following the operation (in euros)
February 10, 2015	Increase in capital by cash contribution through the exercise of Kepler BSA warrants	676.00	1,081,172.00	16,900	0.04	4,386,220	175,448.80
March 20, 2015	Increase in capital by cash contribution through the exercise of Kepler BSA and BCE warrants	820.00	1,236,375.00	20,500	0.04	4,406,720	176,268.80
April 2, 2015	Increase in capital by cash contribution through the exercise of Kepler BSA warrants	2,000.00	3,181,270.00	50,000	0.04	4,456,720	178,268.80
November 5, 2015	Increase in capital by cash contribution through the exercise of Kepler BSA and BCE warrants	4,048.60	5,665,363.40	101,215	0.04	4,557,935	182,317.40
December 9, 2015	Increase in capital by cash contribution through the exercise of Kepler BSA warrants	800.00	1,020,700.00	20,000	0.04	4,577,935	183,117.40
February 10, 2016	Increase in capital by cash contribution through the exercise of Kepler BSA warrants	600.00	468,000.00	15,000	0.04	4,592,935	183,717.40
April 12, 2016	Increase in capital by cash contribution through private placement	53,966.36	49,945,866.18	1,349,159	0.04	5,942,094	237,683.76
August 29, 2016	Increase in capital by cash contribution through the exercise of BCE warrants	80.00	15,920.00	2,000	0.04	5,944,094	237,763.76
December 12, 2016	Increase in capital by cash contribution through the exercise of BCE warrants	3,274.00	651,526.00	81,850	0.04	6,025,944	241,037.76
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 warrant	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 warrant	2,644.00	1,760,686.00	66,100	0.04	6,139,544	245,581.76
September 25, 2017	Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrant	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 warrant	6,200.00	3,402,140.00	155,000	0.04	6,371,544	254,861.76
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

Note that Kepler Cheuvreux does not intend to retain the shares subscribed under the new share issue agreement made in January 2015, and will subsequently sell them to investors or on the open market.

5.3 MAJOR SHAREHOLDERS

5.3.1 DISTRIBUTION OF CAPITAL AND VOTING RIGHTS

CURRENT DISTRIBUTION OF CAPITAL AND VOTING RIGHTS

The table below shows the distribution of the capital and voting rights (please refer to Paragraph 5.3.2 « Voting rights » of this registration document, which indicates the conditions under which double voting rights may be obtained) of the Company at December 31, 2017, to the best of the Company's knowledge:

Shareholders (December 31, 2017)	Number of shares	Number of voting rights	% of capital	% of voting rights
Matra Défense (Airbus Group)	1,333,798	2,315,198	14.8%	20.7%
Professor Alain Carpentier	548,583	1,097,166	6.1%	9.8%
Research Association of the Alain Carpentier Foundation	115,000	230,000	1.3%	2.1%
Funds managed by Truffle Capital	765,366	1,287,853	8.5%	11.5%
Air Liquide	76,982	76,982	0.9%	0.7%
Cornovum [1]	458,715	458,715	5.1%	4.1%
Babalia [2]	1,291,709	1,291,709	14.3%	11.5%
Santé Holdings SRL [3]	688,881	688,881	7.6%	6.1%
Treasury stock	2,206	-	0.0%	-
Secondary offering	3,735,304	3,763,185	41.4%	33.6%
Total	9,016,544	11,209,689	100.0%	100.0%

[1] Investment vehicle owned equally by the French State and Bpifrance.

[2] Family office of Mr. Pierre Bastid, having acquired the Existing Shares originally subscribed by ZAKA (another family office of Mr. Pierre Bastid) as part of the Company's private placement executed in 2016.

[3] Family office of Dr. Antonino Ligresti.

To the best of the Company's knowledge, there is no other shareholder owning more than 5% of the capital or the voting rights.

Truffle Capital

Founded in 2001 in Paris, Truffle Capital is an acknowledged European player in the area of investment capital, investing in and developing innovative SMEs and building technological leaders in the areas of Life Sciences, Information Technology and Energy.

Truffle Capital often acts as leader, as the single or majority investor, and finances in particular technology spin-offs from large industrial groups, technological research institutes and universities, but also new start-ups. Truffle Capital is a co-founder and shareholder of CARMAT.

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 Foundation for Medical Research Grand Prize, and vice-chairman of the 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 - 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.

CorNovum

This entity is an investment vehicle, a structure held at parity, at the initiative of the French State and BPI France.

CHANGE IN THE DISTRIBUTION OF CAPITAL AND VOTING RIGHTS

The table below shows the distribution of capital and voting rights in the Company as at December 31, 2016, December 31, 2015 and as at December 31, 2014, insofar as known to the Company:

It should be noted that on February 26, 2016 the Company announced a significant fund-raising initiative, for €50 million, via a reserved capital increase operation after the effective extraordinary general meeting held on April 12, 2016, capital increase subscribed by a pool of strategic investors, composed of Air Liquide via its investment holding company ALIAD, of the joint investment vehicle of Bpifrance and the State (Programme des Investissements d'Avenir (future investments program - CorNovum), the family offices of Mr. Pierre Bastid (ZAKA) and of Dr. Ligresti (Santé Holdings SRL) and by the reference shareholders, Matra Défense (Airbus Group) and Truffle Capital (via one previous fund and several new funds).

In addition, last December, the Company launched a capital increase operation through a public offering, a transaction that benefited from the support of the historic shareholders, in particular the family offices of Mr. Pierre Bastid (Babalia) and Dr. Ligresti (Santé Holdings SRL).

These two operations explains the observable changes in the composition of the shareholders between the end of December 2015 and the end of December 2017.

Shareholders	As at December 31, 2016		As at December 31, 2015		As at December 31, 2014	
	% of capital	% of voting rights	% of capital	% of voting rights	% of capital	% of voting rights
Matra Défense (Airbus Group)	22.1	27.5	22.6	28.4	23.7	28.9
Professor Alain Carpentier	9.1	13.0	12.0	15.5	12.5	15.7
ARSFAC	1.9	2.7	2.5	3.2	2.6	3.3
Funds managed by Truffle Capital	15.4	19.6	19.2	24.6	22.0	27.4
Air Liquide	0.5	0.3	-	-	-	-
Cornovum [1]	7.6	5.4	-	-	-	-
Babalia [2]	4.8	3.5	-	-	-	-
Santé Holdings SRL [3]	3.1	2.2	-	-	-	-
Treasury stock	0.1	0.0	0.1	0.0	0.1	0.0
Secondary offering	35.4	25.7	43.6	28.3	39.1	24.7
Total	100.0	100.0	100.0	100.0	100.0	100.0

[1] Investment vehicle owned equally by the French State and Bpifrance.

[2] Family office of Mr. Pierre Bastid, having acquired the Existing Shares originally subscribed by ZAKA (another family office of Mr. Pierre Bastid) as part of the Company's private placement executed in 2016.

[3] Family office of Dr. Antonino Ligresti.

5.3.2 VOTING RIGHTS

The voting right attaching to shares is proportional to the percentage of capital that they represent and each share gives an entitlement to at least one vote.

However, in accordance with Article 14 of the Articles of Association and in accordance with the provisions of the French Commercial Code, all fully paid up shares which can be shown to have been registered to the same shareholder for at least two years will benefit, with effect from the first listing of the shares of the Company on the Euronext Growth market, from double voting rights compared with those given to other shares having regard to the percentage of share capital that they represent.

5.3.3 STATEMENT CONCERNING CONTROL OF THE COMPANY

As at the date of this registration document, to the best of the Company's knowledge, no single shareholder 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 THE CONTROL

As at the date of this 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 MEMORANDUM AND ARTICLES OF ASSOCIATION)

The purpose of the Company is, either directly or indirectly, both in France and abroad:

- research and development in the field of medical devices and equipment, specifically in the cardiovascular field, and in all scientific fields directly or indirectly related thereto;
- production and marketing of (i) medical devices and equipment in the cardiovascular field and (ii) all associated technologies;
- acquisition or creation of technology products and licenses connected with the cardiovascular field;
- investment in French or foreign enterprises having 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, movables or real estate – that may be directly or indirectly connected with the above-mentioned object or likely to contribute to the development thereof.

5.4.2 PROVISIONS OF THE MEMORANDUM AND ARTICLES OF ASSOCIATION, A CHARTER OR BYLAWS OF THE COMPANY CONCERNING THE MEMBERS OF THE BOARD OF DIRECTORS AND THE GENERAL MANAGEMENT (ARTICLES 15 - 21 OF THE MEMORANDUM AND ARTICLES OF ASSOCIATION)

ARTICLE 15 - BOARD OF DIRECTORS

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.

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 general meeting. However, in the event of a merger or demerger, appointments may be made by an extraordinary general meeting. Their term of office is six (6) years. It concludes at the end of the ordinary general meeting of shareholders that approves the financial statements for the period just closed, and which is held in the year in which the term of office of the said director expires.

Any outgoing director may be re-elected subject to fulfilling the conditions of this Article.

Directors may be removed from office and replaced at any time by the ordinary general meeting.

Natural persons aged more than eighty-five (85) years may not be directors; where a director passes this age during a term of office they are deemed to have officially resigned at the next general meeting. Any appointment made in breach of the above provisions is null and void,

with the exception of those which may be made on an interim 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 sociétés anonymes (corporations) based in Metropolitan France, save as otherwise provided for by law.

A Company staff member may only be appointed as a director if their contract of employment relates to an actual position within the Company. The number of directors having a contract of employment with the Company may not exceed one third of the directors in post.

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 revokes the mandate of its permanent representative, it is required to notify the Company, without delay, by registered letter, of this revocation 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 mandate are subject to the same publication formalities as if they were a director in their own right.

III. Vacancies, death, resignation

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 general meetings.

When the number of directors falls below the legal minimum, the remaining directors must immediately call an ordinary general meeting in order to bring the board up to strength.

Interim appointments made by the board are subject to ratification by the next ordinary general meeting. In the absence of ratification, resolutions passed and acts performed previously by the board will remain valid.

ARTICLE 17 - ORGANIZATION AND DELIBERATIONS OF THE BOARD

I. Chairman

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 remuneration of the chairman.

The chairman of the board of directors organizes and directs the work of the latter, and reports thereon to the general 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 passes 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-election.

The board of directors may revoke the appointment at any time.

In the event of the chairman being temporarily unavailable, or of his death, the board of directors may delegate the duties of chairman to a director.

In the event of a temporary impediment, this delegation is made for a limited period; it is renewable. 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 dictate, 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 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 and even verbally.

The board meets at the head 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 Bylaws where videoconferencing and other means of telecommunication are used.

Unless otherwise stipulated by these Articles of Association and subject to the arrangements laid down in the Bylaws, 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 video-conference or telecommunication under the conditions defined by the Bylaws of the board of directors. However, physical presence or representation will be necessary for all deliberations of the board relating to adoption 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 and the deputy chief executive.

Furthermore, half of the directors in post may oppose a meeting of the board being held via video-conference or telecommunication. Such opposition must be notified in the forms and by the deadline required by the Bylaws 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 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 deliberations

The deliberations of the board of directors are recorded in minutes drawn up in a special register, numbered and initialed, and kept at the head office in accordance with the regulatory provisions.

VI. Observers

Throughout the lifetime of the Company, the ordinary general meeting may proceed with the appointment of observers 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 conclude at the end of the ordinary general meeting of shareholders called to approve the financial statements for the period just closed, and held in the year during which their terms of office cease.

Any outgoing observer may be re-elected subject to meeting the conditions of this Article.

Observers may be removed and replaced at any time by the ordinary general meeting without any compensation being due to them. The functions 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 duty within the Company through advice and monitoring. In the context of their duties they may make observations to the board of directors and request access to information at the head 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 deliberations of the board of directors.

ARTICLE 18 - POWERS OF THE BOARD OF DIRECTORS

The board of directors sets the business policy of the Company and ensures that this is implemented.

Save for the powers expressly reserved to the meetings of shareholders 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 acts 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 act 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 the general management all documents he considers useful.

The board of directors may decide to set up working groups to look into matters that the board or its chairman may refer to them.

ARTICLE 19 - GENERAL MANAGEMENT – DELEGATION OF POWERS

I. Organizational principles

In accordance with the legal provisions, the general management of the Company is undertaken, 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.

The choice between the two methods of exercising general 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 the method of exercising general management 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 video-conference or other means of telecommunication.

A change in the method for undertaking general management does not result in a change to the Articles of Association.

Where general management of the Company is undertaken by the chairman of the board of directors, the following provisions relating to the chief executive are applicable to him.

II. General management

Chief executive

Depending on the choice made by the board of directors in accordance with the provisions of the above paragraph, the general management of the Company is exercised by the chairman of the board of directors, or by a natural person, who may or may not be a director, who is appointed by the board of directors and bears the title of chief executive. Where the board of directors chooses to separate the functions of chairman and chief executive, it will proceed to appoint the chief executive, define his term of office, determine his remuneration and, as necessary, the limits to his powers.

A person over the age of eighty-five (85) years may not be appointed as chief executive. If a chief executive in post passes this age he is deemed to have officially resigned.

The chief executive may be removed from office at any time by the board of directors. Where the chief executive 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 is invested with the widest 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 the meetings of shareholders and to the board of directors.

He represents the Company in its relations with third parties. The Company assumes an obligation, even for acts of the chief executive that do not fall within the scope of the corporate purpose, unless it can prove that the third party was aware that the act 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 may not take any decision on behalf of the Company in the following areas without the prior authorization of the board of directors:

- the securing of loans or advances in order to acquire shares or securities of any subsidiary company except where such subsidiary is wholly-owned;
- the furnishing of 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;
- the disposal, transfer, licensing or pledging of any industrial or intellectual property or of any substantial asset;
- approval of the budget and the strategic plan.

The chief executive 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 executives

At the proposal of the chief executive that this function be assumed by the chairman of the board of directors or by another person, the board of directors may appoint one or more actual persons, known as deputy chief executives, who may or may not be chosen from among the directors and shareholders, who are charged with assisting the chief executive. The number of deputy chief executives may not exceed five. If the deputy chief executive is a director, his term of office may not exceed that of his term of office as a director.

A person over the age of eighty-five (85) years may not be appointed as deputy chief executive. If a deputy chief executive in post passes this age he is deemed to have officially resigned.

Deputy chief executives may be removed at any time by the board of directors at the proposal of the chief executive. Removal without just cause may give rise to damages. By agreement with the chief executive, the board of directors decides on the scope and the duration of the powers granted to the deputy chief executives. The deputy chief executives have the same powers in respect of third parties as the chief executive.

Where the chief executive ceases or is prevented from performing his duties, the deputy chief executives will retain their functions and powers until the new chief executive is appointed, unless otherwise decided by the board.

The board of directors decides on the remuneration of the deputy chief executives.

III. Delegation of powers

The board of directors may entrust to its agents, who may or may not be directors, the permanent or temporary duties it decides upon, delegate powers to them and set the remuneration it considers appropriate.

ARTICLE 20 - DIRECTORS' REMUNERATION

The general 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 the 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 those directors who are members of working groups than that allocated to the other directors.

The board of directors may award exceptional remuneration 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 COMPANY AND A DIRECTOR, THE CHIEF EXECUTIVE OR A DEPUTY CHIEF EXECUTIVE

I.Agreements subject to 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 executives or deputy chief executives, 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 for prior authorization by the board of directors.

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 the Company and an enterprise are also subject to prior authorization if they are with an enterprise where the chief executive, one of the deputy chief executives or one of the directors of the Company, is the owner, partner with unlimited liability, manager,

director, member of the supervisory committee or, generally speaking, an executive of the enterprise.

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, 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 Civil Code or Articles L. 225-1 and L. 226-1 of the 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 notified by the interested party to the chairman of the board of directors. A list and subject-matter of such agreements are notified 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 ATTACHING TO SHARES (ARTICLES 9 - 14 OF THE MEMORANDUM AND 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 any increase in capital, cash shares are settled, upon subscription, for at least a quarter of their face value and, as appropriate, the full issue 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 notified to the subscribers and shareholders at least fifteen days prior to the date set for payment by individual recorded delivery 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 sanctions provided for by Articles L.228-27 et seq. of the French Commercial Code.

ARTICLE 11 - FORM OF SHARES

The ordinary shares are in registered or bearer form at the option of the holders. They can take the bearer form only after their complete release. Preferred fully paid-up shares are nominative.

The Company is authorized to identify holders of bearer shares by simple request, to the body in charge of the clearing of 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 - EXCEEDING OF LIMITS

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 negotiable following the winding up of the Company and until liquidation is complete. Preferred shares are transferable in accordance with paragraph 12.2.

The ordinary shares and the preferred 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 capital of the Company is composed of ordinary shares and preferential 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 the capital it represents. It gives the right to participate, in the conditions set by the law and the present articles of association, at general meetings and vote on resolutions.

The ownership of an ordinary share automatically entails unreserved compliance with the articles of association and decisions of the general meeting of the Company.

The rights and obligations attached to the ordinary shares follow the title regardless of the holder.

Whenever it is necessary to own more than one share to exercise any right, in case of exchange, consolidation, allocation of shares, capital increase or reduction, merger or any other owners of individual securities or less than the required number can exercise these rights only if they do their personal business of grouping and possibly purchasing or saling the necessary number of securities.

II. Rights attached to preferential shares

Preferential 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 preferential shares that may be issued is 7,600.

The preferential shares are classified into three distinct categories 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, and « AGAP 2017-03 » for a maximum of 5,280.

From the time of their definitive grant and until they become convertible, the preferential shares have the right to vote at the ordinary and extraordinary meetings of ordinary shareholders, with one voting right per preferential share. From the date on which they become convertible, the number of voting rights to which each preferential share entitles becomes equal to the number of ordinary shares to which the conversion of each preferential share gives entitlement.

Preferential shares shall have the right to vote at a special meeting of the holders of each class of preferential shares. The holders of each class of preferential shares shall meet in a special meeting for any proposed amendment to the rights attached to such class of preferential 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 will be subject to the approval of any special meeting concerned, could not be exchanged for shares with specific equivalent rights.

Special meetings shall only validly deliberate if the shareholders present or represented possess at least, on the first convocation, one third of the preferential shares and, on the second convocation, one fifth of the preferential shares with the right to vote. In the event of a change or amortization of the share capital, the rights of the holders of preferential 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 preferential shares are set out in the following paragraph.

From the time of their definitive allocation and until they become convertible, the preferential shares benefit from a dividend and give right to the reserves. The amount of the dividend (and, where applicable, the reserves) to which each preferential 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 preferential share gives right. For this purpose, the preferential shares shall bear dividends from the first day of the financial year preceding the year in which they are finally allocated. From the date on which they become convertible, the amount of the dividend (and, where applicable, the reserves) to which each preferential 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 preferential share is entitled.

In the event of the liquidation of the Company, preferential shares enjoy the same right to the liquidation bonus as the ordinary shares, ie a right proportional to the share that their nominal amount represents in the share capital.

Preferential shares are entitled to preferential 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 issue premiums, distribution of reserves or any issue equity securities or securities giving the right to the allocation of capital securities with a subscription right reserved for shareholders before the preferential shares are convertible under the conditions set out in paragraph III. the maximum number of

ordinary shares to which the preferential shares may be entitled 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 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 to which each preferential share entitles, the conversion ratio applicable according to the degree to which the performance criteria are met, such as this is 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 preferential shares he / she has benefited from.

After the preferential shares have become convertible and the board of directors has calculated the conversion ratio as provided for in paragraph III. 5. below (as adjusted in accordance with this Article, if any), no adjustment shall be made to this conversion ratio, as the holders of preferential shares may thereafter convert them freely.

The preferential shares will be fully paid up when they are issued by capitalizing the Company's reserves, premiums or profits.

III. Conversion of preferential shares into ordinary shares

The issue of preferential 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 preferential shares will be definitively vested (the « Final Award ») by 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 is invalid for classification in the second or third of the categories provided for in Article L. 341-4 of the Social Security Code (or their equivalent in applicable foreign law), the preferential shares will be allocated definitively 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 Commercial Code, the beneficiary's heirs or beneficiaries may, if they wish, apply for the definitive allocation of the preferential shares within six months of the date of death. In the event of retirement, the beneficiaries will retain their right to the definitive allocation of preferential shares even though they are no longer bound by a contract of employment.

Holders of preferential shares may request conversion of their preferential shares into new or existing ordinary shares (at the Company's option) of the Company as follows:

1. Preferrential shares become convertible by their holder into new or existing ordinary shares (at the option of the Company) at the end of a two year retention period beginning on the date of the Final Assignment (the « Lock-Up Period ») under the conditions set out in paragraphs 2 to 9 below. From the date they become convertible (the « Convertibility Date »), preferential shares may be converted for five (5) years and three (3) months (the « Conversion Period »).

2. In accordance with the provisions of Article L. 225-197-1 I, paragraph 7 of the Commercial Code, preferential shares will be freely transferable during the Lock-Up Period if the beneficiary becomes disabled in accordance with his classification in the second or third of the categories provided for in Article L. 341-4 of the Social Security Code (or their equivalent in applicable foreign law), regardless of whether the disability occurs before or after the Final Award 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-assignment commitment, so that the preferential shares they have applied for the definitive allocation shall become freely transferable.

3. Preferential 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 preferential share will give entitlement will depend on whether one or more (or all) of the Performance Criteria have been met on the Convertibility Date (the « Performance »).

For the « AGAP 2017-01 » preferential shares, the Performance Criterion will be the definition of the Company's industrial development plan, which will give the right to convert each preferential share into 100 ordinary shares.

For the « AGAP 2017-02 » preferential shares, the Performance Criterion will be the successful implementation of the bioprosthesis evaluated on a total of 10 patients worldwide, which will give the right to convert each preferential share into 20 ordinary shares.

For the « AGAP 2017-03 » preferential shares, the Performance Criteria will be as follows:

- the filing of the clinical module of the CE marking of the bioprosthesis, which will give the right to convert each preferential share into 15 ordinary shares;
- the CE marking of the bioprosthesis, which will give the

right to convert each preferential share into 20 ordinary shares;
- 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 preferential share into 25 ordinary shares being that such financing may take the form of, in particular, capital increases, debt instruments, conditional advances, operating subsidies or revenues received from collaborative arrangements or licence ;
- the establishment of a production process that (i) meets the applicable regulatory and quality standards, and (ii) enables the bioprosthesis to be produced in sufficient number and time 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 products sold, which will give the right to convert each preferential share into 15 ordinary shares;
- the effective commercialization of the bioprosthesis at 15 European centers, which will give the right to convert each preferential share into 10 ordinary shares;
- the successful implementation of the bioprosthesis evaluated on 10 patients in the United States, which will give the right to convert each preferential share into 10 ordinary shares;
- the successful implementation of the bioprosthesis evaluated on 100 patients worldwide, which will give the right to convert each preferential share into 10 ordinary shares;
- the change in the price of the common share according to the following criteria, which will give the right to convert each preferential share into a maximum of 10 ordinary shares.

(a) If the Final Price is strictly lower than the Initial Price, the number of ordinary shares in which each preferential share will be converted will be equal to 0;

(b) If the Final Price is comprised 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 in which each preferential share will be converted 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 in which each preferential share will be converted will be equal to 10.

The « Final Price » is the highest average of the closing prices of the ordinary shares of the stock exchange sessions 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, with 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.

It is specified that the conversion ratio thus determined for each category of preferential shares will be adjusted to take account of the shares to be issued in order to preserve the rights of holders of securities giving access to the capital of the Company and holders of preferential shares in accordance with the applicable legal and regulatory provisions and paragraph II above.

4. The performance of each Performance Criterion shall be determined at a meeting of the board of directors held as soon as possible after completion of the Performance Criterion, which shall determine the number of ordinary shares to which each preferential share will be entitled to this date. As soon as possible after the Convertibility Date, the board of directors will meet to determine the final number of ordinary shares to which each preferential share will be entitled, with the conversion ratio of AGAP 2017- 03 may under no circumstances exceed 100, regardless of the number of Performance Criteria performed.

However, in the event of a takeover bid or exchange on the ordinary shares:
- happening as of the Provisional Allocation Date,
- whose definitive results are announced no later than the day before the Convertibility Date, and
- 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 to which the preferential shares will be entitled 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 cumulative number of ordinary shares to which all the preferential shares (all categories) which have been allocated entitle the beneficiary to be entitled according to the realization of the Performance Criteria on the date of the announcement of the final results of the Offer, on (ii) the aggregate number of ordinary shares to which all preferential shares (all classes) all Performance Criteria are met.

- If « p » is less than or equal to 0.35, the « N » number of ordinary shares to which each of the preferential shares (whichever class) has been allocated 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 and 100 for AGAP 2017-03

n being equal to 100 for AGAP 2017-01, 20 for AGAP

2017-02 and 100 for AGAP 2017-03

with

R = (Acquisition Price) / (Initial Price)

The « Acquisition Price » is equal to the closing price of the common 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 allotment of preferential shares, with a minimum of €30 and a maximum of €38 per ordinary share.

- 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, that is to say 35 for AGAP 2014-01, 7 for AGAP 2017-02 and 35 for AGAP 2017-03.

The preferential shares concerned will be definitively allocated to the beneficiaries on the Final Award Date, irrespective of whether or not a new attendance condition is provided for in the terms of the Preferential Share Plan and of the Performance Criteria above. In any case, preferential shares will become convertible only on the Convertibility Date.

5. If on the Convertibility Date none of the Performance Criteria is satisfied or if no takeover bid has been made under the conditions described above, the Company may (but without being an obligation for the Company) to redeem the preferential shares at any time at nominal value.

Similarly, preferential shares which may be converted but which have not been converted at the end of the Convertibility Period, may (without this being in no case an obligation for the Company) be bought at any time by the Company at their nominal value.

6. At the end of the Convertibility Period, the Company may, in accordance with the applicable legal and regulatory provisions, cancel preferential shares not yet converted, including those which it has bought back. The share capital will then be correlatively reduced, creditors having a right of opposition under the conditions provided for in Article L. 225-205 of the Commercial Code.

7. The new ordinary shares resulting from the conversion of the preferential shares shall be assimilated to the ordinary shares in circulation and shall bear dividend from the first day of the financial year preceding that in which the preferential 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 Alternext Paris market on the same trading line as the ordinary shares.

8. The board of directors will recognize the conversion of the preferential 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 preferential shares and amendments to the articles of association, in particular as regards the allocation of shares by category. This option may be delegated to the Director General under the conditions laid down by law.

9. Shareholders will be informed of the conversions made by 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 of the convening of each meeting.

10. Capital increases resulting from the creation of preferential 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 – Exceeding of limits

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 capital or the voting rights in excess of the limits set by law, will inform the Company within the statutory period, counting from when the holding limit is reached, 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 limits mentioned in this paragraph.

A person required to provide this information will state the number of securities held giving access to capital and the voting rights attaching to these.

If required by the rules of a securities market other than a regulated market on which the securities of the Company are admitted for trading, this person will also inform the 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 limit to the holding is passed. If necessary, this information is made public under the conditions laid down by the General Regulations of the 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 meeting of shareholders held within a

period expiring two years after the date that the notification is dealt with.

Similarly, voting rights attaching 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 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 general 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 General Meetings and to the bare owner at Extraordinary General Meetings. However, shareholders may agree any other distribution of the voting right at General 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 expiry of a period of one month after such letter is sent.

The voting right is exercised by the owner where securities are pledged.

ARTICLE 14 - DOUBLE VOTING RIGHT

The voting right attaching to capital or dividend shares is proportional to the percentage of the capital that they represent. Each share gives an 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 issue 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 of property between spouses or donation between living persons to a spouse or a parent entitled to inherit, does not result in 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 GENERAL MEETINGS OF SHAREHOLDERS (ARTICLES 24 - 31 OF THE MEMORANDUM AND ARTICLES OF ASSOCIATION)

ARTICLE 24 - QUORUM AND MAJORITY

General meetings deliberate under the conditions set by law.

The ordinary general meeting takes all decisions other than those reserved to the extraordinary general meeting by law and by these Articles of Association. It may not validly deliberate at the first calling unless the shareholders present or represented hold at least one fifth of shares with voting rights. At the second calling no quorum is required. It acts by a majority of the votes cast by the shareholders present or represented.

The extraordinary general meeting alone has the power to modify any of the provisions of the Articles of Association. It may not validly deliberate unless the shareholders present or represented hold at least one quarter of shares with voting rights at the first calling and one fifth of the shares at the second calling. In the absence of the latter quorum, the second meeting may be postponed to a later date not more than two months after that when 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 GENERAL MEETINGS

General meetings are called either by the board of directors, or by the auditors, or by a proxy appointed by a court under the conditions and arrangements laid down by law.

They take place at the head 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.

General meetings are called by publication in a journal authorized to carry legal notices in the department where the head office is based and also in the Bulletin des Annonces Légales et Obligatoires (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 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, cancelation may not take place 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 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 correspondence in general meetings, of whatever kind.

A legal right of participation in General 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 timings, 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 head office at the latest six days prior to the date of the meeting.

ARTICLE 29 - OFFICERS FOR THE MEETING

Shareholder 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 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 need not be a shareholder.

ARTICLE 30 - MINUTES OF DELIBERATIONS

The deliberations of shareholder meetings are recorded in minutes drawn up by the meeting officers and signed 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 head 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 INFORMATION AND CONTROL

Before each meeting, the board of directors must make available to shareholders 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 communication 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 head 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, A CHARTER OR BYLAWS OF THE COMPANY THAT MAY HAVE THE EFFECT OF DELAYING, DEFERING OR PREVENTING 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 MEMORANDUM AND ARTICLES OF ASSOCIATION)

1 - The capital stock may be increased by any process and under any arrangements provided for by law.

Only an extraordinary general meeting is competent to decide on an increase in capital based on a report from the board of directors.

Shareholders have a preferential 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 meeting may decide to withdraw this preferential right of subscription in accordance with the statutory provisions.

2 - A reduction in capital is authorized or decided upon by the Extraordinary General 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 PARTICULARS OF THE LEGAL AFFAIRS OF THE COMPANY IN THE FINANCIAL PERIOD

5.5.1 PARTICULARS OF COMPANY REPRESENTATIVES AND AUDITORS

BONUS SHARES AND STOCK OPTIONS

The Company has not set up any share purchase or subscription plan.

As detailed in sections 4.5.1 and 5.2.1 of the registration document, the board of directors of the Company, making use of the delegations of authority approved at the time of the general meeting of April 27, 2017, awarded free of charge on May 15, 2017:

- 270 AGAP 2017-01, including 70 AGAP 2017-01 to Marc Grimmé (R&D Director) and 180 AGAP 2017-01 to Stéphane Piat (Chief executive officer and Director),
- 1,800 AGAP 2017-02, including 200 AGAP 2017-02 to Marc Grimmé (R&D Director), 400 AGAP 2017-02 to Dr. Piet Jansen (Medical Director), 1,000 AGAP 2017-02 to Stéphane Piat (Chief executive officer and Director) and 200 AGAP 2017-02 to Eric Richez (Director of Development), and
- 3,180 AGAP 2017-03, including 180 AGAP 2017-03 to Benoît de la Motte (Financial Director), 280 AGAP 2017-03 to Marc Grimmé (R&D Director), 310 AGAP 2017-03 to Dr Piet Jansen (Director medical), 90 AGAP 2017-03 to Joëlle Monnier (Director of Quality), 1,720 AGAP 2017-03 to Stéphane Piat (Chief executive officer and Director), 140 AGAP 2017-03 to Eric Richez (Director of Development) and 60 AGAP 2017-03 to Raouia Bouyanzer (Human Resources Manager).

The board of directors of the Company, once again making use of the delegations of authority approved at the general meeting of April 27, 2017, awarded free of charge on September 25, 2017:

- 50 AGAP 2017-01 and 200 AGAP 2017-02 to Wenzel Hurtak (Manufacturing Director), and
- 310 AGAP 2017-03, including 190 AGAP 2017-03 to Wenzel Hurtak (Manufacturing Director) and 120 AGAP 2017-03 to Francesco Arecchi (Marketing Manager).

Preferential shares are subject to vesting and retention periods and performance criteria to enable their conversion to ordinary shares, as described in section 5.2.6 of the registration document.

SHARE TRANSACTIONS BY THE EXECUTIVES

We indicate below the transactions made by the directors and their relatives on the shares of the Company during the 2017 financial year, as declared by these officers and their relatives pursuant to the provisions of Articles 223-22 A and 223- 26 of the AMF General Regulation.

Refer to the following pages

For the record, the lock-up commitment made as part of the Company's capital increase of April 2016 does not apply to certain investment funds managed by Truffle Capital to the extent necessary to enable them to their liquidation regulatory obligations (see section 4.2.2 of the registration document).

Persons concerned	Type of operation	Date of transaction	Number of shares	Value of the transaction
Truffle Capital	Sale	January 2, 2017	1,505	€44,327.07
Truffle Capital	Sale	January 3, 2017	751	€22,614.71
Truffle Capital	Sale	January 4, 2017	1,073	€32,207.92
Truffle Capital	Sale	January 5, 2017	496	€14,797.07
Truffle Capital	Sale	January 17, 2017	218	€6,409.66
Truffle Capital	Sale	January 18, 2017	392	€11,597.79
Truffle Capital	Sale	January 19, 2017	622	€18,194.50
Truffle Capital	Sale	January 20, 2017	375	€11,005.01
Truffle Capital	Sale	January 23, 2017	226	€6,701.08
Truffle Capital	Sale	January 24, 2017	245	€7,216.96
Truffle Capital	Sale	January 25, 2017	482	€14,158.89
Truffle Capital	Sale	January 26, 2017	1,982	€57,464.52
Truffle Capital	Sale	January 27, 2017	1,432	€41,372.06
Truffle Capital	Sale	January 30, 2017	320	€9,225.18
Truffle Capital	Sale	January 31, 2017	1,548	€44,844.48
Truffle Capital	Sale	February 1, 2017	721	€21,171.08
Truffle Capital	Sale	February 2, 2017	373	€10,902.01
Truffle Capital	Sale	February 3, 2017	943	€27,809.35
Truffle Capital	Sale	February 6, 2017	6,848	€191,823.44
Truffle Capital	Sale	February 7, 2017	2,880	€80,692.70
Truffle Capital	Sale	February 8, 2017	2,296	€62,472.78
Truffle Capital	Sale	February 9, 2017	529	€14,356.90
Truffle Capital	Sale	February 10, 2017	510	€13,999.40
Truffle Capital	Sale	February 14, 2017	580	€17,352.85
Truffle Capital	Sale	February 15, 2017	1,475	€44,155.90
Truffle Capital	Sale	February 16, 2017	945	€27,923.14
Truffle Capital	Sale	February 17, 2017	1,012	€29,995.88
Truffle Capital	Sale	February 20, 2017	1,111	€22,700.29
Truffle Capital	Sale	February 21, 2017	916	€26,509.68
Truffle Capital	Sale	February 22, 2017	371	€10,708.25
Truffle Capital	Sale	February 23, 2017	796	€22,976.30
Truffle Capital	Sale	February 24, 2017	727	€21,057.05
Truffle Capital	Sale	February 27, 2017	377	€10,883.84
Truffle Capital	Sale	February 28, 2017	754	€21,412.48
Truffle Capital	Sale	March 1, 2017	616	€17,508.57
Truffle Capital	Sale	March 2, 2017	987	€28,112.72
Truffle Capital	Sale	March 6, 2017	1,324	€37,215.12
Truffle Capital	Sale	March 7, 2017	790	€21,868.31
Truffle Capital	Sale	March 8, 2017	1,303	€35,613.47
Truffle Capital	Sale	March 9, 2017	800	€21,782.48
Truffle Capital	Sale	March 10, 2017	1,385	€37,371.73
Truffle Capital	Sale	March 13, 2017	684	€18,390.37
Truffle Capital	Sale	March 14, 2017	660	€17,661.86
Truffle Capital	Sale	March 15, 2017	1,396	€36,932.02
Truffle Capital	Sale	March 16, 2017	1,442	€39,600.78
Truffle Capital	Sale	March 17, 2017	1,090	€30,500.93
Truffle Capital	Sale	March 20, 2017	611	€17,051.60
Truffle Capital	Sale	March 21, 2017	480	€13,231.49
Truffle Capital	Sale	March 22, 2017	1,298	€35,144.65
Truffle Capital	Sale	March 23, 2017	340	€9,241.23
Truffle Capital	Sale	March 24, 2017	363	€9,794.83
Truffle Capital	Sale	March 27, 2017	2,658	€74,612.98
Truffle Capital	Sale	March 28, 2017	2,018	€58,569.42

Persons concerned	Type of operation	Date of transaction	Number of shares	Value of transaction
Truffle Capital	Sale	March 29, 2017	1,454	€42,040.37
Truffle Capital	Sale	March 30, 2017	699	€19,808.61
Truffle Capital	Sale	March 31, 2017	1,201	€33,722.88
Stéphane Piat	Acquisition	April 3, 2017	758	€21,299.80
Truffle Capital	Sale	April 4, 2017	826	€23,235.71
Truffle Capital	Sale	April 5, 2017	725	€20,297.75
Truffle Capital	Sale	April 6, 2017	505	€14,076.98
Truffle Capital	Sale	April 7, 2017	406	€11,299.75
Truffle Capital	Sale	April 10, 2017	749	€20,683.71
Truffle Capital	Sale	April 11, 2017	542	€14,803.75
Truffle Capital	Sale	April 12, 2017	479	€13,025.06
Truffle Capital	Sale	April 13, 2017	788	€21,289.55
Truffle Capital	Sale	April 18, 2017	639	€17,159.90
Truffle Capital	Sale	April 19, 2017	1,325	€35,135.42
Truffle Capital	Sale	April 20, 2017	500	€13,207.35
Truffle Capital	Sale	April 21, 2017	536	€14,147.77
Truffle Capital	Sale	April 24, 2017	630	€16,829.38
Stéphane Piat	Acquisition	April 24, 2017	29	€785.90
Truffle Capital	Sale	April 25, 2017	718	€19,126.95
Truffle Capital	Sale	April 26, 2017	813	€21,648.97
Truffle Capital	Sale	April 27, 2017	479	€12,816.03
Truffle Capital	Sale	April 28, 2017	1,151	€30,652.86
Truffle Capital	Sale	May 2, 2017	1,187	€31,662.04
Truffle Capital	Sale	May 3, 2017	17,106	€536,278.23
Truffle Capital	Sale	May 4, 2017	8,000	€237,376.80
Truffle Capital	Sale	May 5, 2017	3,300	€97,771.74
Truffle Capital	Sale	May 8, 2017	1,693	€51,605.52
Truffle Capital	Sale	May 9, 2017	3,909	€120,396.81
Truffle Capital	Sale	May 10, 2017	2,545	€76,942.73
Truffle Capital	Sale	May 11, 2017	1,591	€47,503.28
Truffle Capital	Sale	May 12, 2017	1,009	€29,910.09
Truffle Capital	Sale	May 15, 2017	1,748	€51,604.28
Truffle Capital	Sale	May 16, 2017	1,712	€51,744.17
Truffle Capital	Sale	May 17, 2017	2,878	€86,613.12
Truffle Capital	Sale	May 18, 2017	649	€19,230.91
Truffle Capital	Sale	May 19, 2017	418	€12,308.85
Truffle Capital	Sale	May 22, 2017	442	€13,086.47
Truffle Capital	Sale	May 23, 2017	620	€18,325.59
Truffle Capital	Sale	May 24, 2017	651	€19,163.23
Truffle Capital	Sale	May 25, 2017	565	€16,661.23
Truffle Capital	Sale	May 26, 2017	1,104	€32,200.15
Truffle Capital	Sale	May 29, 2017	1,395	€40,435.61
Truffle Capital	Sale	May 30, 2017	888	€25,848.17
Truffle Capital	Sale	May 31, 2017	857	€24,829.00
Truffle Capital	Sale	June 1, 2017	1,137	€32,944.57
Truffle Capital	Sale	June 2, 2017	404	€11,759.87
Truffle Capital	Sale	June 5, 2017	659	€19,164.31
Truffle Capital	Sale	June 6, 2017	1,091	€31,367.56
Truffle Capital	Sale	June 7, 2017	623	€17,806.71
Truffle Capital	Sale	June 8, 2017	1,873	€52,768.40
Truffle Capital	Sale	June 9, 2017	563	€15,929.41
Truffle Capital	Sale	June 12, 2017	843	€23,993.21
Truffle Capital	Sale	June 14, 2017	777	€21,972.55

Persons concerned	Type of operation	Date of transaction	Number of shares	Value of transaction
Truffle Capital	Sale	June 14, 2017	756	€21,218.12
Truffle Capital	Sale	June 15, 2017	788	€21,979.13
Truffle Capital	Sale	June 16, 2017	1 168	€32,304.43
Truffle Capital	Sale	June 19, 2017	1 003	€27,860.63
Truffle Capital	Sale	June 20, 2017	656	€18,183.86
Truffle Capital	Sale	June 21, 2017	919	€25,287.11
Truffle Capital	Sale	June 22, 2017	611	€16,722.83
Truffle Capital	Sale	June 23, 2017	723	€19,733.63
Truffle Capital	Sale	June 26, 2017	1,022	€27,766.72
Truffle Capital	Sale	June 27, 2017	1,354	€36,529.02
Truffle Capital	Sale	June 27, 2017	19,500	€500,175.00
Truffle Capital	Sale	June 28, 2017	731	€19,728.59
Truffle Capital	Sale	June 30, 2017	1,316	€39,435.65
Truffle Capital	Sale	June 30, 2017	386	€10,384.40
Truffle Capital	Sale	July 3, 2017	407	€10,987.78
Truffle Capital	Sale	July 4, 2017	1,145	€30,780.00
Truffle Capital	Sale	July 5, 2017	442	€11,896.56
Truffle Capital	Sale	July 6, 2017	397	€10,695.34
Truffle Capital	Sale	July 7, 2017	1,324	€35,621.69
Truffle Capital	Sale	July 10, 2017	1,543	€41,164.00
Truffle Capital	Sale	July 11, 2017	2,082	€55,288.76
Truffle Capital	Sale	July 12, 2017	463	€12,239.31
Truffle Capital	Sale	July 13, 2017	866	€22,929.77
Truffle Capital	Sale	July 14, 2017	329	€8,735.02
Truffle Capital	Sale	July 17, 2017	997	€26,486.90
Truffle Capital	Sale	July 18, 2017	823	€21,830.49
Truffle Capital	Sale	July 19, 2017	1,214	€32,123.90
Truffle Capital	Sale	July 20, 2017	1,603	€41,926.14
Truffle Capital	Sale	July 21, 2017	677	€17,612.76
Truffle Capital	Sale	July 24, 2017	934	€24,264.11
Truffle Capital	Sale	July 25, 2017	245	€6,413.44
Truffle Capital	Sale	July 26, 2017	663	€17,444.26
Truffle Capital	Sale	July 27, 2017	244	€6,467.17
Truffle Capital	Sale	July 28, 2017	300	€7,875.60
Truffle Capital	Sale	July 31, 2017	640	€16,623.81
Truffle Capital	Sale	August 1, 2017	600	€15,536.28
Truffle Capital	Sale	August 2, 2017	548	€14,144.04
Truffle Capital	Sale	August 4, 2017	27	€694.71
Truffle Capital	Sale	August 18, 2017	812	€21,112.00
Truffle Capital	Sale	August 24, 2017	302	€8,021.15
Truffle Capital	Sale	August 25, 2017	138	€3,669.17
Truffle Capital	Sale	October 6, 2017	3,543	€81,481.91
Truffle Capital	Sale	October 9, 2017	952	€22,875.13
Truffle Capital	Sale	October 30, 2017	5,000	€132,883.50
Truffle Capital	Sale	October 31, 2017	5,000	€125,934.00
Truffle Capital	Sale	November 1, 2017	5,000	€126,547.50
Truffle Capital	Sale	November 2, 2017	2,000	€49,462.80
Truffle Capital	Sale	November 3, 2017	1,000	€24,748.10
Truffle Capital	Sale	November 6, 2017	1,000	€24,697.50
Truffle Capital	Sale	November 7, 2017	1,000	€24,451.70
Truffle Capital	Sale	November 8, 2017	166	€4,027.91
Stéphane Piat	Sale	December 13, 2017	3,908	€77,691.04
Stéphane Piat	Acquisition	December 14, 2017	1,004	€20,080.00

Sales and acquisitions made by executives and their relatives on the Company's shares in during the 2017 financial year, as declared by these leaders and their relatives in accordance with the provisions of Articles 223-22 A and 223-26 of the the AMF, would cover a total of 214,311 shares and 5,699 shares respectively.

Persons concerned	Type of operations	Total number of shares	Total amount related to the transactions
Truffle Capital	Sales	214,311	€5,804,071.10
Stéphane Piat	Sale	3,908	€77,691.04
Stéphane Piat	Acquisitions	1,791	€42,165.70

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.

As at December 31, 2017, as far as the Company is aware, employees and managers (including ARSFAC, represented by Professor Alain Carpentier) held 7.4% of the Company's share capital.

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 period ended December 31, 2017, the Company made the following dealings 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 general meetings of June 28, 2016 (Resolution 5) and of April 27, 2017 (Resolution 12):

- purchase of 143,661 shares at an average price of €25.90;
- sale of 145,631 shares at an average price of €26.08.

As at December 31, 2017, the Company held 2,206 treasury shares, i.e. 0.02% of the share capital, acquired at a total purchase price of €43,670.

These disposals of treasury shares performed under the liquidity agreement resulted in a net loss of €44,115.

SECURITIES GIVING ACCESS TO CAPITAL

In total, these securities confer subscription rights to 943,025 new shares (10.5% of the existing capital as at December 31, 2016), which includes 103,9255 shares at a unit price of €8, 34,000 shares at a unit price of €108.48, 6,700 shares at a unit price of €122 and 12,000 shares at a unit price of €30.10.

For details on the securities giving access to the Company's capital and in force, see Paragraph 5.2.5 « Other securities giving access to 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 REGULATED AGREEMENTS

5.6.1 REGULATED AGREEMENTS DESCRIPTION

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 will 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. 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 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 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 –Indice du Prix à la Production de l'Industrie et des Services aux Entreprises – Matériel médicochirurgical et d'orthopédie-exportation zone Euro – Code PVIC 3310921007M (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 renewed in 2014 and in 2015. Under the terms of this agreement, the Company committed to repay to ARSFAC all the costs mentioned in the appendices to said agreement. For 2017, no expenses were recorded under this agreement.

RELATIONS BETWEEN CARMAT AND THE MARIE LANNELONGUE 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 2017, no expenses were recorded under this agreement.

5.6.2 SPECIAL REPORT OF THE STATUTORY AUDITORS ON THE REGULATED AGREEMENTS

CARMAT SA
36, Avenue de l'Europe
78941 Vélizy-Villacoublay cedex

To shareholders,

As auditors of your company, we present to you our report on regulated agreements.

It is our responsibility to communicate to you, on the basis of the information given to us, the characteristics and the essential terms and the reasons justifying the interest for the company of the agreements of which we have been informed or which we would have discovered at the time. opportunity of our mission, without having to pronounce on their usefulness and their merits nor to seek the existence of other conventions. It is your responsibility, under the terms of Article R. 225-31 of the French Commercial Code, to assess the interest involved in concluding these agreements with a view to their approval.

In addition, it is our responsibility, if applicable, to provide you with the information provided for in Article R. 225-31 of the French Commercial Code relating to the execution, during the past financial year, of agreements already approved by the general meeting.

We have performed the due diligence that we have deemed necessary in light of the professional standards of the National Company of Auditors relating to this engagement. These procedures consisted in verifying the concordance of the information given to us with the basic documents from which it came.

AGREEMENTS SUBMITTED FOR THE APPROVAL OF THE GENERAL MEETING

We inform you that we have not been given notice of any agreement authorized during the past financial year to be submitted for the approval of the general meeting in application of the provisions of Article L. 225-38 of the Code. of business.

AGREEMENTS ALREADY APPROVED BY THE GENERAL MEETING

Agreements approved in previous years

a) without execution during the past financial year

Pursuant to Article R.225-30 of the French Commercial Code, we have been informed of the continuation of the following agreements, which have already been approved by the General Meeting in previous financial years, and which have not been enforced during the past financial year.

RESEARCH COLLABORATION AGREEMENT WITH THE SCIENTIFIC RESEARCH ASSOCIATION OF THE ALAIN CARPENTIER FOUNDATION (ARSFAC)

A medical collaboration contract had been concluded with ARSFAC as of January 1, 2014, and included animal training trials. Under the terms of this agreement, your company undertakes to reimburse the costs incurred by ARSFAC as described in the appendix to the said contract.

No expenses were recorded under this agreement in 2017.

ARSFAC is represented by Alain Carpentier, director of your company.

RESEARCH COLLABORATION AGREEMENT WITH THE MARIE-LANNELONGUE SURGERY CENTER (CCML)

A collaboration contract for the training of clinical teams had been concluded with the CCML as of January 1, 2014. Under the terms of this agreement, your company undertakes to reimburse the costs incurred by the CCML as described in the appendix to the said contract.

No expenses were recorded under this agreement in 2017.

Mr. Henri Lachmann, director of your company, is Chairman of the CCML Board of Directors.

ROYALTIES AGREEMENT BETWEEN CARMAT («COMPANY»), PROFESSOR ALAIN CARPENTIER 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 Contract, 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 expiry of the patents presented in Appendix 1 of the Contract.

The Company is also authorized to redeem at any time the right to benefit from these royalties for an amount of € 30,000,000 reduced by the royalties already paid under this contract, this total amount being divided between the two beneficiaries in proportion to their respective share in the capital of the Company on the date of its creation. This amount of 30,000,000 euros is indexed to the Producer Price Index of the Business Services Industry - Euro-area orthopedic and orthopedic equipment.

The rights thus allocated to Professor Alain Carpentier and Matra Défense are not transferable.

As at December 31, 2017, the marketing of the CARMAT Artificial Heart did not begin, no royalty was paid by the Company under the Contract.

Signed in Neuilly-sur-Seine and Paris,
Tuesday, March 20, 2018,

The statutory auditors

PRICEWATERHOUSCOOPERS AUDIT	LISON CHOURAKI AUDIT
THIERRY CHARRON	LISON CHOURAKI

6

SUPPLEMENTARY INFORMATION

6.1 AUTHOR OF THE REGISTRATION DOCUMENT

6.1.1 NAME OF THE AUTHOR OF THE REGISTRATION DOCUMENT

Stéphane Piat, CARMAT's chief executive officer, is the author of the registration document.

6.1.2 DECLARATION OF THE AUTHOR OF THE REGISTRATION DOCUMENT

"Having taken all reasonable steps to verify the contents of this registration document, I affirm that the information contained therein is accurate to the best of my knowledge, and that no material information has been omitted.

I confirm, to the best of my knowledge, that 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 situation and results, and that the information contained in the management report, for which a cross-reference table appears at paragraph 6.7.2 of this document: "Cross-reference table of the annual financial report", gives a true and fair picture of changes to the business, results and financial situation of the Company and a description of the principal risks and uncertainties faced by the Company.

I have obtained a completion letter from the Statutory Auditors, in which they state that they have verified the information concerning the financial situation and the financial statements set out in this registration document, and that they have read the entire registration document.

The financial information for the year ending December 31, 2017 set out in this Document de Référence was the subject of the auditors' report which appears in paragraph 3.3 of this registration document, and which contains no observations.

The historical financial information as at December 31, 2015 and December 31, 2016 that is incorporated by reference into the present registration document was previously presented in the 2015 registration document and the 2016 registration document, which were filed with the Financial Markets Authority respectively on March 29, 2016 under number D.16-0221 and on March 22, 2017 under number D.17-0200, and was the subject of reports by the statutory auditors which contained no observations."

Vélizy, Wednesday March 21, 2018

Stéphane Piat

Chief executive officer, CARMAT

6.2 STATUTORY AUDITORS

6.2.1 STATUTORY AUDITORS IN OFFICE

PricewaterhouseCoopers Audit, member of the Regional Auditors' Association of Versailles.

Represented by Mr Thierry Charron

63, rue de Villiers – 92200 Neuilly-sur-Seine

Date of commencement of duties: appointed upon the incorporation of the Company on June 25, 2008.

Duration of current term: 6 financial years, following renewal of the mandate at the general meeting of June 24, 2015.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2020.

Lison Chouraki Audit, member of the Auditors' Association of Paris

Represented by Ms Lison CHOURAKI

3, rue Anatole de la Forge – 75017 Paris

Date of commencement of duties: Wednesday, June 24, 2015.

Duration of current term: 6 financial years.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2020.

6.2.2 ALTERNATE AUDITORS

Mr Jean-Christophe GEORGHIOU, member of the Regional Auditors' Association of Versailles

63, rue de Villiers – 92200 Neuilly-sur-Seine

Date of commencement of duties: Wednesday, June 24, 2015.

Duration of current term: 6 financial years.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2020.

Ms. Soulika BENZAQUEN, member of the Auditors' Association of Paris

5, rue de Prony – 75017 Paris

Date of commencement of duties: October 16, 2008.

Duration of current term: 6 financial years, following renewal of the mandate at the general meeting of June 24, 2015.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2020.

6.2.3 STATUTORY AUDITORS WHO RESIGNED, WERE DISMISSED OR WERE NOT REINSTATED

Since their appointment, the statutory auditors and their substitutes have not been dismissed from their positions, nor have they resigned.

6.3 INFORMATION FROM THIRD PARTIES, DECLARATIONS BY EXPERTS AND DECLARATIONS OF INTEREST

None.

6.4 PUBLICLY ACCESSIBLE DOCUMENTS

Copies of this registration document are available free of charge from the Company and from the Company's website (www.carmatsa.com) and from the website of the French Financial Markets Authority (www.amf-france.org).

All documents which must be made available to shareholders (such as the articles of association, minutes of general meetings, historical financial information and the valuations and declarations made by an expert at the Company's request included or referred to in this registration document) may be consulted at the Company's registered office at 36, avenue de l'Europe – 78140 Vélizy-Villacoublay.

All regulatory information, as defined in Article 221-1 of the General Regulations of the AMF, is available on the Company's website.

6.5 INFORMATION ON HOLDINGS

As at the date of this registration document, the Company did not have any holdings in the share capital of other companies.

6.6 RECENTS EVENTS

Since the end of the 2017 financial year, the Company has published the following press releases:

- On February 13, 2018, a press release entitled: 2017 annual results.
- On February 20, 2018, a press release entitled: CARMAT advances the internationalization of the pivotal study and obtains the approval to perform implants in Denmark.

The full text of these press releases may be viewed on the Company's website, http://www.carmatsa.com/fr/investisseurs/documentation/communiques-de-presse.

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

6.7 CROSS-REFERENCE TABLES

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6.8 GLOSSARY

Accident vasculaire cérébral (AVC)
Sudden neurological deficit of vascular origin caused by an infarctus or a 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 ANSM. One of two authorizations required to carry out biomedical research on humans in France, the other being that of the Ethics 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 judges and monitors the safe use of health products, examines their quality in the laboratory and inspects their production, distribution and testing sites. It

also produces information campaigns to ensure the correct use of health products. It was replaced by the ANSM (see corresponding entry) through law n° 2011-2012 of December 29, 2011.

Annuloplasty
Intervention with the aim of correcting a mitral insufficiency linked to an expansion of the mitral annulus.

ANSM
French National Agency for Medicines and Health Products Safety (Agence nationale de sécurité du médicament et des produits de santé – ANSM). This is a French public institution whose objective is to evaluate the health risks of health products for humans. It has authority over the regulation of biomedical research.

Platelet antiaggregant
Drug preventing the blood platelets, which are partly responsible for the coagulation phenomenon (see corresponding entry) of blood, from sticking together and forming the beginning of a clot. The most well known is aspirin.

Anticoagulant
Drug limiting blood-clotting to avoid the formation of clots by acting on coagulation factors other than platelets (see previous entry). Their dosing is complicated: too much risks hemorrhages, not enough risks thromboembolic accidents. Their use at high doses is required for all implantable metallic or plastic devices which are not hemocompatible and are the source of many complications.

Aorta
The aorta is the largest artery of the body and allows oxygenated blood to be supplied from the left ventricle to all parts of the body.

Pulmonary artery
Arteries that carry blood from the heart to the lungs.

Betablockers
Drugs which reduce the cardiac rhythm and output to decrease blood pressure.

Bioprosthetic (valve) or bioprosthesis
Artificial valve manufactured from animal tissues in order to replace a failing heart valve. By extension, it refers to a medical device containing biological components.

Bpifrance
French public investment bank – Banque Publique d'Investissement française (which has incorporated the activities of Oseo Innovation, e.g. ANVAR, aiming to promote innovation through financial guarantees and partnerships).

Cardiogenic shock
Inability of the myocardial pump to generate a blood flow rate sufficient for the peripheral organs.

Coagulation (blood)
Phenomenon of blood clot formation. It is the body's normal reaction to stop a hemorrhage. Nevertheless, when clots form in the heart, a blood vessel or in a device, they may obstruct a blood vessel and can cause a pulmonary embolism or cerebrovascular accident

Total orthotopic artificial heart
Artificial cardiac prosthesis (or total artificial heart – TAH) intended to completely replace the natural heart. It is different from ventricular assistance which functions in parallel to the diseased heart.

Critical Event Committee (CEC)
Committee consisting of members who are totally independent of the sponsor and study investigators, established as part of the ISO 13485 standard and the Good Clinical Practice (GCP) guidelines: its role is to review all adverse events, serious or otherwise, and to determine their causal link with the device under investigation.

Ethics Committee (Comité de Protection des Personnes – CPP)
Ethics committee whose role is to ensure that all biomedical research projects on humans carried out in France complies with the various considerations (medical, ethical and legal) aimed at ensuring the protection of the persons participating in the research.

Safety Committee (DSMB)
DSMB: Data Safety and Monitoring Board.
Committee consisting of members who are totally independent of the sponsor and study investigators, established as part of the ISO 13485 standard and the Good Clinical Practice (GCP) guidelines: its role is to review all study data and to issue an opinion to the sponsor on whether to continue with inclusions in the clinical study.

Compliance
In medical terms, the ability of an organic cavity to change volume under the influence of a variation in pressure.

Research Tax Credit (RTC)
Financial aid created to encourage research and development efforts in companies.

Diastole
Relaxation phase of the muscle of a cardiac cavity that allows it to be filled.

Diuretic
Drug to remove excess fluids and, in this way, lighten the load on the heart and prevent pulmonary edema.

Pulmonary embolism
Situation where a blood clot blocks a pulmonary artery.

Ex vivo
Refers to tests which are performed on cadavers (see In

vivo).
Etiology Medical field which studies and analyses the causes of diseases.

FDA – Food & Drug Administration.
American regulatory agency that authorizes the marketing of drugs and medical devices in the United States.

Altered ejection fraction:
Is termed terminal chronic heart failure affecting a patient whose ejection capacities are reduced to less than 40%.

HDE – Humanitarian Device Exemption
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 an HUD (Humanitarian Use Device : Device for compassionate use). 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
The biological compatibility quality of non-living materials used in a medical device in contact with blood and other biological organs.

Hemolysis
Destruction of red corpuscles with the release of hemoglobin into the blood plasma, thus reducing the capacity to transport oxygen.

HUD
See HDE.

Hyperlipidemia
Pathology referring to the dysfunctions caused by an increased level of fat in the blood.

High blood pressure
Cardiovascular disease characterized by an arterial pressure greater than the norm and causing an increase in the left ventricular volume.

Hypertrophy
Excessive growth of an organ or an element of the body.

IDE – Investigational Device Exemption
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 a PMA.

Immunosuppressant
An agent that limits the immune reactions of the organism in order to reduce the rejection risks following the transplantation of a graft. The most well known is cyclosporin.

Incidence
The number of new cases of a disease observed during a given period and in a determined population. It differs from the prevalence, which is a status measurement which counts all the cases (new or not) at a given time.

Myocardial infarction
Necrosis (death) of part of the cardiac muscle. In plain language, heart attack. It occurs when one or more coronary arteries become blocked so that the cells of the myocardium (the muscle that makes up the heart), irrigated by this artery (or these arteries), are no longer oxygenated, thereby causing them to suffer (pain felt) and possibly resulting in their death.

Angiotensin-converting enzyme (ACE) inhibitors
Drugs reducing vascular resistance.

Inotrope
Drug increasing the contractility of the cardiac muscle. Dependence on inotropes marks the terminal phase of heart failure.

In silico
Refers to tests which are performed on computers and/or by digital simulation.

Acute cardiac insufficiency
Sudden incapacity of the heart to provide a sufficient blood flow to deal with the oxygen needs of the various 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 decompensation).

Chronic cardiac insufficiency
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 cardiac insufficiency are angina and myocardial infarction, high blood pressure, valvular disease and degenerative diseases of the myocardium. In each of these cases, the result is the progressive destruction of the cardiac muscle with loss of its contractile power.

In vitro
Refers to tests which take place outside of the organism, in the laboratory or on a test bench. Originally, these tests were carried out in glass tubes.

In vivo
Refers to tests which are performed in living organisms. (also see ex vivo)

Ischemia
Decrease of the arterial blood flow to an organ.

Coronary disease
Decrease in the power of one or more arteries of the heart

(or coronary arteries) and brings about angina and myocardial infarction (or heart attack).

CE marking
A declaration from the manufacturer certifying that the product complies with the applicable legal requirements and with the European directives (meeting a number of safety, efficacy and traceability of manufacture, etc. conditions).

Mitral (valve)
Cardiac valve which separates the left auricle from the left ventricle.

New York Heart Association (NYHA)
A scale based on symptoms that aims to quantify and monitor the functional impact (on activity) of cardiac insufficiency for an individual.

ISO standard
Standard created by the International Organization for Standardization (ISO) in order to guarantee reliable and good quality products and services.

Pulmonary edema
Invasion of the pulmonary alveoli by blood plasma that has passed through the wall of the capillaries (small vessels). Acute pulmonary edema (APE) is an absolute emergency and the common consequence of cardiac decompression.

Medical Board
Professional, administrative and legal body for the defense and regulation of the medical profession in France.

Auricle (atrium)
One of two small upper cavities in the heart which receives blood before passing it into the corresponding ventricle. Each auricle 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 pericardium
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, glutaraldehyde. It is known to be the least thrombogenic biomaterial and does not bring about the rejection phenomenon.

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.

PMA – Post Market Approval
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)
The software used to create and maintain the definition of products throughout their life cycle, from the issuing of the quotation until the end of its life. PLM covers the management of the definition of products, including configuration management, development management 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 by polymerization.

Proteinic Concerning proteins.
PulsatileAnimated by rhythmic pulsations of the heart beat.

Clean room
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. Parameters such as temperature, humidity and relative pressure are also maintained at a precise level.

Whole human blood
This is blood with all its constituents, in particular plasma, red corpuscles, white corpuscles and platelets.

Septicemia
Serious generalized infection of an organism due to the discharges of pathogenic bacteria in the blood.

HIL simulator
A real time simulator that makes the computers believe they are navigating the actual system (Hardware in the Loop test principle).

Stasis
In medical terms, this refers to the abnormal stagnation of blood in an organ.

Systole
Phase of contraction of the muscle of a cardiac cavity

allowing ejection of the blood it contains.

Telemetry
Means of monitoring certain biological, particularly cardio-respiratory, parameters or technical parameters, at a distance.

Thrombosis
Obturation, through the formation of a clot (thrombus), of an arterial or venous blood vessel or of a cardiac cavity (embolism). The blood no longer flows and the organs are no longer supplied with it.

Thromboembolic
Ailment characterized by the formation of coagulated blood clots in veins (thrombus) which, upon detaching, risk causing embolisms (sudden blockages of blood vessels).

Thrombogenic, thrombogenicity
Refers to causing a thrombus (blood clot).

Destination therapy
Definitive implantation – Destination Therapy, as opposed to the pending transplantation indication (Bridged Therapy) Transplantation Surgical operation consisting of replacing a diseased organ with a healthy one.

Vasodilator
Drug which relaxes the blood vessels to increase the blood and oxygen flow to the heart without increasing its workload.

Design and production:
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