
CARMAT

# 2020 Universal Registration Document

Including the Annual Financial Report

## GENERAL REMARKS

In this Universal Registration Document, the terms “Carmat” or the “Company” shall mean Carmat.

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

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

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

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

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

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

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

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

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

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

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


The original version of this Universal Registration Document (URD) in French was filed with the French financial markets authority (Autorité des marchés financiers – AMF) as competent authority under Regulation (EU) 2017/1129 without prior approval pursuant to Article 9 of said Regulation. The English version of the Universal Registration Document has been prepared for the convenience of English-speaking readers, and is a free translation of the original French. It is intended for general information only and in the event of discrepancies, the French original shall prevail.

The Universal Registration Document may be used for the purposes of an offer to the public of securities or admission of securities to trading on a regulated market if approved by the AMF, together with any amendments, if applicable, and a securities note and summary approved in accordance with Regulation (EU) 2017/1129.

# CONTENTS



Items included in the Annual Financial Report are clearly identified in the table of contents by the symbol*.
Items included in the Corporate Governance Report are available in sections 4.1, 5.6, 5.2.6 and 4.4.3.

# Q&A WITH THE CHAIRMAN

## JEAN-PIERRE GARNIER

**Just two years after your appointment as Chairman, Carmat obtained CE marking. How satisfying was that for you?**

As I have already said in previous interviews, I have always believed that Carmat would achieve the challenge laid down by Professor Carpentier more than 30 years ago, and my belief has only strengthened over the years.

For me, this success is based on two key factors. The first is that no mechanical circulatory support device has ever achieved the level of sophistication of the Carmat heart. It is a distillation of technology that has been developed by the best cardiologists and the best engineers from various sectors, including the aerospace industry. The second factor is the people who make up Carmat's outstanding workforce. Carmat has dozens of employees and consultants with a remarkable array of skills, who are entirely devoted to this artificial heart project, which is not only a groundbreaking technological innovation, but also has a strong emotional dimension to it.

I would therefore like to applaud their commitment, especially as 2020 was a particularly challenging year for the reasons we all know only too well. Achieving our shared objective in such an unusual year can only be a source of satisfaction.

**Now that you are on the brink of the sales and marketing phase, your experience will no doubt be of great benefit to Carmat?**

Yes, in fact, during my career I have held a number of management positions, mainly in companies with a well-established sales and marketing activity. So I am delighted to reach this stage with Carmat and I am confident that Aeson®'s rolling launch across Europe will be a success. We have a very clear and carefully considered launch strategy. In 2021, we want to focus on markets that have the greatest therapeutic needs in Europe, and we worked on the reimbursement strategy well ahead of obtaining CE marking. Given our progress to date, I believe that we will be ready to make our first sales in Germany in the second quarter of 2021. Our approach in France will be different because Carmat will make its first sales there as part of the EFICAS study. As a result of our discussions with the French National Authority for Health (HAS) and the budget authorities in 2020, the cost of our artificial heart will be reimbursed within the framework of the "Forfait Innovation" program. So we have two countries with two different rollout strategies, which will help to secure our commercial development as soon as we launch.

Obviously we are already working on strategies for other European countries and in the short term we could also capitalize on other opportunities outside Europe in countries that recognize CE marking.

**Apart from marketing, what are Carmat's next challenges?**

First of all, I am delighted that we are gradually achieving the short-term and medium-term objectives we have set ourselves. One of my goals when I arrived was to make our artificial heart available to as many people as possible. I believe that with CE marking and our marketing rollout strategy in Europe, we are making considerable progress towards that objective.

Our next challenge is to move into the clinical phase in the United States. Here again, I prefer to take a methodical approach so that we can move quickly rather than hastily. The aim is to begin our trials in the United States under optimum conditions, with the most recent version of our artificial heart. We have therefore submitted protocol amendments to the FDA, which have already been approved. Admittedly, this has pushed back our first implantations in the United States by a few months, although we still expect them to be performed in the first quarter of this year. But I am convinced that, thanks to this decision, we will save time in the longer run.

Meanwhile, we have to continue investing in our production facilities to guarantee a flawless quality for our artificial heart, which will gradually be manufactured in longer runs to meet demand as and when Carmat addresses new markets.

I am delighted to be taking part in this new era for Carmat as a commercial company, and for Aeson®, which is an exceptional product unrivaled in the market today.

# MESSAGE FROM THE CEO

## STÉPHANE PIAT

**How would you describe 2020?**

2020 was the start of a new chapter for Carmat. On December 22, 2020, we obtained CE marking for the bridge to transplant indication, the culmination of years of efforts by all Carmat employees and everyone involved in the project. Once more, I wish to thank all those who have helped to make Professor Carpentier's vision a reality.

The Carmat heart, which we will market under the name Aeson®, is now within the reach of many patients who previously had no therapeutic options due to the shortage of available donor hearts. CE marking will enable us to sell Aeson® throughout the whole of the European Union and in some other countries such as Russia for example.

Professor Carpentier realized that medical expertise alone would not be enough to develop an artificial heart that could function almost identically to a normal human heart, and that a combination of leading-edge expertise would be required. By bringing together industry experts and new technology developers, backed by long-term investors, the Carmat project has become a one-of-a-kind venture in the medical world, including on a global level.

While there have been pitfalls on the way, we have learned how to act decisively in various fields over the last 12 months, despite the unprecedented crisis caused by the pandemic. Firstly, after constructive talks with the FDA, we obtained approval to conduct a feasibility study in the United States, which means that we will very soon be able to begin implantations there. The artificial hearts will also be reimbursed, which is a reflection of the high degree of confidence in our therapy. In France, we have obtained authorization from HAS to conduct EFICAS, an extensive clinical study that will be two-thirds funded by the French government and will bring Carmat its first sales in France in 2021. As regards the ongoing pivotal study, several significant milestones have been reached. For example, our bioprothestic heart has provided one of the patients enrolled in the study with continuous support for more than two years. Secondly, Denmark joined the study despite the pandemic and the first implantation was performed in the Copenhagen center. We also resumed the study in France with two implantations performed in December, bringing the total number of patients who have received implants under the study to 15.

Obtaining CE marking just before Christmas was the culmination of years of effort and the particularly eventful and intense year that was 2020.

**What are Carmat's objectives in 2021?**

Our long-term objective is, of course, to make Aeson® a commercial success. This will be achieved in several ways. Firstly, the launch of Aeson® in the second quarter of this year on two key European markets: Germany and France. These two countries between them represent 55% of the market for mechanical circulatory support devices in the European Union. It is therefore an important first step.

Secondly, we have to ramp up our production activities. I have said this before, and it is all the more important now that we have obtained CE marking – our challenge is not to create demand but to meet it. We therefore have to be capable of significantly ramping up the number of Aeson® hearts coming out of our Bois d'Arcy facility, with the help of our many suppliers and sub-contractors. At full operation, we should be able to manufacture 350 to 400 devices a year, which will almost certainly be enough during its first few years on the market, but this will have to be ramped up.

Lastly, we must continue to implement our clinical plan to collect more performance and safety data about our heart, and also to generate medico-economic data that will help us to develop and embed our therapy and make it easier to obtain national health coverage in various countries, including France.

In the longer term, we obviously want to address the US market and ultimately obtain approval of our heart as a destination therapy.

# PURPOSE AND VISION

Vision: Our vision is to become the primary alternative to heart transplants with the Carmat artificial heart implant.

Purpose: Our mission is to provide physicians with innovative technologies to save lives and improve the quality of life of patients with terminal heart failure.

The Company also aims to address a major public health challenge, heart failure, the leading cause of death worldwide. More specifically, Carmat aims to provide a lasting solution to the treatment of terminal heart failure, a disease for which there are very few effective options today, the main one being heart transplants.

Heart failure is a progressive disease affecting 20 million patients in Europe and the United States. Within this population, tens of thousands of people are terminally ill. Each year, there are only some 5,500 donor hearts available. The Carmat artificial heart provides a lasting solution to these patients with no further therapeutic options.

## MARKET

A fast-growing, high-potential market with more than 200,000 patients suffering from terminal biventricular heart failure each year

In Europe, more than 2,000 patients are currently on the waiting list to receive a heart transplant, including 700 in Germany and 900 in France

**ONLY 5,500 DONOR HEARTS AVAIL-ABLE PER YEAR**

## CARMAT TEAM

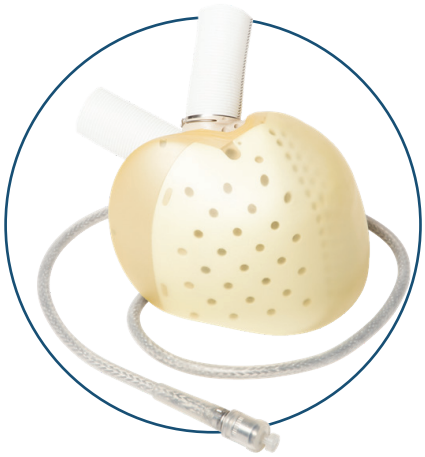
A multidisciplinary and highly qualified team of around 120 people

A Board of Directors chaired by Jean-Pierre Garnier, comprising ten directors, six independent directors and two internationally recognized cardiology experts

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

Board members as at December 31, 2020 (Alain Carpentier is Honorary President of the Company, Karl Hennessee and André Muller are missing from the photo)

# CARMAT PROSTHESIS



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

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

Prosthesis features:

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

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

# NEW FINANCING IN 2020

Financing **€23.0m**

In October 2020, Carmat obtained €13.0 million of funding from the French national innovation fund to conduct a clinical study (EFICAS) in France*

In November 2020, Carmat obtained a government-guaranteed syndicated loan of €10.0 million

* The funds will be received by Carmat as and when patients receive their implants during the EFICAS study.

# CORPORATE PROFILE

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

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

This unique partnership combines:

- the experience of more than 30 years of Professor Alain Carpentier, father of modern valvular heart surgery. Professor Carpentier developed treatments for biological animal tissues, which enabled him to design the most widely used biological valves in the world (Carpentier-Edwards® valves). He also developed restorative surgery and mitral valve annuloplasty* techniques used today all over the world, on the principle that a device must always be associated with a reproducible procedure;

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

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

The Carmat artificial heart project aims to offer a therapeutic solution to patients suffering from advanced biventricular heart failure, who are ineligible for or awaiting transplants, who have exhausted all treatment options or to whom no satisfactory solution is currently available.

The Carmat artificial heart (Aeson®) offers a unique combination of three key features:

- Hemocompatible: the only artificial heart whose surfaces in contact with blood are made using highly hemocompatible materials to reduce thromboembolic risks;

- Self-regulating: the first "smart" artificial heart to immediately and automatically adapt to the metabolic needs of the patient;

- Pulsatile: an artificial heart that produces blood flow and pressure profiles similar to those of the natural heart.

This unique combination offers the patient a better quality of life and makes Aeson® a genuine physiologic heart replacement therapy (PHRT)* which sets it apart from other available total artificial hearts (TAH).

* The PHRT therapeutic class was developed by Carmat and differs from the TAH class through its unique combination of three features: pulsatility, self-regulation and hemocompatibility. It can be used either as a temporary treatment (bridge to transplant or BTT) or as a long-term treatment (destination therapy or DT). The physiologic nature of Aeson® is documented in Richez U et al.; Hemocompatibility and safety of the Carmat Total Artificial Heart hybrid membrane. Heliyon. Dec. 2019; 5(12): e02914. Published online 2019 Dec 8. doi: 10.1016/j.heliyon.2019.e02914

**Carmat obtained CE marking* on December 22, 2020 enabling it to market its Aeson® artificial heart as a bridge to transplant in all countries that recognize the CE marking, which includes all European Union countries.**

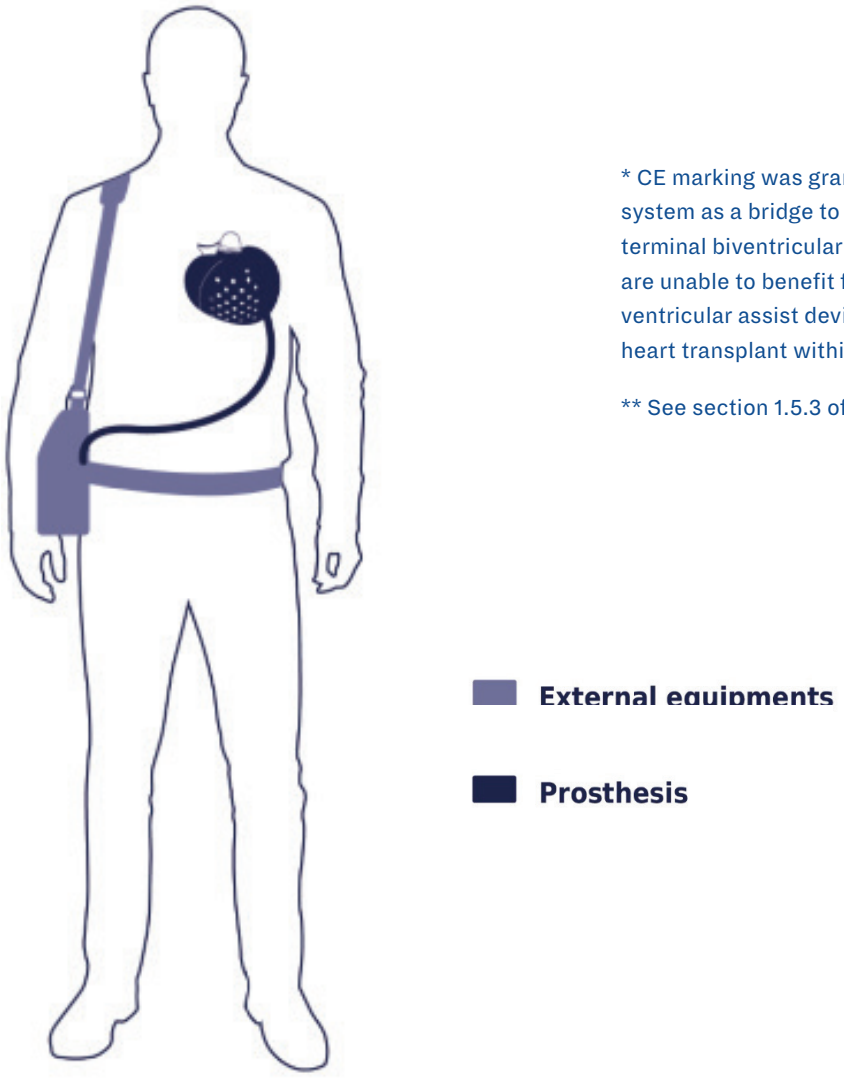
The Company intends to start marketing Aeson® in Europe in the second quarter of 2021, initially focusing on Germany.

Carmat also aims to obtain pre-market approval (PMA) over the next few years, which would allow the Company to market its artificial heart in the United States.

In this context, in February 2020, the Company obtained the FDA's full approval to conduct an early feasibility study (EFS) on ten patients in the United States. The study is due to begin in the first quarter of 2021. If it is successful, this study would be followed by a larger pivotal study to obtain PMA.

Meanwhile, Carmat continues to roll out a robust clinical plan** that includes the EFICAS clinical study in France (52 patients), finalization of the ongoing pivotal study (target of 20 patients) and broad post-marketing surveillance (PMS) which will include the first 95 patients treated in a commercial setting, in order to generate additional safety, performance and medico-economic data. These data should promote acceptance of the product and support Aeson®'s value proposition (particularly to obtain social security reimbursement for the product in France) and, ultimately, obtain indication for use as a destination therapy (DT). As the BTT indication is based on temporary use of the Carmat device, obtaining the DT indication would also enable Carmat to target patients who are not eligible for a heart transplant and would remain reliant on the Carmat device for much longer.

Carmat's clinical, industrial and commercial development will generate additional financial needs. Fundraising or other types of financing will therefore be required beyond the funding currently available to the Company.

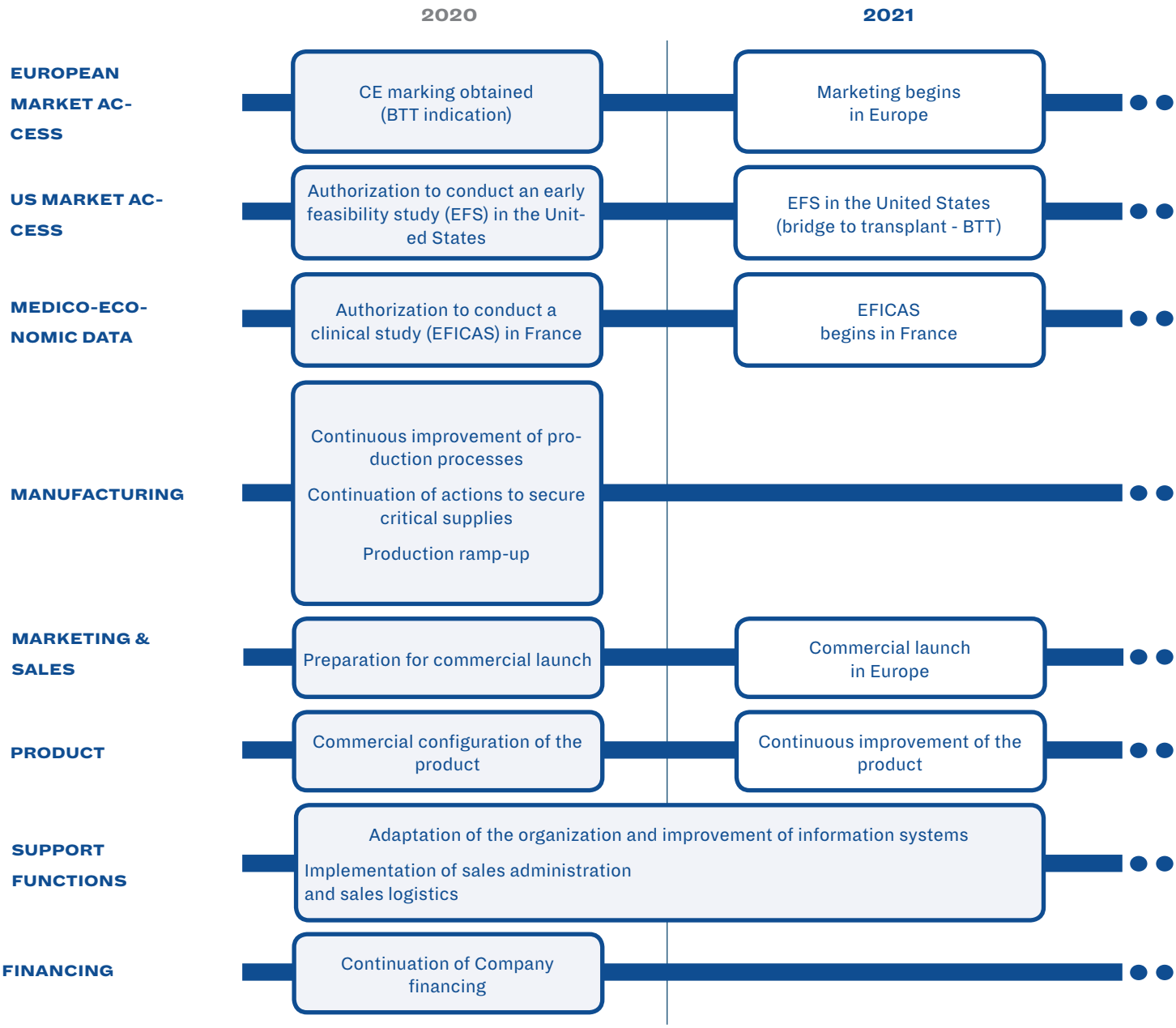



* CE marking was granted for Carmat's total artificial heart system as a bridge to transplant for patients suffering from terminal biventricular heart failure (Intermacs levels 1-4), who are unable to benefit from a maximum medical therapy or a left ventricular assist device (LVAD) and who are likely to be given a heart transplant within 180 days of receiving the implant.

** See section 1.5.3 of this document.

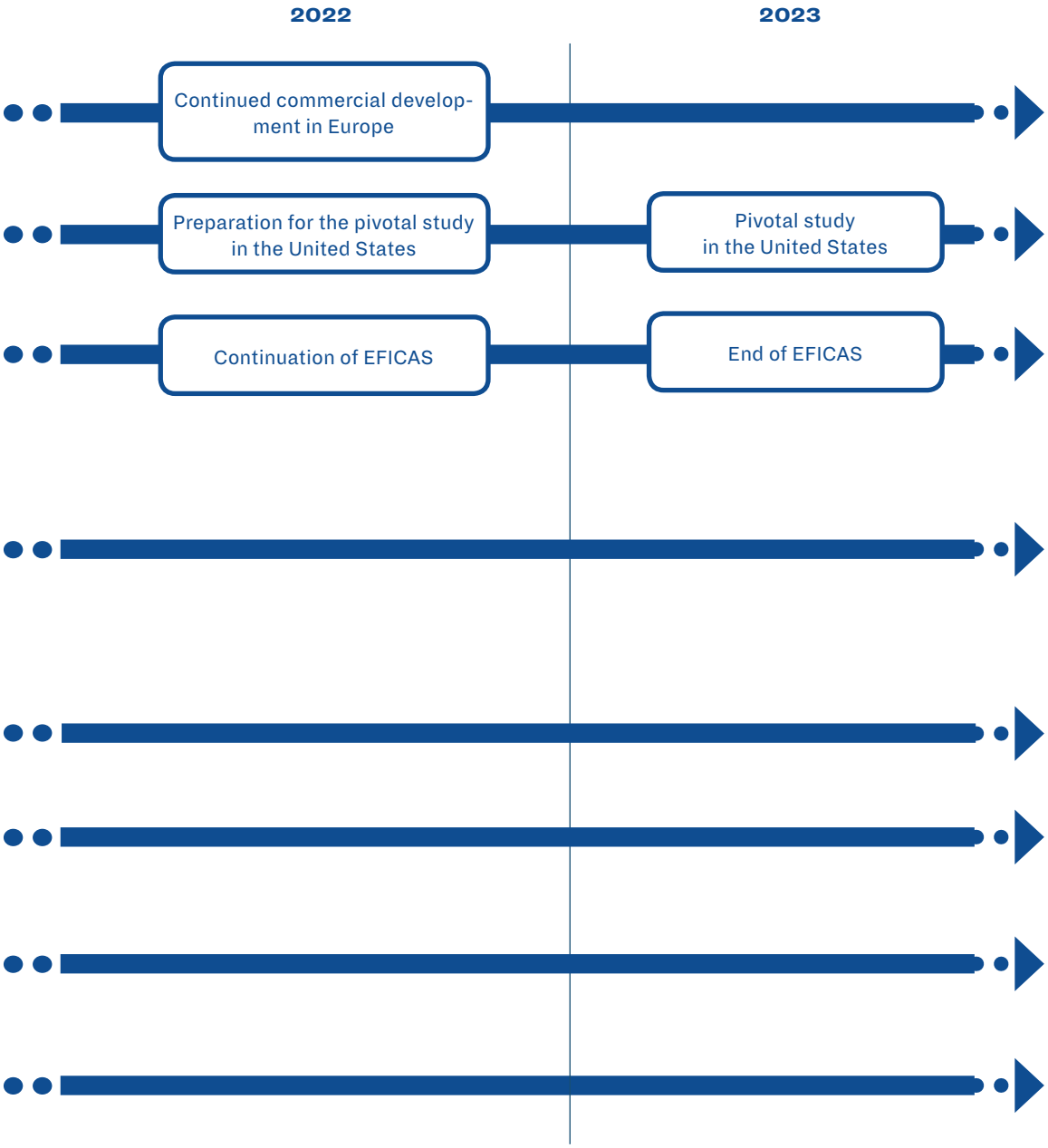
# CARMAT'S EXPECTED TIMELINE

**BUSINESS AREA**



Carmat's timeline has been updated as follows, insofar as compared with the timeline presented in the 2020 Universal Registration Document, the start date of the EFS in the United States has been postponed from 2020 to the first quarter of 2021, and the start date of the pivotal study planned in the United States from 2022 to 2023.

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




Source: Carmat - Expected timeline

# HISTORY OF THE COMPANY

## 2008

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

€33m

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

## 2009

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

## 2010

€16m

Capital increase of €16 million at the time of Carmat's flotation on Euronext's Alternext market in Paris.

Edwards

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

## 2011

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

## 2012

€29m

Capital increase of €29 million.

## 2013

EUROPEAN MEDISCIENCE AWARDS 2012

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

## 2014 - 2015

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

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

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

€50m

Carmat raises €50 million via a private placement, with the support in particular of certain historical shareholders as well as new investors.

## 2016

The fourth Carmat heart was implanted on December 22, 2015 as part of the feasibility study.

At the end of August, the first implantation under the pivotal study is carried out.

Stéphane Piat is appointed CEO to define and support Carmat's commercial strategy to address the market.

## 2017

Pivotal study extended in Europe (Kazakhstan and Czech Republic)

Discussions begin with the FDA in the United States to conduct a feasibility study.

## 2018

€53m

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

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

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

€30m

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

Banque européenne d'investissement

## 2019

€60m

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

## 2020

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

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

€10m

In November 2020, Carmat obtains a €10 million government-guaranteed loan.

€13m

In October 2020, Carmat obtains €13 million of funding from the French national innovation fund to conduct a clinical study (EFICAS) on 52 patients in France.

## 2021

**On December 22, 2020, CE marking obtained for the bridge to transplant (BTT) indication.**

Bridge to transplant experience published in the Journal of Heart and Lung Transplantation.

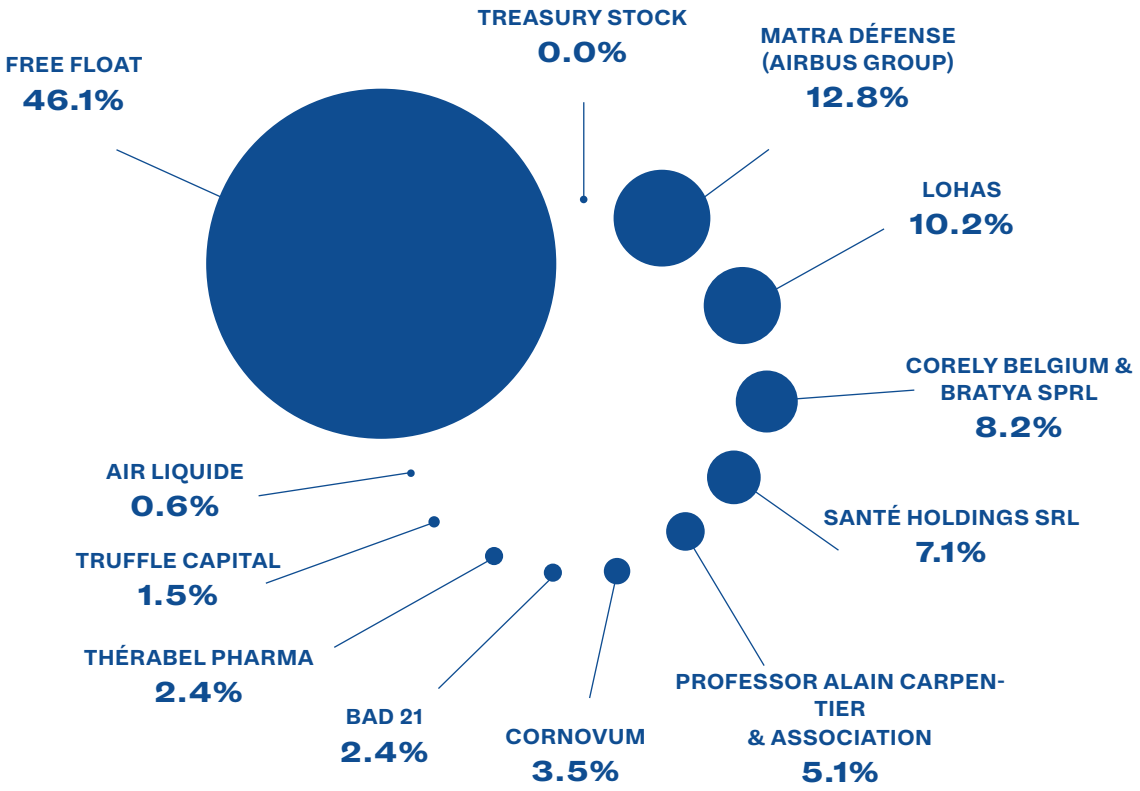
Final approval by the French National Authority for Health (HAS) of Carmat's "Forfait Innovation" application (EFICAS clinical study on 52 patients).

Approval from CMS (Centers for Medicare & Medicaid Services) in the United States for reimbursement of the device and associated services as part of the EFS.

# CARMAT AND ITS SHAREHOLDERS

## SHAREHOLDERS AS AT DECEMBER 31, 2020

(to the knowledge of the Company)




## ANALYSTS' COVERAGE

| Broker/Analyst | Opinion | Target share price | Date of opinion |
|---|---|---|---|
| Gilbert Dupont | Buy | €43.00 | February 10, 2021 |
| Portzamparc | Buy | €59.00 | December 24, 2020 |
| Oddo BHF | Buy | €39.00 | January 4, 2021 |
| Ladenburg-Thalmann | Buy | €38.25 | February 10, 2021 |
| Edison | -* | -* | January 11, 2021 |

* Edison does not give recommendations but only an assessment of the company (€747 million, i.e., €58.83 per share).

# INFORMATION ON THE CARMAT SHARE

| Market | Number of shares out-standing (Decem-ber 31, 2020) | Ticker & ISIN code | Share price & market capitaliza-tion (December 31, 2020) | Average trading volume (in 2020, over 12 months) | Status |
|---|---|---|---|---|---|
| Euronext Growth | 13,012,484 | ALCAR<br><br>FR0010907956 | €28.30/share<br><br>€368.3m | 17,807 shares/day | ELIGIBLE PEA PME |

# CONTACTS

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

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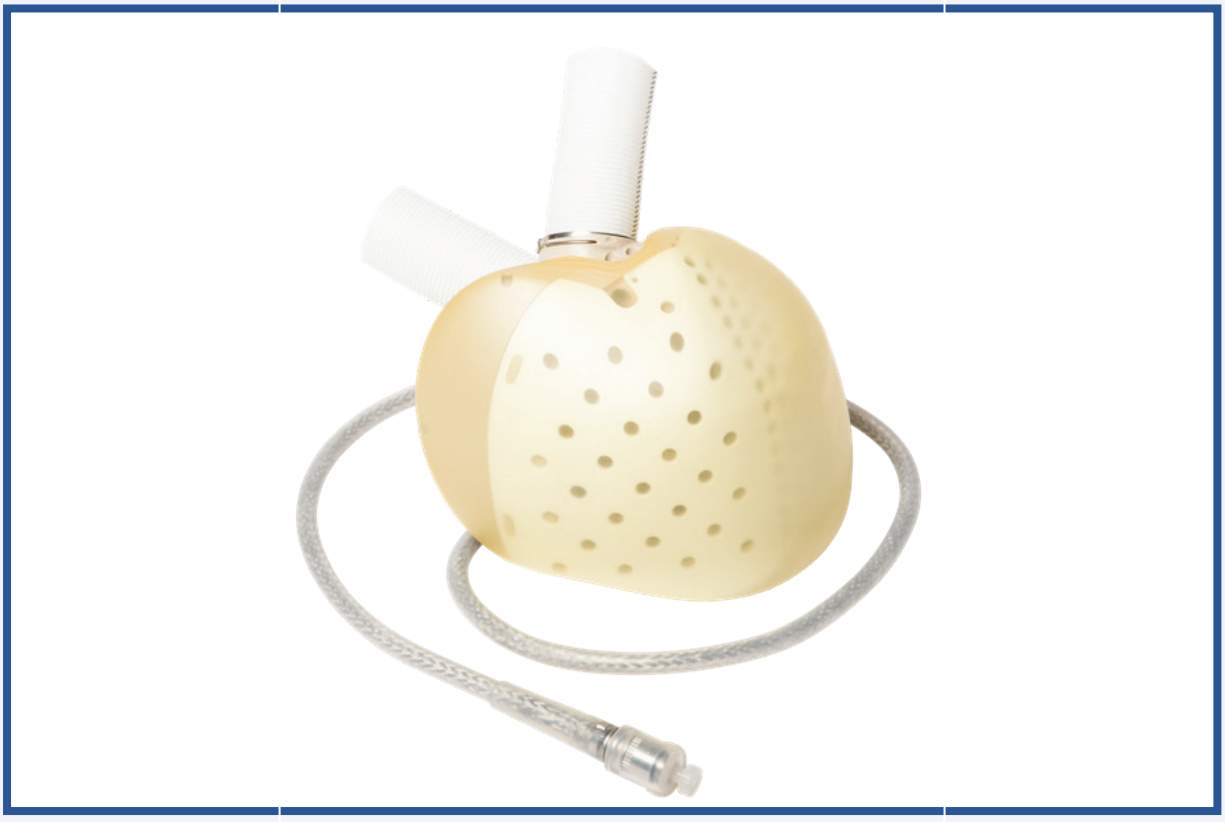
# 1

# BUSINESS OVERVIEW



# 1.1 HEART FAILURE

## 1.1.1 PATHOLOGY AND ETIOLOGY*

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

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

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

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

Major causes of heart failure

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

Heart failure can affect the heart in different ways:

- The most common failure affects the left ventricle (the main pumping chamber), which can fail in two ways. It may lose its ability to contract forcefully enough (systolic failure) or it may not relax enough, in order to fill properly (diastolic failure).

- In the event of right heart failure, the weaker right ventricle is unable to pump enough blood through the lungs and since the left side relies on receiving blood from the right side, the entire pumping action of the heart is compromised. The right ventricle has much less resilience than the left and can therefore fail more easily. Right heart failure is most often secondary to left heart failure, because blood volume increases as a result of a compromised left function. Right heart failure may also be secondary to lung disease or an acute event such as an allergic reaction, infection or a blood clot that lodges in the lungs. Up to 30% of patients whose left heart failure is treated with a left ventricular assist device (LVAD) develop right heart failure[01/02/03/04].

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

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

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

A shift to class III is a decisive moment[07]:

- for the patient: it marks the shift from a virtually normal life to considerably reduced activity, very often involving a loss of autonomy;

- clinically, this translates to more aggressive therapies, a dependence on drugs, and, with class IV, the start of repeated hospitalization;

- for society as a whole, this represents an explosion in costs, particularly due to hospitalization: a class IV patient costs the community up to 15 times more than a class II patient[08].

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

| NYHA | Class I | Class II | Class III | Class IV |
|---|---|---|---|---|
| Symptoms | No symptoms | Tiredness, palpitations, shortness of breath after a sustained effort | Symptoms and discomfort during minimal exertion | Symptomatic even at rest |
| Activity | No limitation | Slight limitation | Marked reduction | Inability to perform any activity, permanently confined to bed |

**01** 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.

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

**03** 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.

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

**05** Blackledge HM et al. Prognosis for patients newly admitted to hospital with heart failure: survival trends in 12,220 index admissions in Leicestershire 1993-2001. Heart. 2003; 89:615-620.

**06** Stewart S et al. More 'malignant' than cancer? Five-year survival following a first admission for heart failure. Eur J Heart Fail. 2001; 3:315-322.

**07** Launois R et al. Coût de la sévérité de la maladie ; le cas de l'insuffisance cardiaque. Journal d'économie médicale. 1990, T. 8, n° 7-8, p. 395-412.

**08** Kulbertus HE et al. What has long medical treatment to offer and what does it cost? Eur Heart J 1987 (suppl F) 26-28.

## 1.1.2 EPIDEMIOLOGY, PREVALENCE AND INCIDENCE

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

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

In Europe, the disease affects approximately 2% of the general population[11/12], i.e., some 15 million people in Europe[13/14]. Prevalence increases greatly with age[15]. A French epidemiological study has shown that it can affect nearly 12% of patients over the age of 60[16].

**09** Mosterd A, Hoes AW. Clinical epidemiology of heart failure. Heart 2007; 93:1137-1146.

**10** Global public health burden of heart failure. Card Fail Review 2017 Apr; 3(1):7-11. Doi: 10.15420/cfr.2016:25:2.

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

**12** Davies MK et al. Prevalence of left ventricular systolic dysfunction and heart failure in the Echographic Heart of England Screening Study: a population based study. Lancet 2001; 358:439-444.

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

**14** McMurray JJ et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. Eur Heart J 2012; 33:1787-1847 (number including the 51 member countries of the European Society of Cardiology).

**15** Conrad N, et al. Temporal trends and patterns in heart failure incidence: a population-based study of 4 million individuals. The Lancet. 2018; 391(10120):572-80.

**16** Saudubray T et al. Prévalence et prise en charge de l'insuffisance cardiaque en France : enquête nationale auprès des médecins généralistes du réseau Sentinelles. La revue de médecine interne 26 (2005) 845-850.

Table 1

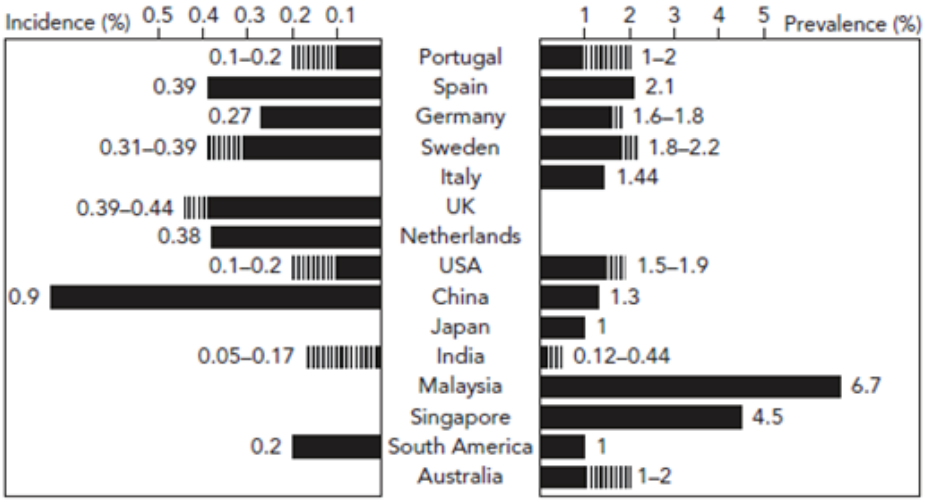
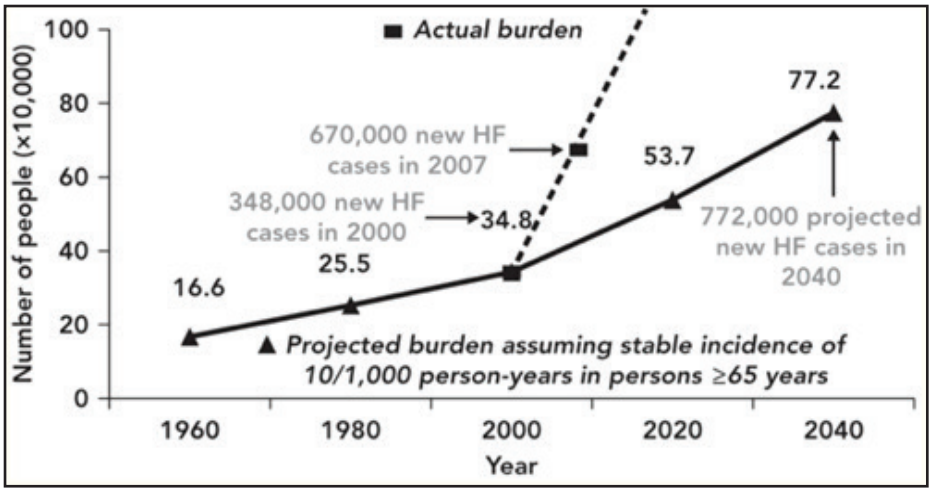



Table 2




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

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

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

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

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

**17** Heidenreich PA et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013; 6:606-619.

**18** The ECHOES study, Midlands, UK: Davies M, Hobbs F, Davis R, et al. Prevalence of left-ventricular systolic dysfunction and heart failure in the Echocardiographic Heart of England Screening study: a population based study. Lancet. 2001 Aug 11; 358(9280):439-44.

**19** CARLA study, Sachsen-Anhalt, Germany: Tiller D, Russ M, Greiser KH, Nuding S, Ebelt H, et al. (2013) Prevalence of Symptomatic Heart Failure with Reduced and with Normal Ejection Fraction in an Elderly General Population.

**20** Évaluation de l'assistance ventriculaire en attente ou en alternative à la transplantation cardiaque. Rapport de l'ANAES (Agence nationale d'accréditation et d'évaluation de santé) – Avril 2001 – E.

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

Heart transplants are currently only available to some 5,500 patients[23] per year, and durable Mechanical Circulatory Support (MCS) devices offer treatment to a further 8,000 patients, with variable results. This means that we currently do not have an effective therapy for the majority of patients. More than 30% of patients supported by a durable MCS device require biventricular support (see section 1.2.2).

**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.

**23** J Heart Lung Transplant 2019; 38:1056-66.

## 1.1.3 ECONOMIC CHALLENGES

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

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

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

There are no recent studies dealing with the cost of heart failure on a European level. As an example, the direct cost of advanced chronic heart failure in France amounted to some €1.5 billion[24] (€3.3 billion for the long-term condition class combining serious cardiovascular diseases – ALD 5 – in 2009, for the French health insurance system alone) and was reported to affect over 730,000 people in 2011 (a 9% increase compared to the previous year).

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

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

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

Overall, heart failure represents 2.5% of total healthcare expenditure in Western countries, with costs linked to hospitalization alone representing more than 70% of the total cost of the disease[25]. Due to repeated hospitalizations, class IV chronic heart failure represents between 61% and 92% of the total cost of heart failure[26].

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

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

## 1.1.4 AVAILABLE TREATMENTS

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

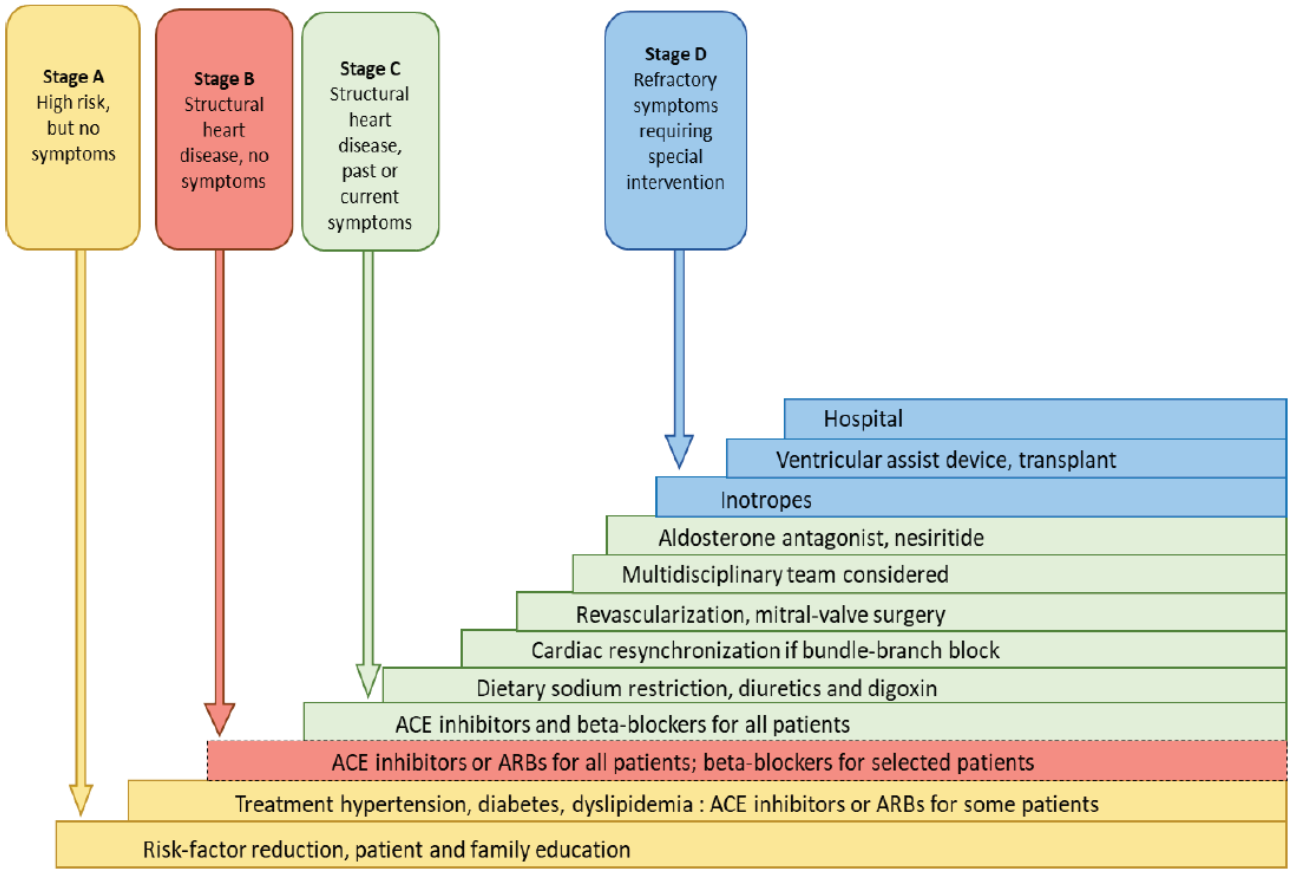
Heart failure can be classified based on its severity and associated treatment plans. In the chart below, four stages are identified, ranging from Stage A (high risk of developing heart failure) to Stage D (advanced heart failure)[27].

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

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

The four stages of heart failure and associated treatment plans

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




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

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

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

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

### MEDICATION

At early stages (typically classes I and II of the NYHA classification), treatment is essentially drug-based[28] and, depending on the severity and symptoms, combines:

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

The complexity of treatment and the need for frequent adjustments leads to low patient compliance: 40% of patients do not take their treatment correctly after three months[29].

Positive inotropes* are generally also introduced at the most advanced stage of the disease. These drugs, administered intravenously in hospitals, increase cardiac contractility and allow, at least temporarily, critical situations of low cardiac output in episodes of acute decompensated heart failure* or cardiogenic shock* to be resolved. Dependence on inotropes marks the terminal phase of heart failure with a mean survival of three and a half months[30].

### DEVICES

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

- mono or biventricular pacemakers to prevent arrhythmias;
- implantable defibrillators to treat ventricular tachycardia and prevent sudden death;
- left ventricular reconstruction;
- restrictive mitral annuloplasty*;
- implantable and non-implantable mechanical ventricular assist devices, and artificial hearts.

For the most part, these options seek to recover the native heart's function. For example, biventricular pacemakers aim to rehabilitate the ventricles by synchronizing their contractions.

Restrictive mitral annuloplasty aims to rehabilitate the left ventricle by helping to remodel its geometry. However, although these approaches temporarily provide relief to some patients, they do face major difficulties in terms of patient selection[31] or technical implementation[32], which restrict their scope of application and do not stop the progression of the disease.

Finally, the use of stem cells to regenerate damaged heart muscle is a promising research approach, but remains relatively controversial[33], in particular due to difficulties in collection, generation, administration (a large number of cells "die" during the injection), and the current lack of a clinical demonstration of long-term regeneration of the myocardium.

Mechanical right or left ventricular assist devices:

Mechanical ventricular assist devices (right - RVAD or left - LVAD) are devices that can be considered to have the closest function and indication to the Carmat artificial heart. Their characteristics and development are detailed in section 1.2.2 "Technologies and market players". However, unlike artificial hearts, which replace both ventricles, MCS leaves the diseased heart in place, which can continue to deteriorate.

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

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

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

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

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

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

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

Although LVAD is the most frequently recommended MCS intervention, up to 30% of these patients will suffer from a failure of both ventricles (biventricular failure), thus giving rise to suboptimal outcomes. For this reason, some practitioners in practice implant two LVADs (biventricular assist device or BiVAD), the only other solution being an artificial heart implant. However, given their drawbacks, these solutions are very few in number. For example, only 14 BiVADs and 15 Syncardia® artificial hearts were implanted in Germany in 2019. [34]

**34** ISHLT 2020 BiVAD Virtual

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

* ECLS: Extracorporeal Life Support (short-term system connected to patient by tubes).

** LVAD: Left Ventricular Assist Device.

*** TAH: Total Artificial Heart.

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

MCS strategies

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

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

## TRANSPLANTS

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

The mechanical ventricular assist devices available on the market (approved or pending approval) for this chronic destination therapy (DT) have unfortunately not obtained equivalent results to those of heart transplants, which remain the gold standard for these patients.

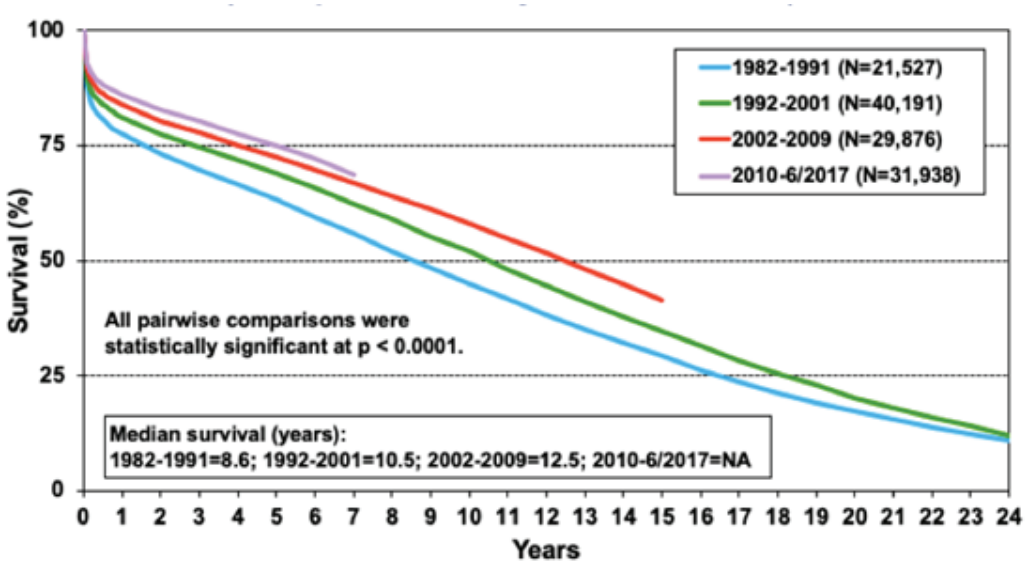
Professor Christian Bernard performed the first heart transplant in South Africa on December 3, 1967. The first transplant patients, with few exceptions, did not survive more than a few weeks after the operation, notably due to rejection (the host body's reaction against the transplant, which it considered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

Several major advances have increased patient survival:

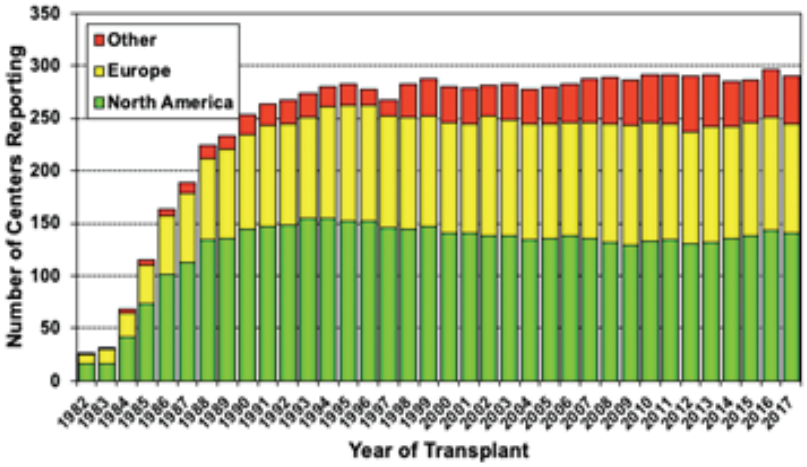
- the preservation of donor hearts thanks to refrigeration, allowing the removal at a distance from the place of transplantation;
- endomyocardial biopsy allowing early diagnosis of rejection: a probe is inserted, under radiological control and under local anesthesia, into a large vein and pushed until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

Today, some 5,500 transplants are carried out across the globe, with survival rates of 85% at one year and 69% at five years, in nearly 300 centers (see tables below). However, attrition rates do not improve significantly.

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




Survival rate after transplantation: ISHLT Registry 2018




Number of transplant centers worldwide: ISHLT Registry 2018

The first reason can be found in the very strict eligibility criteria both for harvesting the organ and the transplant. In theory, the donor[35] must be under the age of 61, brain dead, not a carrier of certain viruses such as HIV or hepatitis B and C, not be a drug addict or have a cancer and, of course, not be suffering from heart disease. This therefore limits the possibility of donation mainly to trauma deaths (in particular road accidents, which are constantly decreasing). Only 435 hearts were therefore harvested in France in 2012 and 397 were implanted[36].

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

In light of this organ shortage, the eligibility criteria of the recipient are even stricter[37] 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, kidney failure and morbid obesity.

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

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

In addition, post-transplant survival decreases significantly with age. Only 80% of patients over 60 are still alive after one month, and 67% after one year[38].

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

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

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

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

**37** 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.

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

| | France | United States | Germany | United Kingdom****** |
|---|---|---|---|---|
| Transplants | 450* | 3,244*** | 312***** | 177 |
| Patients on waiting list | 900** | 3,782**** | 700***** | 246 |

* 2018 – Agence de la biomédecine

** https://rams.agence-biomedecine.fr

*** 2017 – UNOS

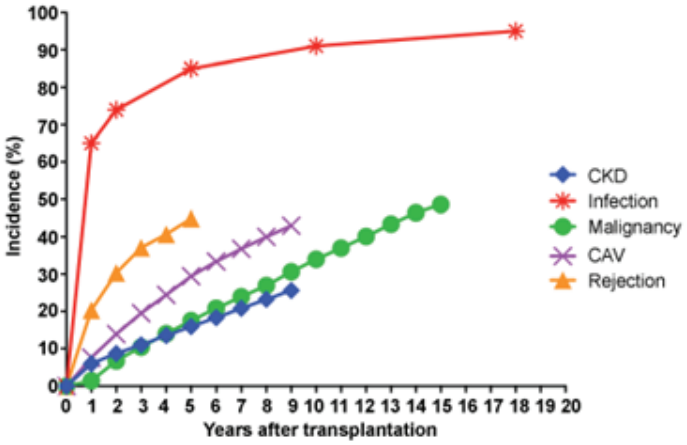
**** At January 17, 2019 – UNOS

***** 2018 – EuroTransplant

***** statistics.eurotransplant.org: 9023P_2019

****** 2017 – NHS Organ Donation Annual Report

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




Post-transplant complication rate:
Alba A Int J Tx Res and Med 2016.
CKD = chronic kidney disease; CAV = cardiac allograft vasculopathy.

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

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

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

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

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

# 1.2 ADDRESSABLE MARKETS AND MARKET PLAYERS

## 1.2.1 ADDRESSABLE MARKET FIGURES

Carmat eventually intends to market its artificial bioprosthetic heart for patients suffering from terminal class IV heart failure, according to the NYHA Classification, that is either chronic or ischemic heart disease (including "acute myocardial infarction", which is only a sub-group) in both the bridge to transplant indication, i.e., pending a transplant (see section 1.2.2 "Technologies and market players") and the destination therapy indication.

Bridge to transplant indication:

At this stage, Carmat has obtained CE marking for its artificial heart as a bridge to transplant. At end-2019, in the European Union alone, more than 2,000 patients were on the waiting list for a heart transplant, including some 700 in Germany[39] and 900 in France,[40] while for example only 14 BiVADs and 15 Syncardia® artificial hearts were implanted in Germany in 2019[41] (with similar figures in France).

Only a fraction of the patients potentially eligible for a heart transplant are actually registered on the waiting lists, mainly due to the notorious shortage of human donor hearts.

Destination therapy indication:

Chronic heart failure affects approximately 15 million European patients[42] and 5.8 million patients in the United States[43], i.e., a total of approximately 20.8 million patients in this geographical area.

Referring to the indications obtained by similar devices, the Carmat artificial bioprosthetic heart could be indicated

**39** statistics.eurotransplant.org: 9023P_2019.

**40** https://rams.agence-biomedecine.fr.

**41** ISHLT 2020 BVAD Virtual.

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

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

for patients under 70 suffering from acute or chronic terminal heart failure who cannot receive a transplant, without obvious contraindications such as cancer that reduce their life expectancy to less than six months.

Considering that:

- each year, 2.3% of these patients will reach the terminal stage of the disease, involving the first hospitalization, i.e., approximately 478,400 patients (including around 130,000 in Europe) [44];
- 38% of these people are under 70 years old, i.e., approximately 182,000 patients (including around 49,000 in Europe) [45/46];
- some 5,500 eligible patients receive transplants each year; and
- the anatomical compatibility of the Carmat heart for men and women is 86% and 14% respectively (with a weighting of 80/20 between men and women). Note that the available clinical data indicate that these compatibility rates could increase in the near future.

There are approximately 125,000 potential patients (including 33,000 in Europe) for the indication class IV terminal chronic heart failure.

**44** Jhund PS et al. Long-term trends in first hospitalization for heart failure and subsequent survival between 1986 and 2003: a population study of 5.1 million people. Circulation 2009; 119:515-523.

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

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

## 1.2.2 TECHNOLOGIES AND MARKET PLAYERS

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

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

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

These devices are indicated in two main cases:

- Pending transplants (bridge to transplant [BTT])

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

- Definitive treatment (Destination therapy [DT])

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

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

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

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

## VENTRICULAR ASSIST DEVICES [47]

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

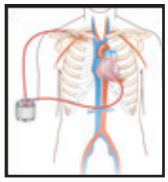
However, as their name indicates, they are implanted to assist the native heart by supplementing its flow, meeting metabolic needs, but not replacing it.

Categories of Ventricular Assist Devices (VAD)

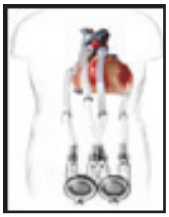
These devices can be categorized depending on their connection to the patient's vascular system (extracorporeal, paracorporeal, or intracorporeal):

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

Extracorporeal:
- Pump connected by long tubes
- Short-term support



Paracorporeal:
- Pump located outside body
- Medium-term support



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

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

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

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

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

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

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

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

The second-generation pumps were developed in the 1990s using rotary pump designs, after animal studies showed that the non-pulsatile flow and pressure profiles produced by this type of pumping action were compatible

with chronic survival. This allowed the pump size to be significantly reduced, and avoided the inclusion of valves. The most frequently used device of this design was the HeartMate II®. Results were significantly better than with first-generation devices and the small size resulted in an improved patient quality of life. However, chronic loss of a pulse produced coagulation and abnormal blood vessel development complications, as well as issues with infection.

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

### TOTAL ARTIFICIAL HEARTS (TAHS)

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

Syncardia

Until Carmat obtained CE marking for its artificial heart in December 2020, the only total artificial heart marketed in Europe and the United States was manufactured by the eponymous private company Syncardia.[48] After facing financial difficulties (“Chapter 11”), the company was financed by private equity fund Versa Capital Management in September 2016.

The Syncardia® device was designed in the 1970s and implanted for the first time in 1982 under the name Jarvik 7. The patient survived for 112 days. In 1985, a patient reached the transplant stage for the first time after surviving for nine days with the artificial heart. In 1990, the FDA closed Symbion, Inc., which held the rights for Jarvik 7 and stopped the ongoing clinical study (IDE*) due to regulation breaches. The technology was taken up again by the Health Sciences Center at University of Arizona under the name CardioWest™. A new clinical study restarted in 1992 in the United States and lasted ten years, resulting in FDA approval in 2004 for a bridge to transplant indication and CE marking. Meanwhile, a new privately funded company, Syncardia Systems, Inc., was created in 2001 to prepare and market the product[49]. Syncardia announced the 1,000$^{th}$ implantation of its artificial heart in February 2012, 19 years after the first implant in December 1982. Today, to our knowledge, the annual number of Syncardia implants is about 50.

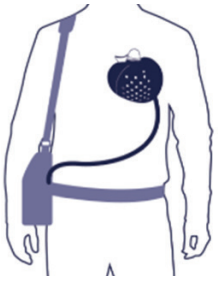
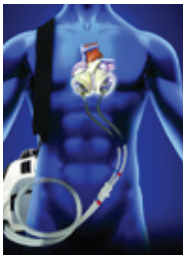
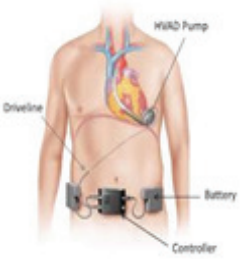
This means that the only TAH on the market was designed more than 40 years ago. The two polyurethane ventricles are actuated by pneumatic pressure, and air pressure actuates the internal flexible membranes separating each ventricle into blood and air compartments. Forward flow is achieved with the use of four mechanical heart valves: two percutaneous plastic pipes approximately 7 feet (2 meters) long connect the device to the external compressor, whose portable driver version, Freedom™, weighs 13.5 pounds (6.12 kilograms), excluding carrying accessories such as a backpack or carry case. It has an autonomy of three hours[50].

**48** www.syncardia.com – all information concerning Syncardia is taken from the company's website, unless specifically stated.

**49** Historical information on Jarvik 7 can be found on the Jarvik Heart website www.jarvikheart.com.

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

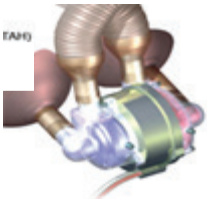
Comparative table of different devices addressing heart failure

| | Carmat artificial heart (Aeson®) | Syncardia® | Thoratec ventricular assist device (HeartMate III®) | Heartware Medtronic ventricular assist device |
|---|---|---|---|---|
| Visual of the system |  |  |  |   |
| Corporate information | Listed company<br>€60 million last fundraising in September 2019 | Company supported by private equity fund Versa Capital Management since September 2016 | Acquired by Saint Jude Medical in 2015<br>Saint Jude Medical acquired by Abbott in 2016 | Acquired by Medtronic in 2016 |
| Market access | CE marking (bridge to transplant) obtained in December 2020<br>Pivotal study ongoing | Bridge to transplant approval: 2004 (USA) and 1995 (CE marking Europe)<br>Study for destination therapy: pending | Bridge to transplant approval: 2017 (USA) and 2015 (Europe)<br>Destination therapy approval: 2015 (CE marking Europe) and 2018 (USA) | Bridge to transplant approval: 2012 (USA) and 2009 (Europe)<br>Destination therapy approval: 2017 (USA) |
| Technology | Bioprosthetic artificial heart, hemocompatible, pulsatile, self-regulating (hydraulic activation) | Pneumatic artificial heart, with limited automation<br>(Jarvik 7) | Ventricular assist device, with centrifugal pump | Ventricular assist device, with centrifugal pump |
| Advantages | Hemocompatible materials reducing risk of strokes and hemorrhages<br>Autoregulation matching patient physiologic needs<br>Pulsatile | Relatively simple technology<br>Pulsatile<br>2 sizes (50 cc and 70 cc)<br>Product marketed for several years | Small devices – large patient size compatibility Simple implantation | |
| Disadvantages | Some patient size restrictions | Relatively high complication rates<br>Limited automatic function<br>Noisy | Left support only<br>Relatively high complication rates<br>Native heart problems impact<br>Non-pulsatile<br>Minimal autoregulation | |

Other artificial heart projects

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

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

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

# 1.3 THE FIRST PHYSIOLOGIC HEART REPLACEMENT THERAPY*

## 1.3.1 MARKET POSITIONING

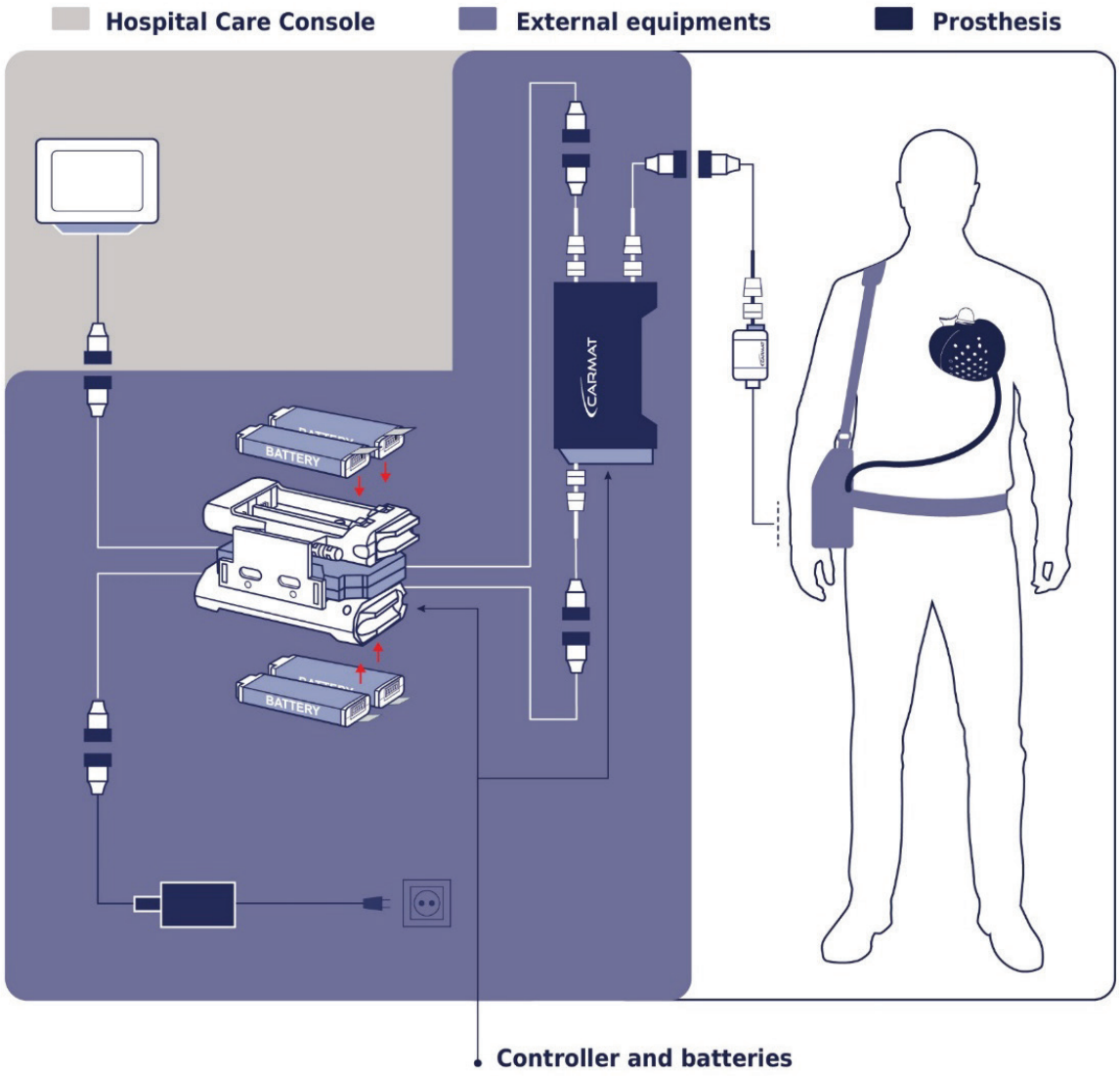
Carmat's artificial heart, which is marketed under the brand name Aeson®, obtained CE marking in December 2020 as a bridge to transplant for patients with terminal biventricular heart failure (Intermacs levels 1-4), who are unable to benefit from a maximum medical therapy or a left ventricular assist device (LVAD) and who are likely to be given a heart transplant within 180 days of receiving the implant.

In due course, Carmat also intends to seek the destination therapy indication for Aeson®.

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

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

* Hereafter PHRT.




Source: Carmat – The complete Carmat system

Aeson® thus provides a unique combination of three features: pulsatility[51], self-regulation[52] and hemocompatibility[53], enabling Carmat to create a new therapeutic class known as physiologic heart replacement therapy (PHRT).[54]

**51** Bizouarn P et al.; Effects of pre-load variations on hemodynamic parameters with a pulsatile autoregulated artificial heart during the early post-operative period. J Heart Lung Transplant. 2018; 37(1):161-3.

**52** Bizouarn P et al.; Effects of pre-load variations on hemodynamic parameters with a pulsatile autoregulated artificial heart during the early post-operative period. J Heart Lung Transplant. 2018; 37(1):161-3.

**53** JACC 2017 Smadja, Bioprosthetic total artificial heart induces a profile of acquired hemocompatibility with membranes recellularization, July 2017:403-9.

**54** The PHRT therapeutic class was created by Carmat and differs from the TAH class through its unique combination of three features: pulsatillity, self-regulation and hemocompatibility. It can be used either as a temporary treatment (bridge to transplant or BTT) or as a long-term treatment (destination therapy or DT). Aeson®'s physiologic nature is documented in Richez U et al.; Hemocompatibility and safety of the Carmat Total Artificial Heart hybrid membrane. Heliyon. 2019 Dec; 5(12): e02914. Published online 2019 Dec 8. doi: 10.1016/j.heliyon.2019.e02914.

## 1.3.2 CARMAT PROSTHESIS TECHNICAL PROPERTIES

As presented above, the system consists of:

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

### IMPLANTABLE PROSTHESIS

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

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

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

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

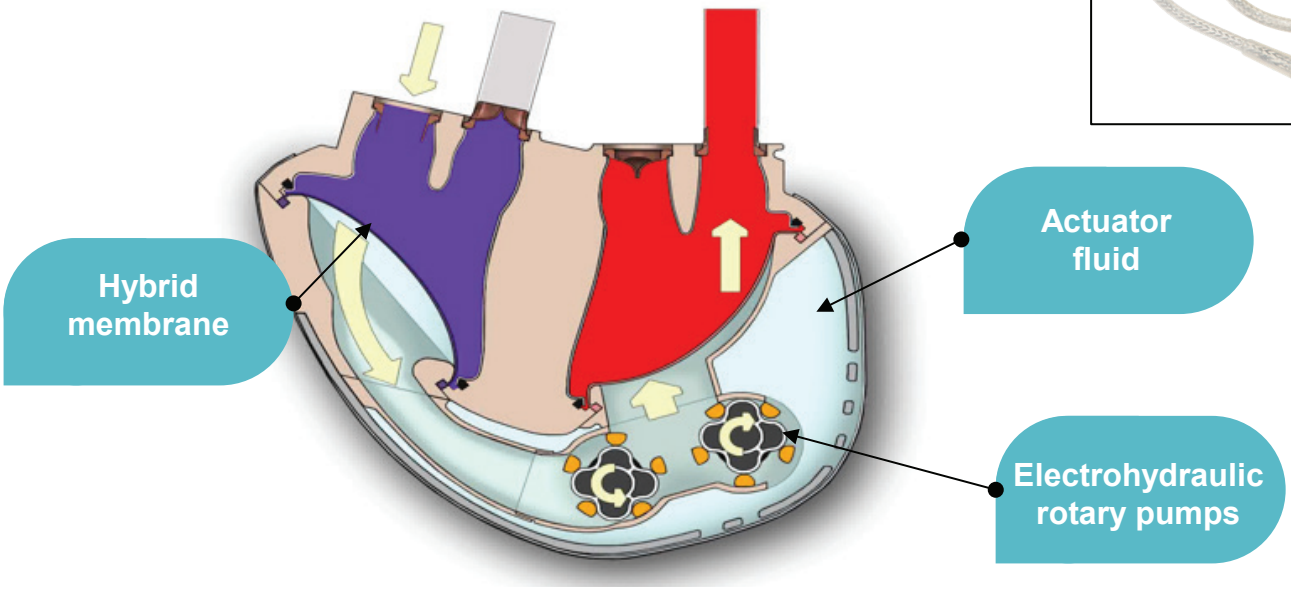
When they are implanted, and when required, physicians can adjust the beat rate (10 to 150 beats per minute), the left ventricular stroke volume (30 to 65 milliliters) and the right to left stroke volume ratio (to correct the bronchial (lung) circulation) and alarm thresholds. The resulting pulsatile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

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

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

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

Source: Carmat – Overview of the full prosthesis



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

Electrical connection

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

Measuring only 8 millimeters in diameter, the driveline delivers power to the Aeson® prosthesis and retrieves information on device performance. The driveline connects to a wearable system, providing an electronic interface for displaying essential device data for the patient, and an uninterrupted power supply for the device. The clinician connects a hospital monitoring console to the wearable system for initial set-up and for subsequent monitoring of the device and changes to the Aeson® settings.

## EXTERNAL EQUIPMENT

The external equipment gives the patient mobility and therefore the ability to leave the hospital and regain the autonomy needed to live a relatively normal life.

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

A stringent training and monitoring program is set up to ensure that the patient and his or her entourage fully understand the safe operating principles of the system.

The external equipment comprises:

- a controller: the direct interface between the patient and the device. It displays functional data about the Aeson® device;
- two battery units each containing two batteries;
- a carry bag designed specially by Carmat to carry the external equipment.

The entire system weighs about four kilograms.

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

## THE HOSPITAL CARE CONSOLE

The hospital care console (HCC) is only used in implantation centers by certified medical staff. It allows the medical team to configure and operate the prosthesis during implantation, and to monitor progress during periodic check ups. It also enables new features or versions of prosthesis software to be downloaded.


Source: Carmat – External equipment

Source: Carmat – The hospital care console

## 1.3.3 INNOVATION AND COMPETITIVE ADVANTAGES

The Aeson® heart includes three innovative design features (hemocompatibility, pulsatility, self-regulation) which, to Carmat's knowledge, are not brought together in any other MCS system on the market or under development, which has enabled Carmat to create a new therapeutic class known as PHRT. [55]

### HEMOCOMPATIBILITY [56]

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

### PULSATILITY [57]

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

### AUTOREGULATION [58]

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

In summary:

- all surfaces that come into contact with blood are covered by proven biocompatible materials;
- biological valves, which have been in clinical use for many years, provide unidirectional flow;
- the pumping action closely mimics human heart dynamics;

**55** The PHRT therapeutic class was created by Carmat and differs from the TAH class through its unique combination of three features: pulsatility, self-regulation and hemocompatibility. It can be used either as a temporary treatment (bridge to transplant or BTT) or as a long-term treatment (destination therapy or DT). Aeson®'s physiologic nature is documented in Richez U et al.; Hemocompatibility and safety of the Carmat Total Artificial Heart hybrid membrane. Heliyon. 2019 Dec; 5(12): e02914. Published online 2019 Dec 8. doi: 10.1016/j.heliyon.2019.e02914.

**56** JACC 2017 Smadja, Bioprosthetic total artificial heart induces a profile of acquired hemocompatibility with membranes recellularization, July 2017:403-9.

**57** Bizouarn P et al.; Effects of pre-load variations on hemodynamic parameters with a pulsatile autoregulated artificial heart during the early post-operative period. J Heart Lung Transplant. 2018; 37(1):161-3.

**58** Bizouarn P et al.; Effects of pre-load variations on hemodynamic parameters with a pulsatile autoregulated artificial heart during the early post-operative period. J Heart Lung Transplant. 2018; 37(1):161-3.

<u>Key features</u>

- Biological:

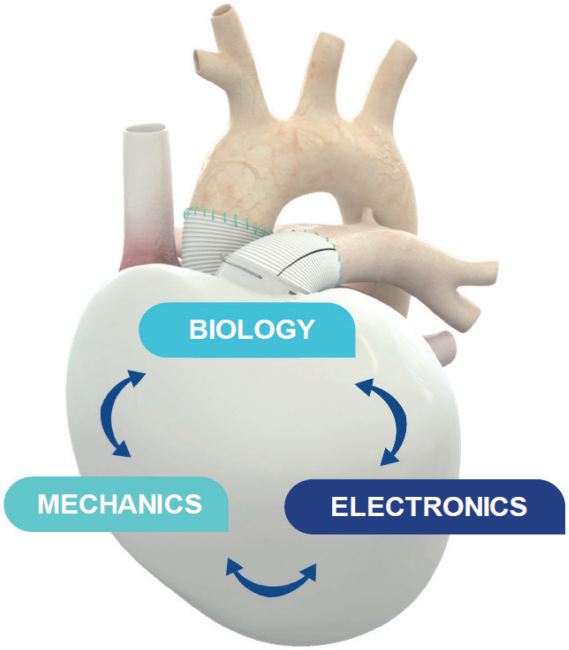
Hemocompatible: biocompatible material for blood contact surfaces

- Electronic:

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

- Mechanical:

Pulsatile: hydraulic pumps mimic diastole and systole



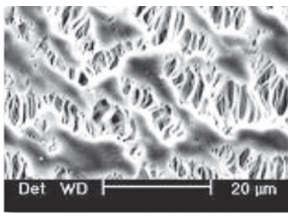

Source: Carmat

- blood damage and the activation of pathological changes are avoided;
- an automatic function responds to changes in patient activity and needs.

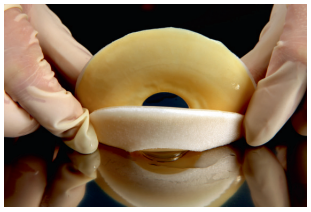
Assessments of explanted clinical pumps confirm the efficacy of biocompatible surfaces (see picture opposite and section 1.4 "Go-to-market process"). Patients were managed with a minimal anticoagulation therapy, which is likely to be reduced further in the future, to a level used for patients with vascular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

Biosynthetic membrane

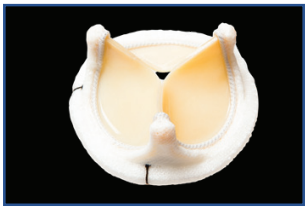
Ventricle in microporous PTFE




Biosynthetic interface with the atria



Carpentier-Edwards® pericardial valve



Source: Carmat – Hemocompatible materials

## OTHER COMPETITIVE ADVANTAGES

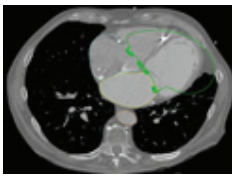
Compatibility with human thoraxes/implantability

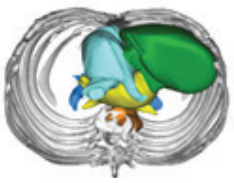
The shape and size of the Aeson® prosthesis have been adapted to the anatomy of the human thorax, in order to fit the largest number of patients. This involved making design adjustments to allow the ejection of a normal volume of blood with each beat, whilst using the minimum thoracic space.

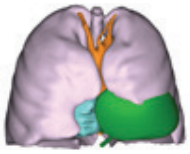
Based on a sophisticated 3D simulation, an advanced virtual 3D implantation system has been developed to produce a reliable non-invasive method for patient selection.

3D virtual transplant simulator

Segmentation of CT image sections → 3D organ reconstruction → Insertion of the Carmat 3D model → Assessment of compatibility





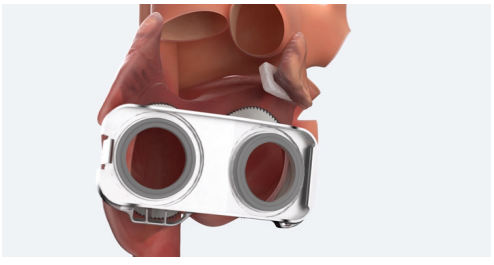


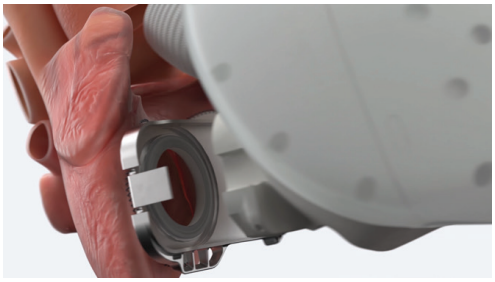
Source: Carmat – 3D virtual transplant simulator

Surgical experience

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

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





Pivotal study experience also indicates that the implantation times of the Carmat prosthesis are similar to those of a human transplant.

The explantation procedure is also greatly facilitated by the fact that there is no adhesion of the tissues to the prosthesis.

# 1.4 GO-TO-MARKET PROCESS

As an active implantable device, the Carmat total artificial heart (TAH) must gain approval from the competent authorities of the various countries where Carmat wishes to sell it. The regulatory pathways differ from one country to another, but in all cases, for such a critical device, the manufacturer is required to demonstrate its safety and efficacy via evidence collected in laboratory testing and clinical studies.

At present, Carmat's objective is to obtain approval to market its device both in Europe and in the United States.

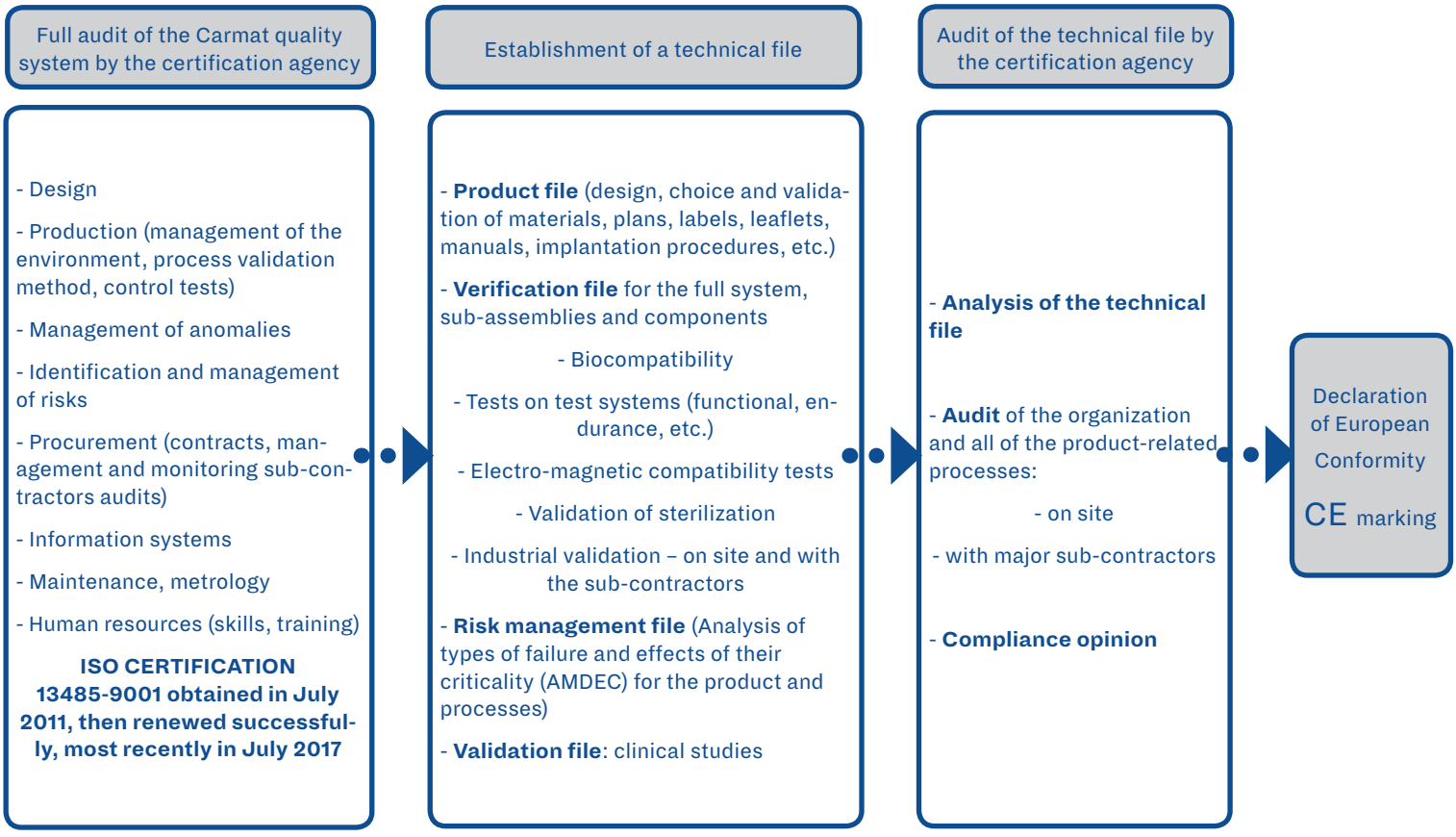
## 1.4.1 GO-TO MARKET PROCESS FOR EUROPE

### PROCESS OVERVIEW

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

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

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




Source: Carmat – CE marking procedure

CE marking allows the product to be marketed throughout the European Union (EU) and in some other non-EU countries, such as Russia, which also recognize CE marking. However, certain EU Member States have put in place additional conditions, such as registration or notification of market introduction.

The Council Directive concerning medical devices will be replaced by a new European medical device regulation from May 2021. This regulation strengthens the requirements to be met for a device to be granted CE marking. Nevertheless, if CE marking is granted before May 2021, it will remain valid until May 2024, provided that there are no significant changes in the design or intended purpose of the device during this so-called "grace period", and the company complies fully with the requirements of the new medical device regulation relating to post-market surveillance, vigilance, and registration of economic operators and devices.

Following the submission of its technical file to the certification agency Dekra, and Dekra's review of the file, **Carmat's artificial heart obtained CE marking on December 22, 2020 as a bridge to transplant for patients suffering from terminal biventricular heart failure (Intermacs 1-4), who are unable to benefit from a maximum medical therapy or a left ventricular assist device (LVAD) and who are likely to be given a heart transplant within 180 days of receiving the implant.**

Carmat could subsequently apply for other indications for its artificial heart. More particularly, it aims to obtain approval for the DT indication, which would enable Carmat to treat patients who are not eligible for a heart transplant and would therefore rely on the device for a longer period (the current BTT indication is a temporary solution). In order to obtain additional indications, Carmat will have to provide the certification agency with further information including clinical data and bench testing results.

The following sections describe the clinical studies carried out and the results so far obtained by Carmat as part of the CE marking process.

## PREPARATION OF CLINICAL TRIALS

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

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

## CLINICAL TRIALS

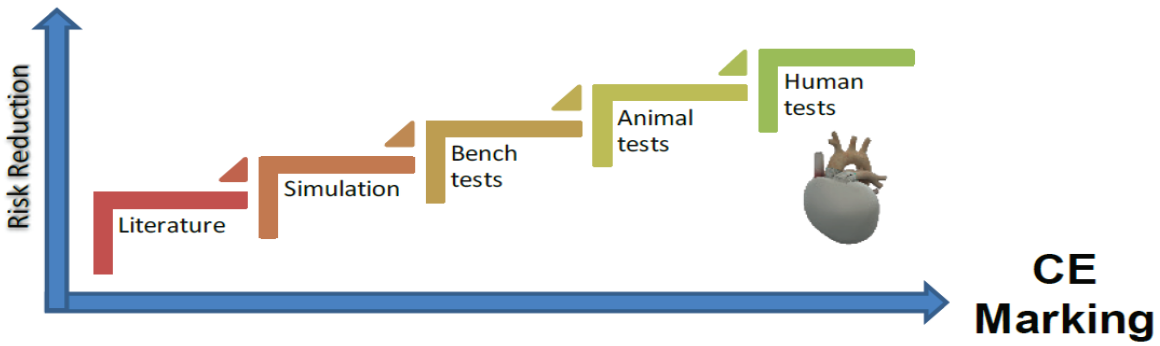
Feasibility study

A first-in-man (FIM) study was conducted in France between 2013 and 2016 with a small cohort (n=4) of sick and elderly patients. During this early clinical stage, the surgical technique for device implantation was validated and the anatomic compatibility of the device confirmed. Technical improvements to the prosthesis were implemented following device failures in the first two patients receiving implants. The Carmat TAH was capable of providing adequate blood flows, with cumulative support of 618 days, allowing two patients to return home and regain an almost normal quality of life. Results of the FIM study have been published in peer-reviewed medical journals such as *The Lancet*[59], *The Journal of the American College of Cardiology*[60] and *The Journal of Heart and Lung Transplantation*[61].

**59** 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.

**60** Smadja DM, Bioprosthetic Total Artificial Heart Induces a Profile of Acquired Hemocompatibility With Membranes Recellularization. Journal of the American College of Cardiology 2017; 70:404-6.

**61** Latrémouille C, et al. A bioprosthetic total artificial heart for end-stage heart failure: Results from a pilot study. J Heart Lung Transplant. 2018 Jan; 37(1):33-37.




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

Pivotal study

The feasibility study was followed by a pivotal study initially covering 20 patients (two cohorts of 10 patients), a number that could be adjusted up or down during the study. The primary objective of the pivotal study, which is still in progress, was the patient's survival for six months with the Carmat heart or a successful transplant within six months of the device being implanted. The study aims to demonstrate the safety and performance of the Carmat TAH in patients suffering from irreversible biventricular heart failure. The results are analyzed in a Clinical Evaluation Report (CER), which is an integral part of the Technical File for the CE marking file. Neither a specific number of implants nor a predetermined success rate for the project was required to obtain CE marking.

The pivotal study (ClinicalTrials.gov - Identifier: NCT02962973) began enrolling patients in 2016 with authorizations in France (2016), Kazakhstan (2017), the Czech Republic (2017) and Denmark (2018). At December 31, 2020, 15 patients had received implants as part of the study.

Intermediate results of the pivotal study

In accordance with good clinical practice and subject to any regulatory requirements or special circumstances, Carmat has said that it will not report on individual implants or the health of individual patients, but will only report when significant milestones in its clinical trials have been achieved[62].

Carmat presented an update of the pivotal study in January 2019 and in November 2019. The intermediate analysis presented in November 2019 covered the first 11 patients, enrolled between August 2016 and August 2018.

The survival rate for these 11 patients one month after implantation of Carmat's total artificial heart was 91%. More importantly, 73% of these patients (i.e., a total of eight) reached the primary objective of the study, six patients having survived for at least six months with the device, and two having received a successful heart transplant within six months of the Carmat device being implanted. Nine patients were discharged from hospital to either a home setting or to a rehabilitation unit, where they spent more than 70% of their time.

Of the six patients surviving for more than six months with the device, three ultimately received a successful heart transplant and one survived with the device for more than 24 months, bearing in mind that in bench tests, the longest period that the device has functioned without failure is now more than five years.

Of the 11 patients included in the intermediate results, five patients eligible for transplants received donor hearts after 109, 155, 243, 304 and 308 days of Carmat support, respectively, without any procedure-related complications. In particular, there was no tissue adhesion around the device, a known procedural issue with other circulatory support devices. In addition, explant analysis confirmed the early findings of ongoing endothelialization of all of the surfaces coming into contact with blood, which attests to the utility of using these particular biocompatible materials. The results of this bridge to transplant experience were published in the Journal of Heart and Lung Transplantation[63] in December 2020.

The experiment and the results of this cohort of 11 patients in the pivotal study have also demonstrated a positive safety and performance profile, particularly in terms of the absence of hemocompatibility-related complications. The Carmat artificial heart compares favorably with the current Syncardia® TAH in terms of survival rate at six months (73% versus 54-62%), stroke (0% versus 23%), gastrointestinal bleeding (0% versus 20%), percutaneous driveline infection (0% versus 22%), and surgery-related bleeding requiring further surgery (36% versus 41%).

**62** The next report on the results of the pivotal study will be published when the study has been completed.

**63** Netuka I, Pya Y, Bekbossynova M, et al. Initial bridge to transplant experience with a bioprosthetic autoregulated artificial heart. J Heart Lung Transplant. 2020 Dec; 39(12):1491-1493.

The table below summarizes the results obtained on the 11 initial patients enrolled in Carmat's study compared with other therapies (monitored at six months after transplantation):

| Device | Survival rate at 6 months | Stroke | Bleeding/ Reintervention | Gastrointestinal bleeding | Percutaneous driveline infection |
|---|---|---|---|---|---|
| Carmat Feasability study (n=4) | 50% | 0% | 75% | 0% | 0% |
| Carmat Pivotal study (n=11) | 73% | 0% | 36% | 0% | 0% |
| SynCardia* | 54%-62% | 23% | 41% | 20% | 22% |
| BIVAD ** (n=14) | 46%-68% | 7% | N/A | 7% | 7% |

* Arabia F et al, J Heart Lung Transplant, 2018; 37; 1304-1312 (n=450). Demondion P et al, Eur J Cardiothorac Surg. 2013 Nov: 44(5):843-8 (n=27).

** Lavee J et al, J Heart Lung Transplant 2018; 37; 1399-1402

Source: Carmat – Intermediate results pivotal study

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

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

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

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

Having applied to the FDA in August 2018 for authorization to conduct an early feasibility study (EFS), Carmat obtained conditional approval in September 2019 followed by full approval on February 5, 2020 to conduct a clinical feasibility study on 10 patients in the United States, which it expects to start in the first quarter of 2021.

In May 2020, Carmat also obtained approval from the Centers for Medicare and Medicaid Services (CMS) for reimbursement of the device and associated services within the framework of the EFS.

If successful, the EFS will be followed by a broader pivotal study, for which a new application will be made to the FDA, and which will start being prepared in 2022. The results of the pivotal study would be used to support Carmat's application for PMA. This strategy would allow for the integration into the PMA application of certain clinical data obtained in Europe, thereby limiting the size of the pivotal study to be conducted in the United States.

Subject to reaching the clinical and regulatory milestones described above, the Company believes that marketing of its artificial heart will not begin in the United States before 2024.

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

# 1.5 COMPANY STRATEGY

## 1.5.1 REGULATORY STRATEGY

Firstly, Carmat was seeking to obtain CE marking, notably to allow it to market its prosthesis in the European Union; and secondly, pre-market-approval (PMA), to enable the Company to market its prosthesis in the United States.

CE marking (Europe)

CE marking for the BTT indication was obtained on December 22, 2020 (see section 1.4.1). Carmat could subsequently apply for other indications for its artificial heart. More particularly, it aims to obtain approval for the DT indication, which would enable Carmat to treat patients who are not eligible for a heart transplant and would therefore rely on the device for a longer period (the current BTT indication is a temporary solution). In order to obtain additional indications, Carmat will have to provide the certification agency with further information including clinical data and bench testing results.

PMA (United States)

The process for obtaining PMA and Carmat's progress in this matter are described in section 1.4.2. At this stage, Carmat estimates that it could obtain PMA for its artificial heart in 2024.

## 1.5.2 MARKETING STRATEGY

### EUROPE

Having obtained CE marking on December 22, 2020, the Company can now market its product as a bridge to transplant throughout the European Union, subject to the extent to which the national health systems cover the cost of the device (see section 2 of this document for a description of the risks associated with social security reimbursement and coverage).

Currently, the Company intends to market its device through a direct team of sales representatives and clinical specialists in the main European countries. As appropriate, this may later be expanded to carefully selected distributors or agents in countries deemed lower priority, or when this method seems more appropriate given the local context.

The choice of a direct team was based on two factors:

- 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, which will consist in focusing initially on the core target, i.e., active heart transplantation centers, followed by the less active centers.

The sales force will therefore initially consist of very clinical profiles to ensure the training and adoption of therapy by the medical and surgical community,

An approach expected to enable progressive investments. Given the very limited number of human donor hearts, the number of truly active heart transplant centers – i.e., those that perform a sufficient amount of transplants to keep teams available and trained – is very low, representing only around 20 in each large country.

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

With regard to the pricing policy, the price targets for the Carmat artificial heart are consistent with current reimbursement practices for available devices. For example, an implantable device for left mono-ventricular assistance is currently reimbursed in Europe between €60,000 and €110,000 excluding taxes (approximately €90,000 excluding taxes in France)[64]. As the Carmat heart treats both parts of the heart and is made up of a system that includes an implantable part as well as external parts and associated pre- or post-operative services, the pricing variables are numerous and should make it possible to adapt to the conditions specific to each center or each market, while maintaining overall price consistency at European level.

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

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

The Company considers that no reimbursement offered would not be synonymous with no sales or income, in particular insofar as hospitals in certain countries have their own budgets to finance innovation, but would not allow the development of sales in line with its financial objectives.

Initial target markets: Germany and France

In 2021, Carmat intends to focus on Germany and France, which together represent 55% of the mechanical circulatory support (MCS) device market in the European Union[65]:

- Aeson® will be launched on the market in Germany in the second quarter of 2021;
- the French market will be first addressed through the EFICAS clinical study.

In addition, Carmat could take advantage of business opportunities in other countries that recognize CE marking.

The order in which the various European countries will be addressed will depend on market size and the extent to which the cost of the device will be covered by their national health systems.

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

### UNITED STATES

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

65 GlobalData: EU5 Cardiac Assist Devices Market Outlook To 2025 - Intra-Aortic Balloon Pumps, Mechanical Circulatory Support Devices And Short-Term Circulatory Support Devices (Report GDMECR1561DB)

## 1.5.3 CLINICAL STRATEGY

Carmat intends to implement a robust clinical plan, aiming to:

- generate additional safety and performance data for its artificial heart, particularly over the longer term;
- generate medico-economic data to support its product's value proposition.

These data should promote acceptance of the product and support Aeson®'s value proposition (particularly to obtain social security reimbursement for the product in France) and, ultimately, obtain indication for use as a destination therapy (DT) and obtain PMA in the United States.

Carmat's clinical plan is summarized in the table below:

| | Name of study | Purpose | Sample size | Enrollment | Objectives |
|---|---|---|---|---|---|
| **European studies** | Europe pivotal study | Safety and performance data | Target of 20 patients | Study in progress (15 patients treated as at December 31, 2020) | Support the clinical evaluation report for CE marking |
| | EFICAS in France | Safety and performance data, medico-economic data | 52 patients eligible for a heart transplant | Begins Q2 2021 | Encourage acceptance, support the value proposition and obtain social security reimbursement in France |
| | PMS (post-market surveillance) | Safety and performance data surveillance for the BTT indication | Target of 95 patients | Begins Q2 2021 | LT data (more than 1 year) to support extension of the indication to destination therapy (DT) for more seriously ill patients |
| **US studies** | EFS | Safety and performance data | 10 patients eligible for a heart transplant | Begins Q1 2021 | Support application to conduct a pivotal trial in the US and ultimately PMA* |

* If successful, the EFS would be followed by a broader pivotal study in the United States.

## 1.5.4 INDUSTRIAL STRATEGY

### CHOICE OF INTEGRATION MODEL

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

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

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

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

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

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

### INTERNALIZED PRODUCTION AND PRODUCTION CAPABILITIES

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

2017 was marked by the construction of a new dedicated production site ultimately intended to manufacture around 350 to 400 units per year. The site was opened and certified in 2018, has an area of 1,600 square meters, is located in Bois-d'Arcy in Greater Paris, and has a 270-square-meter clean room in compliance with ISO 7 standards. The manufacture, integration and sterilization of prostheses are carried out in a controlled environment, by specialized and highly qualified staff. Prostheses are now entirely produced at this site.

remains a challenge, particularly on a large scale. Industrially, in addition to its actions to secure supplies, the Company continually seeks to improve its information systems, and adapt its production processes with an objective of reliability and better replicability, and, in particular, quality. These improvements also aim to increase production capacities, in particular with a view to marketing the prosthesis.

Over the period 2020-2022, Carmat will thus convert a prototyping facility producing a few dozen artificial hearts per year into a 'large-scale' manufacturing plant capable of producing several hundred hearts per year.


## 1.5.5 INNOVATION AND R&D MANAGEMENT

### APPLYING SKILLS

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

In addition to contributions specific to the medical and aerospace fields, the Company also successfully brought together talents – who had never collaborated with each other before – on such a complex project, allowing them to acquire know-how specific to these fields.

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

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

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

Details of these patents are set out below:

| Title | Geographical area | Submission/Publication no. | Date of submission | Status |
|---|---|---|---|---|
| "Quick-connection device between a completely implantable artificial heart and natural atria" | France | FR0605331<br>FR2902343 | June 15, 2006 | Granted Sept. 5, 2008<br>Expiring on June 15, 2026 |
| | Europe | EP07290723.1<br>EP1867350 | June 11, 2007 | Granted Sept. 24, 2008<br>Expiring on June 11, 2027 |
| | International | PCT/FR2007/000959<br>WO2007/144495 | June 11, 2007 | Published on Dec. 21, 2007 |
| "Connection device between an artificial heart and the natural atria" | France | FR0605332<br>FR2902344 | June 15, 2006 | Granted Sept. 5, 2008<br>Expiring on June 15, 2026 |
| | Europe | EP07290724.9<br>EP1867351 | June 11, 2007 | Granted Sept. 24, 2008<br>Expiring on June 11, 2027 |
| | International | PCT/FR2007/000960<br>WO2007/144496 | June 11, 2007 | Published on Dec. 21, 2007 |
| "Method of manufacturing a haemocompatible object with complex configuration and object thus obtained" | France | FR0703339<br>FR2915903 | May 10, 2007 | Granted on June 4, 2010<br>Expiring on May 10, 2027 |
| | Europe | EP08290405.3<br>EP1992369 | April 28, 2008 | Granted on May 6, 2015<br>Expiring on April 28, 2028 |
| | International | PCT/FR2008/000607<br>WO2008/145870 | April 28, 2008 | Published on Dec. 4, 2008 |
| "Process to form an hemocompatible composite material and material obtained" | France | FR1001724<br>FR2959134 | April 22, 2010 | Granted on July 13, 2012<br>Expiring on April 22, 2030 |
| | Europe | EP11161291.7<br>EP2380608 | April 6, 2011 | Granted Sept. 12, 2012<br>Expiring on April 6, 2031 |
| | International | PCT/FR2011/050768<br>WO2011/131887 | April 6, 2011 | Published on Oct. 27, 2011 |
| "Prosthesis for connecting an anatomical canal" | France | FR1152364<br>FR2972919 | March 22, 2011 | Granted on July 4, 2014<br>Expiring on March 22, 2031 |
| | Europe | EP12158011.2<br>EP2502577 | March 5, 2012 | Granted on Nov. 2, 2016<br>Expiring on March 5, 2032 |
| | International | PCT/FR2012/050449<br>WO2012/127145 | March 5, 2012 | Published on Sept. 27, 2012 |

| Title | Geographical area | Submission/Publication no. | Date of submission | Status |
|---|---|---|---|---|
| "Flexible barrier membrane and method for manufacturing the flexible barrier membrane" | France | FR1756847<br>FR3069186 | July 19, 2017 | Granted on July 26, 2019<br>Expiring on July 19, 2037 |
| | Europe | EP18179971.9<br>EP3431286 | June 26, 2018 | Published on Jan. 23, 2019 |
| | International | PCT/FR2018/051562<br>WO2019/102085 | June 26, 2018 | Published on May 31, 2019 |
| "Anatomically implantable prosthesis in one piece" | France | FR0605333<br>FR2902345 | June 15, 2006 | Granted on Sept. 5, 2008<br>Expiring on June 15, 2026 |
| | Europe | EP07290725.6<br>EP1867352 | June 11, 2007 | Granted on July 15, 2009<br>Expiring on June 11, 2027 |
| | International | PCT/FR2007/000962<br>WO2007/144497 | June 11, 2007 | Published on Dec. 21, 2007 |
| "Implantable single-piece artificial heart" | France | FR0800184<br>FR2926223 | Jan. 14, 2008 | Granted on Jan. 22, 2010<br>Expiring on Jan. 14, 2028 |
| | Europe | EP09290009.1<br>EP2078533 | Jan. 7, 2009 | Granted on Jan. 12, 2011<br>Expiring on Jan. 7, 2029 |
| | International | PCT/FR2009/000008<br>WO2009/112662 | Jan. 7, 2009 | Published on Sept. 17, 2009 |
| "Hemocompatible composite material and its process of manufacture" | France | FR0511430<br>FR2892939 | Nov. 10, 2005 | Granted on Jan. 22, 2010<br>Expiring on Nov. 10, 2025 |
| | Europe | EP06291657.2<br>EP1785154 | Oct. 25, 2006 | Granted on Sept. 23, 2009<br>Expiring on Oct. 25, 2026 |
| | International | PCT/FR2006/002471<br>WO2007/054637 | Nov. 7, 2006 | Published on May 18, 2007 |
| "Rotary positive displacement pump with reduced radial space requirement" | France | FR0604206<br>FR2900988 | May 12, 2006 | Granted on Jan. 1, 2010<br>Expiring on May 12, 2026 |
| | Europe | EP7290571.4<br>EP1855005 | May 7, 2007 | Granted on Jan. 28, 2009<br>Expiring on May 7, 2027 |
| | International | PCT/FR2007/000778<br>WO2007/135261 | May 7, 2007 | Published on Nov. 29, 2007 |

- Exclusive license agreements

Exclusive license agreements with Pierre and Marie Curie University

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

Although Matra Défense initially used the intellectual property rights granted, the benefit of this license was subsequently assumed by Carmat, to which Pierre and Marie Curie University consented by way of an agreement duly signed by Pierre and Marie Curie University, Matra Défense, the Scientific Research Association of the Alain Carpentier Foundation and Carmat. Under this agreement, (i) Pierre and Marie Curie University expressly waived any benefit from all intellectual property rights linked to or resulting directly or indirectly from the work on the bio-prosthetic artificial heart project and acknowledged that Carmat was the sole owner of all intellectual property rights that could have been attributed to Pierre and Marie Curie University; and (ii) in return, the Scientific Research Association of the Alain Carpentier Foundation granted at no cost, on its behalf and account and in the interest of Matra Défense, 400 Carmat shares (equivalent to 10,000 Carmat shares following the 25:1 stock split) to the benefit of Pierre and Marie Curie University.

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

- Trademarks

The Company has registered the “Carmat” and “Aeson” trademarks in the countries and regions below.

| | Registration number | Status | Date filed | Renewal date | Regions | Classes |
|---|---|---|---|---|---|---|
| ‘Carmat’ trademark | 023184827 | Registered | Sept. 23, 2002 | Sept. 23, 2022 | France | 9, 10, 42 |
| | 007374821 | Registered | Oct. 29, 2008 | Oct. 29, 2028 | Community (European Union) | 10, 42 |
| | UK00907374821 | Registered | Oct. 29, 2008 | Oct. 29, 2028 | United Kingdom | 10, 42 |
| | 1022720 | Registered | June 19, 2009 | June 19, 2029 | International Designations: China, Japan, Switzerland, Russia, Kazakhstan, Turkey | 9, 10, 42 |
| | 3663230 | Registered | Jan. 7, 2009 | Aug. 4, 2029 | United States (USA) | 10, 42 |
| | TMA807717 | Registered | June 25, 2009 | Sept. 27, 2026 | Canada | 10, 42 |
| | 200911637 | Renewal in progress | June 24, 2009 | June 24, 2029 | South Africa | 10 |
| | 200911638 | Renewal in progress | June 24, 2009 | June 24, 2029 | South Africa | 42 |
| | 992759 | Renewal in progress | July 9, 2009 | July 9, 2029 | India | 10, 42 |
| ‘Aeson’ trademark | 4466988 | Registered | July 5, 2018 | July 5, 2028 | France | 10, 42, 44 |
| | 1439429 | Registered | Oct. 12, 2018 | Oct. 12, 2028 | International Designations: Switzerland, European Union, Russian Federation, Kazakhstan, Turkey | 10, 42, 44 |
| | UK00801439429 | Registered | Oct. 12, 2018 | Oct. 12, 2028 | United Kingdom | 10, 42, 44 |
| | 1925415 | Filed | Oct. 16, 2018 | - | Canada | 10, 42, 44 |
| | 88026303 | Registered | July 5, 2018 | July 5, 2028 | United States (USA) | 10, 42, 44 |

- Domain names

The Company has registered the following domain names:

| Domain name | Date reserved | Renewal date | Domain name | Date reserved | Renewal date |
|---|---|---|---|---|---|
| aeson.eu | Aug. 22, 2019 | Aug. 22, 2024 | aeson-phrt.it | Nov. 8, 2019 | Nov. 8, 2021 |
| aeson.fr | Aug. 22, 2019 | Aug. 22, 2024 | aeson-phrt.ru | Nov. 12, 2019 | Nov. 12, 2021 |
| aeson.uk | Aug. 27, 2019 | Aug. 27, 2024 | aeson-phrt.de | Nov. 8, 2019 | Nov. 7, 2021 |
| aeson-phrl.com | Aug. 26, 2019 | Aug. 26, 2024 | aeson-phrl.be | Nov. 8, 2019 | Nov. 8, 2021 |
| carmat.tel | March 23, 2009 | March 22, 2029 | aeson-phrt.nl | Nov. 8, 2019 | Nov. 7, 2021 |
| carmatsas.com | Oct. 29, 2008 | Oct. 29, 2028 | aeson-phrt.dk | Nov. 8, 2019 | Nov. 30, 2021 |
| carmatsas.fr | Oct. 29, 2008 | Oct. 29, 2028 | aeson-phrt.kz | Nov. 10, 2019 | Nov. 10, 2021 |
| carmatsas.eu | Oct. 29, 2008 | Oct. 31, 2028 | aeson-phrt.uk | Nov. 8, 2019 | Nov. 8, 2021 |
| carmatsa.tel | April 29, 2010 | April 29, 2026 | aeson-phrt.es | Nov. 12, 2019 | Nov. 12, 2021 |
| carmatsa.fr | April 29, 2010 | April 29, 2026 | eason-phrt.us | Nov. 8, 2019 | Nov. 8, 2021 |
| carmatsa.com | April 29, 2010 | April 30, 2026 | aesonphrt.com | Nov. 8, 2019 | Nov. 8, 2021 |
| carmatsa.eu | April 29, 2010 | April 29, 2026 | | | |

## 1.5.6 PROVISIONAL PROJECT SCHEDULE

2020 was a defining year for Carmat, with key objectives met despite the Covid-19 crisis:

- CE marking* obtained enabling Carmat to market its total artificial heart as a bridge to transplant in many countries, including the whole of the European Union;
- full approval obtained from the US Food and Drug Administration (FDA) to conduct a feasibility study (EFS) in the United States and the successful training of three US centers in the fourth quarter of 2020, enabling Carmat to envisage its first implantations in the first quarter of 2021;
- €13 million of funding obtained from the French government to conduct a new clinical trial (EFICAS) in France in the second quarter of 2021;
- resumption of the pivotal study in France, with two patients treated in December 2020, bringing the total number of patients treated under the study to 15 at December 31, 2020;
- continued improvement and capacity ramp-up at the Bois d'Arcy production facility, and measures to secure the supply chain;
- preparation for the artificial heart's commercial launch, particularly in terms of marketing and sales, 'access' (social security reimbursement and coverage), logistics and sales administration;
- €10 million government-guaranteed loan obtained.

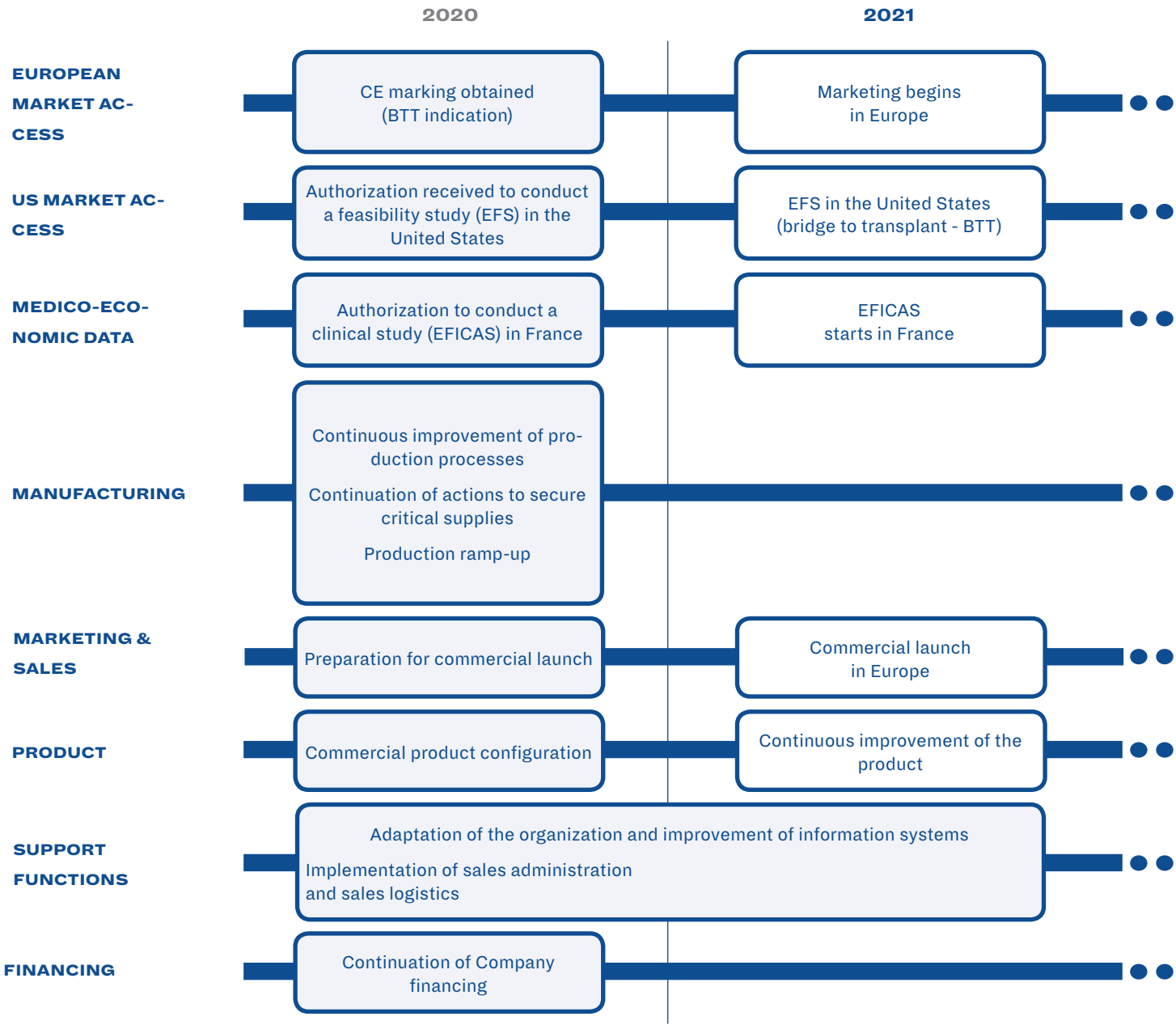
* CE marking was granted on December 22, 2020 for Carmat's total artificial heart system as a bridge to transplant for patients suffering from terminal biventricular heart failure (Intermacs levels 1-4), who are unable to benefit from a maximum medical therapy or a left ventricular assist device (LVAD) and who are likely to be given a heart transplant within 180 days of receiving the implant.

Given this progress, Carmat's timeline has been updated as follows, insofar as compared with the timeline presented in the 2020 Universal Registration Document, the start date of the EFS in the United States has been postponed from 2020 to the first quarter of 2021, and the start date of the pivotal study planned in the United States from 2022 to 2023.

The next key milestones in the Company's timeline are as follows:

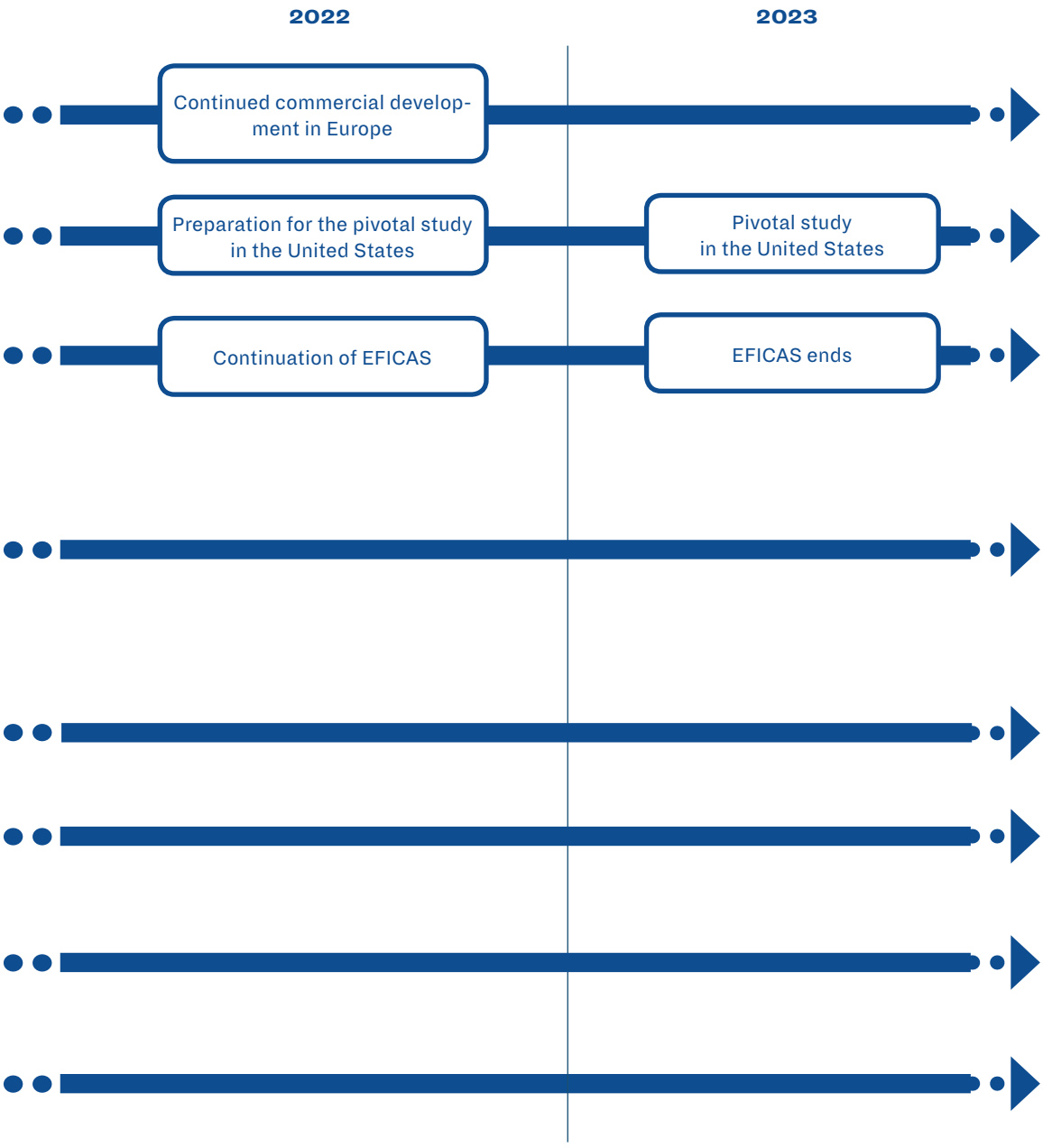
- First quarter 2021 — Implants begin under the EFS study in the United States
- Second quarter 2021 — Sales begin in Europe
- Implants begin under the EFICAS in France

**BUSINESS AREA**




Source: Carmat - Expected timeline

Readers are invited to refer to Chapter 2 “Risk factors” of this Universal Registration Document to make an informed assessment of this schedule, as well as to the Company’s regular press releases on its development.



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# 2

# RISK FACTORS

Note

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

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

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

# 2.1 METHODOLOGICAL APPROACH

## 2.1.1 PREAMBLE

As part of the new Prospectus 3 regulations applicable from July 21, 2019, Carmat redesigned this Risk Factors chapter in 2019 in order to simplify the presentation of information relating to risks and to continue to improve its readability.

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

## 2.1.2 RISKS IDENTIFICATION AND CLASSIFICATION

In 2020, the Company updated the identification and ranking of its risks. The results of this analysis were reviewed by the Audit Committee and are reflected in this Universal Registration Document.

Methodology and risk assessment

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

- financial risks;
- industrial risks (supply chain);
- market access risks;
- human, organizational and regulatory non-compliance risks;
- IT, data and transaction risks;
- risks related to the Covid-19 pandemic

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

- the impact, estimated on a scale[01] from 1 (immaterial) to 5 (critical);
- the probability of occurrence, estimated on a scale[02] from 1 (almost zero probability) to 4 (highly likely).

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

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

Following this analysis, Carmat considered 14 risks to be material and specific, which are summarized in section 2.2.

Carmat also assessed the trend for each risk, which can be positive, negative or neutral, depending on whether Carmat considers that the risk score decreased, increased, or remained more or less the same, between end-2020 and end-2019.

Impact of the Covid-19 pandemic on risks:

The Covid-19 pandemic has had a direct impact on some material and Company-specific risks. In these cases, the impact has been directly taken into account and reflected in the evaluation of the risks considered in sections 2.2 and 2.3.

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

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

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

Furthermore, the pandemic in itself is a risk for Carmat, with potentially many aspects to consider that will depend on developments in the situation over the next few months. The Company has therefore decided to include a separate Covid-19 risk in this document to provide readers with a holistic view of the risk the pandemic represents for Carmat.

## 2.2 SUMMARY OF MATERIAL AND SPECIFIC RISKS

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

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

Each risk is presented in more detail in section 2.3.

| (Part 1 of the table) | Probability | Potential impact | Risk score | Criticality | | | | Trend* |
|---|---|---|---|---|---|---|---|---|
| | | | | Critical risk | Major risk | Moderate risk | Minor risk | |
| **Financial risks** | | | | | | | | |
| Funding risk (estimated cumulative funding gap of €31 million over 12 months) | 2 | 5 | 10 | | Major risk | | | = |
| Risk of operational, economic and financial unviability (particularly in the event that the clinical results are not satisfactory) | 2 | 5 | 10 | | Major risk | | | = |
| Risks related to foreign investment control rules in France** | 2 | 3 | 6 | | | | Minor risk | - |
| **Industrial risks (supply chain)** | | | | | | | | |
| Risk associated with the supply of materials and components | 4 | 3 | 12 | | Major risk | | | = |
| Risk associated with production volumes | 3 | 4 | 12 | | Major risk | | | - |
| Risk associated with production quality | 2 | 5 | 10 | | Major risk | | | = |
| **Market access risks** | | | | | | | | |
| Risk associated with obtaining PMA in the United States | 2 | 5 | 10 | | Major risk | | | = |
| Risk associated with the reimbursement of the prosthesis on European markets | 2 | 5 | 10 | | Major risk | | | = |
| Risk associated with the reimbursement of the prosthesis on the American market (assuming Carmat obtains the PMA) | 2 | 5 | 10 | | Major risk | | | = |
| Risk associated with obtaining CE marking in Europe | 2 | 3 | 6 | | | | Minor risk | + |

* The "+" sign indicates a positive trend, i.e., a decrease in risk.

** New risk.

| (Part 2 of the table) | Probability | Potential impact | Risk score | Criticality | | | | Trend* |
|---|---|---|---|---|---|---|---|---|
| | | | | Critical risk | Major risk | Moderate risk | Minor risk | |
| **Human, organizational and regulatory non-compliance risks** | | | | | | | | |
| Organizational and regulatory non-compliance risks | 3 | 3 | 9 | | | Moderate risk | | = |
| Human resources risks | 3 | 3 | 9 | | | Moderate risk | | - |
| **IT, data and transaction risks.** | | | | | | | | |
| IT, data and unauthorized transaction risks | 2 | 4 | 8 | | | Moderate risk | | = |
| **Covid-19 pandemic risks**[1**] | - | - | - | | | | | |

[1] Given the continued uncertainty as to how the pandemic and measures designed to control it will evolve, Carmat is unable to accurately measure the level of Covid-19 risk or its potential impact on the Company in 2021 and beyond

* The "+" sign indicates a positive trend, i.e., a decrease in risk.

** New risk.

# 2.3 DETAILED PRESENTATION OF MATERIAL AND SPECIFIC RISKS

## 2.3.1 FUNDING RISK (ESTIMATED CUMULATIVE FUNDING GAP OF €31 MILLION OVER 12 MONTHS)

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

### MAJOR RISK

Carmat had a cash position of €36 million at December 31, 2020 including the €10 million of government-guaranteed loans drawn down in November 2020, the remaining €10 million of the conditional EIB* loan drawn down in December 2018, and €13 million in French government funding intended to partially finance the EFICAS** study. In light of this and other considerations, it is in a position to fund its business activities, based on its current business plan, until August 2021.

Carmat can also draw down on the Kepler-Cheuvreux equity financing line until September 27, 2021, the balance of which stood at €16 million at December 31, 2020.

If all of the remaining €16 million were to be drawn down on the Kepler-Cheuvreux equity financing line, the Company would have sufficient cash to fund its business until November 2021.

However, if the Company were not to use the balance of the Kepler-Cheuvreux equity financing line, and had no access to additional funding, its shortage of financial resources, on a 12-month cumulative basis at end-February 2022, would reach €31 million based on the current development plan.

Given the progress of its project and, in particular, having obtained CE marking for the BTT indication on December 22, 2020, the Company estimates that, based on all the information in its possession at this stage, the probability of it being unable to raise the funds needed to complete its project is relatively low, although the possibility cannot be ruled out. In the short term, were the Covid-19 health crisis

* Can be drawn down at any time until December 17, 2021, as the draw down conditions have already been met.

** The funds will be received as and when patients receive their implants during the study.

to continue, some potential investors could be weakened or contacts and negotiations with them could become more difficult, which would make their investment in the Company less certain.

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

The Company has also specifically assessed its liquidity risk and believes it will be able to fund operations for the first three quarters of 2021.

## 2.3.2 RISK OF OPERATIONAL ECONOMIC AND FINANCIAL UNVIABILITY (PARTICULARLY IN THE EVENT THAT THE CLINICAL RESULTS ARE NOT SATISFACTORY)

| Financial risks | Description of risk | Potential impacts |
|---|---|---|
| Risk of operational, economic and financial unviability | Risk that the Company will not be profitable, or will be profitable later than expected, and/or reach the point of self-financing. In particular, this may be due to lower revenues than forecast as a result of lower than expected sales volumes and sales prices, failure of the reimbursement systems to cover the cost of the device, etc. This could also be due to higher than expected necessary costs or investments (R&D and clinical trial costs, cost of production of the prosthesis, other operational costs, etc.). This could also be due, in particular, to the clinical trails not having the expected results, or to problems with the device or the implantation procedure revealed during the clinical trials or the marketing phase. | Negative impact on the market valuation of the Company. Requirement to slow down or temporarily interrupt the Company's operations. Requirement to find additional funding (fundraising, loans, etc.).<br>In the final stage, requirement to give up on marketing the device and end the Company's operations. |

### MAJOR RISK

Carmat's ability to continue its development and deliver positive cash flow and a net profit over time requires reaching a certain level of sales, carefully managing its expenditure and investments, and controlling device production costs. It also requires smooth progress in its clinical trials and its production and, more generally, the absence of any major unexpected events that could seriously slow down or even halt its development and/or marketing of its product.

The Company's artificial heart obtained CE marking for the bridge to transplant (BTT) indication on December 22, 2020. However, Carmat has not yet obtained approval to market its device in the United States or authorization to market its artificial heart as a destination therapy (see sections 2.3.6 and 2.3.7).

In 2021, the Company will continue to conduct its pivotal study and start new clinical trials, mainly in France and the United States. It will also begin marketing its product in Europe as of the second quarter of 2021. It is always possible that the clinical trials may not have the expected results, and/or that the clinical trials or implantations of the artificial hearts sold by Carmat may reveal problems related, for example, to the device itself or to the implantation procedure.

The device represents an expensive therapy, and there is no guarantee that it will be reimbursed at the levels expected by the Company (see sections 2.3.8 and 2.3.9). Furthermore, since the Carmat heart is a unique and innovative therapy, there is no guarantee that adoption by healthcare professionals and patients will be in line with Carmat forecasts.

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

At this stage, therefore, there is still a significant degree of uncertainty as to Carmat's continued development and the effective rollout of its business plan. This risk is further accentuated by the fact that Carmat's development is based entirely on one product at this stage (namely its artificial heart) and is therefore fully dependent on its success.

## 2.3.3 RISKS RELATED TO FOREIGN INVESTMENT CONTROL RULES IN FRANCE

| Financial risks | Description of risk | Potential impacts |
|---|---|---|
| Risks related to foreign investment control rules in France | Risk that the Company's business activities will be considered as sensitive within the meaning of the regulations on foreign investment in France | These regulations could discourage investments from outside the European Economic Area and could therefore limit the Company's access to sources of funding and delay or discourage a purchaser from making a public offer for the Company. |

### MINOR RISK

Under the foreign investment control rules currently applicable in France, prior authorization from the Minister of the Economy is required for any investment:

- made by (a) a foreign individual, (b) a French individual not resident in France within the meaning of article 4B of the French Tax Code (Code général des impôts), (c) a foreign-law entity or (d) a French-law entity controlled by one or more of the individuals or entities referred to in (a), (b) or (c);
- that would have the effect of (a) obtaining control (within the meaning of Article L. 233-3 of the French Commercial Code) of a French-law entity, (b) acquiring all or part of a branch of activity of a French-law entity or (c) in the case of individuals that are not nationals of a European Union Member State or a State party to the agreement on the European Economic Area that has entered into an administrative assistance agreement with France and/or is not resident in one of those States or entities of which at least one of the members of the chain of control is not subject to the laws of or is not a national of and/or is not a resident of one of those States, obtaining more than 25% of the voting rights in a French-law entity; and
- whose activities involve, even on an occasional basis, research and development in "critical" technologies such as medical devices or goods and services essential for the protection of public health.

The Company believes that its business could fall within the scope of those rules.

Accordingly, any proposed investment in Carmat that meets the above criteria must first be authorized by the Minister of the Economy. Authorization may be granted subject to certain conditions to ensure that the investment will not be detrimental to the national interests.

These regulations could potentially discourage investors outside the European Economic Area from making large investments in Carmat or from acquiring control or taking over the Company in the same conditions.

However, the Company does not, at this stage, believe that these regulations will prevent it from raising the funding required for its development in the short or medium term.

## 2.3.4 RISK ASSOCIATED WITH THE SUPPLY OF MATERIALS AND COMPONENTS

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

### MAJOR RISK

As indicated in section 1.5.4 of this document, to manufacture its device, the Company depends on a large number of suppliers and sub-contractors of extremely diverse sizes, some more financially solid than others, and some able to ramp-up more quickly than others. For a large number of materials and components, the Company is dependent on one single supplier. It cannot be excluded that certain components or materials will need to be substituted or modified for reasons of obsolescence or in the context of continuous improvement of the artificial heart. In addition, validating new suppliers or sub-contractors is a long and costly operation, and the quality requirements imposed by Carmat are high.

In order to secure its supplies, Carmat regularly conducts a review of its supplier portfolio and has strengthened the process it uses to assess its needs in terms of materials and components. In this context, a plan for double-sourcing, modification of sourcing and/or capacity building at critical suppliers has been drawn up and is gradually being implemented. However, despite the implementation of this policy, which is already beginning to produce some results but will take several years, the risk of temporary shortages of certain components or materials remains a highly significant risk for Carmat, especially as the volume of devices required to meet the needs of clinical trials and the commercial phase is growing. Furthermore, the Covid-19 crisis has weakened the position of some of the Company's suppliers and sub-contractors, thus increasing the level of risk in the short term, and could force the Company to step up its mitigation plan.

In light of this, the Company is taking steps to gradually build up safety inventories in order to be able to continue production, even in the event of temporary disruptions to the supply of a component of material.

## 2.3.5 RISK ASSOCIATED WITH PRODUCTION VOLUMES

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

### MAJOR RISK

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

The Company has already made several dozen modifications to its production processes, in particular in 2019 and 2020, and will continue its investments and its continuous improvement and automation actions in the coming years to make production operations more reliable and enable ramp-up.

However, the Company believes it possible that the rate of ramp-up in production may be insufficient to prevent demand from exceeding its production capacities, particularly in the short term, while production volumes will have to increase considerably not only to meet the needs of the broader clinical trials (including the EFICAS in France) but also to meet commercial demand after obtaining CE marking in December 2020.

## 2.3.6 RISK ASSOCIATED WITH PRODUCTION QUALITY

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

### MAJOR RISK

Carmat complies with the highest quality requirements and set up a quality management system (QMS) certified ISO 13485-9001 in July 2011. The certification has been successfully renewed regularly since, most recently in 2020. Based in particular on its internal audit results and the audits carried out by Dekra, the Company considers that this system enables it in particular to quickly identify any critical quality defects and implement appropriate preventive and corrective actions. The Company is therefore committed to a continuous improvement process in production quality.

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

## 2.3.7 RISK ASSOCIATED WITH OBTAINING PMA IN THE UNITED STATES

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

### MAJOR RISK

In order to market its artificial heart in the United States, Carmat must first obtain pre-market approval (PMA), issued by the US Food & Drug Administration (FDA). The process to obtain PMA is described in section 1.4.2 of this document.

In September 2019, the FDA gave the Company conditional approval to conduct an early feasibility study (EFS) in the United States, followed by full approval in February 2020 for a study covering 10 patients. In December 2020, Carmat announced that the first patients would receive their implants under the EFS in the first quarter of 2021 and that enrollment would be completed by the end of 2021.

The EFS is the first step in the process potentially leading to obtaining PMA. Given, in particular, this progress, the quality of its clinical results (see section 1.4.1) and its discussions with the FDA, Carmat considers it reasonable to obtain PMA in the United States within a few years.

However, obtaining PMA is a very stringent and potentially lengthy process, which has only just begun. The decision to issue PMA is in the hands of the FDA, and Carmat cannot guarantee that it will be obtained within a few years or even at all.

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

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

### MAJOR RISK

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

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

Given various parameters, including the quality of its clinical results (see section 1.4.1) and the reimbursement of existing devices and therapies (see section 1.5.2), Carmat considers it reasonable to obtain reimbursement levels in line with its assumptions in the European countries targeted for the marketing of its prosthesis (it being recalled that Europe is the first geographic area in which Carmat intends to market its prosthesis, and will remain so for a few years).

However, the Company cannot be sure of obtaining and maintaining optimal reimbursement or coverage in all the European countries concerned, particularly because there is constant economic, regulatory and political pressure to limit healthcare costs. In the short term, this pressure could be exacerbated by the economic crisis triggered by Covid-19, at a time when the Company is planning to start marketing its device in 2021.

## 2.3.9 RISK ASSOCIATED WITH THE REIMBURSEMENT OF THE PROSTHESIS ON THE AMERICAN MARKET (ASSUMING CARMAT OBTAINS THE PMA)

| Market access risks | Description of risk | Potential impacts |
|---|---|---|
| Risk related to the reimbursement of the prosthesis on the American market | Risk that, assuming the Company obtains PMA from the FDA, Carmat's device will not be reimbursed or covered by social security in the United States, or that the level of reimbursement obtained will be lower than forecast by the Company. | Prosthesis sales levels may be much lower than forecast on the American market, with a potential impact on the economic viability of the Company. |

### MAJOR RISK

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

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

Given various parameters, including the quality of its clinical results (see section 1.4.1) and the reimbursement of existing devices and therapies, Carmat considers it reasonable to obtain reimbursement and coverage levels in line with its assumptions in the United States. Furthermore, the May 2020 agreement to reimburse the artificial heart under the EFS due to begin in the United States in the first quarter of 2021 is a highly encouraging sign.

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

## 2.3.10 RISK ASSOCIATED WITH OBTAINING CE MARKING (EUROPE)

| Market access risks | Description of risk | Potential impacts |
|---|---|---|
| Risk associated with obtaining CE marking in Europe | Risk that the Company will not obtain (or will obtain later than expected) an extension to the indication specified in the CE marketing obtained on December 22, 2020, and more generally the destination therapy (DT) indication. | Smaller than initially expected potentially addressable market, which could lead to lower sales or slower growth in sales than initially forecast by investors. |

### MINOR RISK

CE marking was granted on December 22, 2020 for Carmat's artificial heart system as a bridge to transplant for patients suffering from terminal biventricular heart failure (Intermacs 1-4), who are unable to benefit from a maximum therapy or a left ventricular assist device (LVAD) and who are likely to be given a heart transplant within 180 days of receiving the implant. Obtaining CE marking was a prerequisite to marketing the artificial heart in Europe and enables the Company to market it in all countries that recognize the CE marking, including the whole of the European Union.

Carmat believes that the CE marking indication opens up a major market, which should be sufficient to achieve its sales targets over the next few years.

However, Carmat will continue to seek broader indications for its product over time, notably as a destination therapy. This will require Carmat to collect the appropriate clinical data and file new applications with a certification agency.

Although Carmat is confident in its ability to obtain broader indications over the next few years, at this stage it cannot guarantee how long this might take or whether it will obtain them at all.

## 2.3.11 ORGANIZATIONAL AND REGULATORY NON-COMPLIANCE RISKS

| Human, organizational and regulatory non-compliance risks | Description of risk | Potential impacts |
|---|---|---|
| Organizational and regulatory non-compliance risks | Risk that the Company will fail to set up or maintain a sufficiently adapted and robust organization, processes and systems (including IT systems) to support its objectives and growth and meet legal and regulatory requirements. | Difficulty for Carmat to achieve some of its objectives on time, with a possible negative financial impact. Failure to meet all legal and regulatory obligations, which may result in the delay in achieving certain objectives (for example obtaining CE marking or PMA in the United States, or even impossibility for the Company to be listed on the desired market), and/or financial penalties. |

### MODERATE RISK

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

Carmat must therefore constantly adapt its structure, organization, procedures and processes, as well as its systems, which is a challenge and may potentially mobilize a significant amount of resources. The Company is subject to strong operational pressure associated with the delivery of its objectives, and to a binding and constantly evolving legal and regulatory framework (regulatory obligations linked to obtaining CE marking and PMA in the United States, regulatory obligations related to conducting clinical trials, quality-related regulations, obligations as a listed company, GDPR regulations, "Transparency" law in France, tax rules, etc.).

The Company strives to meet all of these imperatives by mobilizing the appropriate resources and systems. Carmat ensures constant legal and regulatory monitoring and calls on external consultants and specialists to assist it on those matters and implement appropriate measures. In 2020, for example, its compliance system was strengthened. However, it cannot be excluded that Carmat, on an ad hoc basis, will experience organizational defects and/or does not comply with all of its legal and regulatory obligations, which could have an unfavorable impact on the achievement of its operational and financial objectives.

## 2.3.12 HUMAN RESOURCES RISKS

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

### MODERATE RISK

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

However, in terms of talent acquisition and retention, Carmat is in competition with a number of other companies, some with more means or potentially certain assets (career development possibilities, compensation packages or work environment, for example) that Carmat is not in a position to guarantee.

In addition, certain skills, particularly technical (in electronics, for example) are in high demand on the job market.

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

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

## 2.3.13 IT, DATA AND TRANSACTION RISKS

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

### MODERATE RISK

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

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

clinical trials are conducted).

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

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

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

## 2.3.14 RISKS RELATED TO THE COVID-19 PANDEMIC

| Covid-19 pandemic risks | Description of risk | Potential impacts |
|---|---|---|
| Risks related to the Covid-19 pandemic | Risk that the Covid-19 pandemic and/or measures taken to control it (e.g., lockdowns) will disrupt the Company's various business activities. | Slowdown, postponement or temporary interruption in various activities (regulatory approvals, clinical trials, production, sales, etc.) that could lead to a delay in achieving the Company's various objectives, thus having a negative financial impact. |

A new strain of coronavirus was detected at the end of 2019. Known as Covid-19, it has since resulted in a global pandemic, causing an economic recession in its wake. Europe and the United States have been particularly badly hit. In an attempt to contain the pandemic, which is still not completely under control, governments have imposed restrictive measures including lockdowns, travel restrictions and increased use of home working arrangements.

Consequently, there is a risk that the Company's various activities could be disrupted by this situation to varying degrees. The main impacts for Carmat could be as follows:

- Delay in the regulatory processes that could, for example, lead to a slowdown in talks with the FDA in the United States regarding approval of the final configuration of the device, which is required before the EFS can begin.
- A delay in or slower than expected enrollment of patients in the various clinical trials in progress (pivotal study in Europe) or due to begin (EFS in the United States and EFICAS in France), particularly in the event of travel restrictions, or should various hospitals be either unavailable to Carmat or less available due to the influx of Covid-19 patients.
- A slowdown or temporary shutdown in production at the Bois d'Arcy facility, which could be due either to the simultaneous absence of key people in the production team or, more probably, to disruptions in the supply of raw materials and components from the Company's suppliers. The health crisis has already weakened a number of these suppliers.
- Slower than expected growth in sales, mainly due to lack of availability of hospitals or potential financial difficulties for some of them.
- Greater difficulties in raising funds, as some potential investors may themselves suffer from the impacts of the crisis or may become more cautious in terms of investing until the pandemic has been brought under control.

In 2020, Carmat felt the effects of the crisis from a regulatory viewpoint (with delays in its talks with the French Health Ministry regarding the EFICAS), although its timetable has not been pushed back by more than three to six months. The Company has also suffered from supply chain problems and difficulties in access to hospitals, which has slowed down patient enrollment in the pivotal study and put a brake on the pace of production and therefore on stockbuilding of devices.

Given the continued uncertainty as to how the pandemic and measures designed to control it will evolve, Carmat is unable to accurately measure the level of Covid-19 risk or its potential impact on the Company in 2021 and beyond. However, it considers that were this risk to materialize, the most likely impacts would be supply chain (and therefore production) disruptions and a potential slowdown in its clinical trials. Furthermore, the Company remains confident that its business model and medium- to long-term prospects will not be jeopardized by this risk.

# 3

# FINANCIAL INFORMATION

# 3.1 2020 FINANCIAL REVIEW

## 3.1.1 SELECTED FINANCIAL INFORMATION

| Income statement (in millions of euros) | Year ended Dec. 31, 2020 | Year ended Dec. 31, 2019 | Year ended Dec. 31, 2018 |
|---|---|---|---|
| Net revenue | 0 | 0 | 0 |
| Net operating income (expense) | (36.4) | (42.4) | (42.8) |
| Net financial income (expense) | (2.5) | (1.8) | (0.9) |
| Net non-recurring income (expense) | 0.2 | (0.1) | (0.0) |
| Research and innovation tax credits | 1.7 | 1.6 | 2.0 |
| **NET PROFIT (LOSS)** | **(37.0)** | **(42.6)** | **(41.8)** |

| Balance sheet (in millions of euros) | Dec. 31, 2020 | Dec. 31, 2019 | Dec. 31, 2018 |
|---|---|---|---|
| Total assets | 59.8 | 64.7 | 36.8 |
| Total equity | (6.7) | 24.5 | 7.5 |
| **(NET CASH) NET DEBT*** | **3.0** | **(39.1)** | **(20.6)** |

* Long-term financial liabilities plus short-term financial liabilities less cash and cash equivalents

| Cash flow statement (in millions of euros) | Year ended Dec. 31, 2020 | Year ended Dec. 31, 2019 | Year ended Dec. 31, 2018 |
|---|---|---|---|
| CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR | 55.5 | 25.3 | 60.7 |
| Net cash from (used in) operating activities | (43.0) | (40.2) | (38.2) |
| Net cash from (used in) investing activities | (2.3) | (0.6) | (2.3) |
| Net cash from (used in) financing activities | 25.8 | 71.1 | 5.0 |
| **CASH AND CASH EQUIVALENTS AT END OF YEAR** | **36.0** | **55.5** | **25.3** |

### 2020 RESULTS: COST DISCIPLINE

Carmat recorded no revenue during 2020, as its artificial heart only obtained CE marking, enabling it to market the device in a large number of countries, including the whole of the European Union, on December 22, 2020. The first sales are expected in the second quarter of 2021.

The operating loss for the year amounted to €36.4 million, an improvement of €6.0 million compared with the previous year.

During 2020, Carmat devoted the main part of its efforts and resources to:

- its production activities: ramp-up in production and improving the reliability of its production processes at the Bois d'Arcy production facility; continuation and strengthening of measures to secure the supply chain; and building up inventories;

- finalizing the product's commercial configuration, including the improvements identified during the clinical research and development phases;

- preparing for marketing in Europe in terms of regulations (CE marking process), marketing and sales, and operations (logistics, information systems, sales administration, etc.);

- continuation of its clinical activities: pivotal study in Europe and preparation for the early feasibility study (EFS) to be conducted in the United States in 2021 and the EFICAS clinical study in France.

The decrease in net operating expense compared with 2019 was driven by tight control over operating expenses, bearing in mind that the Company recognized its inventories as an asset on the balance sheet for the first time at

December 31, 2020 (impact of €9.9 million).[01]

The net financial expense of €2.5 million, up by €0.7 million compared to 2019, is largely explained by the increase in loan interest, notably due to the fact that in May 2020 the Company drew down the second tranche (i.e., €10.0 million) of the €30.0 million loan granted under conditions by the European Investment Bank (EIB) in December 2018.

After taking into account non-recurring income of €0.2 million and the research and innovation tax credit of €1.7 million, the net loss for the 2020 financial year comes to €37.0 million, compared to a net loss of €42.6 million in 2019.

## ROBUST CASH AND FINANCIAL POSITION

Cash and cash equivalents

At December 31, 2020, the Company's cash position stood at €36.0 million compared to €55.5 million at December 31, 2019. The change in cash and cash equivalents in 2020 was due to the following cash inflows and outflows:

| (in millions of euros) | 2020 | 2019 |
|---|---|---|
| Net cash from (used in) operating activities | (43.0) | (40.2) |
| Net cash from (used in) investing activities | (2.3) | (0.6) |
| Net cash from (used in) financing activities | 25.8 | 71.1 |
| **CHANGE IN CASH AND CASH EQUIVALENTS** | **(19.5)** | **30.2** |

The Company obtained the following funds in 2020:

- €10.0 million (second tranche) drawn down in May on the conditional loan granted by the European Investment Bank (EIB) in December 2018;

- €10.0 million of government-guaranteed loans granted by BNP Paribas and Bpifrance in the fourth quarter;

- €5.8 million drawn down in November and December on the flexible equity financing line set up with Kepler-Cheuvreux in September 2018.

Net debt

At December 31, 2020, Carmat's net debt breaks down as follows:

| (in millions of euros) | Dec. 31, 2020 |
|---|---|
| + Long-term financial liabilities | 38.9 |
| + Short-term financial liabilities* | 0.1 |
| - Cash and cash equivalents | (36.0) |
| **NET DEBT** | **3.0** |

* Due within one year.

Financial liabilities comprise the principal (€20.0 million) and interest due on the EIB loan, the principal (€10.0 million) and interest due on the government-guaranteed loans, and the interest due on the €14.5 million repayable advance obtained from Bpifrance. The characteristics and terms of these various loans and the Bpifrance repayable advance are described in section 3.1.10 of this document (material contracts).

Funding horizon

Based on its current business plan, and without additional funding, available financial resources are sufficient for Carmat to fund its business activities until the third quarter of 2021. These resources include:

- €36.0 million of available cash and cash equivalents at December 31, 2020;

- the final €10.0 million tranche of the EIB loan, which can be drawn down at any time until December 17, 2021, as the draw down conditions have already been met;

- €13.0 million of French government funding intended to partially finance the EFICAS study; [02]

- €1.7 million in research and innovation tax credits for 2020, receivable in 2021.

In addition, Carmat can also draw down on the flexible equity financing line until September 27, 2021, the balance of which stood at €16.0 million at December 31, 2020. If the balance were to be drawn down in full, the Company would be able to finance its business activities until November 2021.

Carmat has an ongoing active investor relations and fund-seeking policy and, having obtained CE marking at the end of 2020, is confident in its ability to raise the financial resources needed in the future to continue its development.

**01** Inventories were previously expensed in the year in which they were purchased or produced in the absence of any associated economic benefits.

**02** These funds will be received as and when patients receive their implants during the study, over an estimated period of two years. Implantation is expected to begin in the second quarter of 2021.

## CHANGE IN ACTIVITY IN THE FINANCIAL YEAR

2020 was a defining year for Carmat, with key objectives met despite the Covid-19 pandemic, including obtaining CE marking for its artificial heart.

- Obtaining CE marking and expanding clinical development

Obtaining CE marking and continuation of the pivotal study

On December 22, 2020, CE marking was granted for Carmat's artificial heart as a bridge to transplant for patients suffering from terminal biventricular heart failure (Intermacs 1-4), who are unable to benefit from maximum medical therapy or a left ventricular assist device (LVAD) and who are likely to be given a heart transplant within 180 days of receiving the implant.

Obtaining CE marking is a major milestone for Carmat, as it enables the Company to market its artificial heart as a bridge to transplant in all countries that recognize this certification, including the whole of the European Union.

The positive intermediate results of the pivotal study, which is still ongoing, contributed to receiving CE marking. During 2020, three patients received implants as part of the study (one in Denmark and two in France, where the study resumed in 2020), bringing the total number of patients who have received implants under the study to 15. Information about the study, its progress and intermediate results can be found in section 1.4.1 of this document.

Preparing for the EFS in the United States

Having received conditional approval in September 2019, the Company obtained the FDA's full approval in February 2020 to conduct an early feasibility study (EFS) on ten patients in the United States. Following that, the Centers for Medicare & Medicaid Services (CMS) agreed in May to cover the cost of both the artificial heart and patient care within the framework of the study.

The various stages paving the way to initiating the study (approval by ethics committees, contracts with participating centers, training, setting up logistics, etc.) were successfully completed during the year. To date, three centers (VCU Health Pauley Heart Center in Richmond, Virginia, the University of Louisville Jewish Hospital in Louisville, Kentucky and Baylor University Medical Center in Dallas, Texas) are now ready to enroll patients in the study.

However, in order to be able to use the most recent configuration of its artificial heart in the EFS, Carmat has submitted a number of amendments to the FDA. At this stage, thanks to highly constructive talks with the FDA, eight of nine amendments have already been approved and the final one is expected to be approved shortly.

Carmat therefore still expects the first implantation under the EFS to take place in the first quarter of 2021.

Authorization and funding of the EFICAS study in France under the "Forfait Innovation" program

In April 2020, the Haute Autorité de Santé (HAS) gave its final opinion in favor of the reimbursement of Carmat's artificial heart exceptionally within the framework of a multicentric study (EFICAS) on 52 patients to be conducted in France.

In October, the Ministry of Health and Solidarity granted Carmat €13.0 million of funding for the study, covering two-thirds of its total cost. The funds will be received as and when patients receive their implants.

Carmat expects to begin implantation under the EFICAS study in the second quarter of 2021.

The full clinical plan is described in section 1.5.3 of this document.

- Ramp-up in production and continued measures to secure the supply chain

During 2020, Carmat continued its plan to ramp up production and to improve the reliability of its production processes at the Bois d'Arcy facility. It also took further measures to secure its supply chain and has built up substantial inventories of products in order to meet growth in demand for its devices in 2021.

€2.2 million was invested in the industrial facilities during the year and the manufacturing workforce was increased by 10 people, from 55 at end-2019 to 65 at end-2020.

- Marketing preparation

CE marking for the bridge to transplant indication is a major market opportunity, with more than 2,000 patients currently on the waiting list for a heart transplant in Europe's five largest countries.[03]

Ahead of obtaining CE marking, Carmat took all necessary measures in 2020 to be ready to start marketing its artificial heart in the second quarter of 2021, including:

- ramping up production activities as described above;

- proactive targeting of customers and early support for hospitals for their reimbursement processes;

**03** Statistics.eurotransplant.org: 9023P_2019; https://rams.agence-biomedecine.fr. Five largest European countries: France, Germany, Italy, Spain and the United Kingdom.

- product and brand positioning (the artificial heart will be marketed under the brand name Aeson®);

- setting up logistics, sales administration and information systems, and strengthening the sales and marketing teams.

In 2021, Carmat intends to focus marketing efforts on Germany and France, which together represent 55% of the mechanical circulatory support (MCS) device market in the European Union:[04]

- Aeson® will be launched on the market in Germany in the second quarter of 2021;

- the French market will be first addressed through the EFICAS study.

- Impact of the Covid-19 pandemic

In 2020, Carmat felt the effects of the Covid-19 pandemic from a regulatory viewpoint (with delays in its talks with the French Health Ministry regarding the EFICAS), although its timetable has not been pushed back by more than three to six months. The Company has also suffered from supply chain issues and difficulties in access to hospitals, which has slowed down patient enrollment in the pivotal study and put a brake on the pace of production and therefore on stockbuilding of devices. However, despite these challenges, the Company obtained CE marking for the bridge to transplant indication for its device in December 2020 and did not halt production at any point during the year.

The risks related to the Covid-19 pandemic and its potential impacts are described in more detail in section 2 of this document.

- Governance

André Muller joined Carmat's Board of Directors at the conclusion of the Combined Shareholders' Meeting held on March 30, 2020. He is currently Executive Vice President and Chief Financial Officer of pharmaceutical company Idorsia and brings the Board of Directors his extensive knowledge of the health sector as well as his financial skills.

The Company also increased its workforce by 23 people in 2020, bringing the total number of employees to 130 at December 31, 2020.

**04** GlobalData: EU5 Cardiac Assist Devices Market Outlook To 2025 - Intra-Aortic Balloon Pumps, Mechanical Circulatory Support Devices And Short-Term Circulatory Support Devices (Report GDMECR1561DB)

## 3.1.2 COMPLETED OR FUTURE INVESTMENTS

### MAIN INVESTMENTS COMPLETED IN THE LAST THREE FINANCIAL YEARS

The Company invested €2.2 million during 2020, mainly in its production facility at Bois d'Arcy and primarily with the aim of ramping up the facility's production capacity.

Investments totaled €0.7 million and €2.3 million in 2019 and 2018, respectively.

### PROPERTY, PLANT AND EQUIPMENT IN PROGRESS

Non-current assets in progress at the end of 2020 amounted to €2.6 million, comprising entirely property, plant and equipment, and mainly machinery in the course of validation, which will be used in production when ready.

### MAIN PLANNED INVESTMENTS

In the coming years, the Company intends to continue investing in its Bois d'Arcy production facility to streamline and improve the reliability of its production processes and ramp up its capacity. It also intends to continue investing particularly in information systems.

## 3.1.3 PROGRESS MADE AND DIFFICULTIES ENCOUNTERED DURING THE FINANCIAL YEAR

Progress made by the Company and the difficulties encountered during 2020 (including the Covid-19 impact) are described in section 3.1.1.

## 3.1.4 LEGAL AND ARBITRATION PROCEEDINGS

To the best of the Company's knowledge, there is no litigation, arbitration, governmental or judicial procedure, or exceptional event, likely to have or having had in the last 12 months significant effects on the financial position or profitability of the Company.

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

In 2021, Carmat intends to continue to focus its efforts and resources on its strategic priorities, with the following objectives:

- initiation of the EFS in the United States in the first quarter;

- commercial launch of its device in Europe in the second quarter;

- initiation of the EFICAS clinical study in France in the second quarter;

- start of broad post-marketing surveillance (PMS);

- continued ramp-up in production and measures to secure the production supply chain.

More generally, implementation of its clinical plan (see section 1.5.3 of this document) will enable Carmat to generate additional safety, performance and medico-economic data about its artificial heart. These data should promote acceptance of the product, support Aeson®'s value proposition (particularly to obtain social security reimbursement for the product in France) and, ultimately, obtain indication for use as a destination therapy (DT)[05]. The Company also intends to obtain authorization to market its product in the United States within the next few years.

It continues to keep a close eye on the Covid-19 situation in France and abroad, and, depending on future developments, may have to adjust its timeline accordingly.

Given the continued uncertainty as to how the situation and measures intended to control it will evolve, Carmat is unable to accurately measure the level of Covid-19 risk or its potential impact on the Company in 2021 and beyond. However, it considers that were this risk to materialize, the most likely impacts would be supply chain – and therefore production – disruptions and a potential slowdown in its clinical trials. Furthermore, the Company remains confident that its business model and medium- to long-term prospects will not be jeopardized by this risk.

### SIGNIFICANT EVENTS AFTER THE REPORTING DATE

In January 2021, Carmat announced the appointment of Professor Christian Latrémouille as Director of Surgical Affairs. A Doctor of Medicine, Christian Latrémouille is the only heart surgeon in the world to have participated in the Carmat heart's entire clinical assessment process. In this role, he will be responsible for overseeing hospitals, from the surgical team training phase through to patient treatment.

On February 10, 2021, Carmat announced that it had received FDA approval to use the new version of its artificial heart in the US Early Feasibility Study (EFS).

### MAIN TRENDS SINCE THE END OF 2020 FINANCIAL YEAR

The Company does not have any significant change to report in its financial position since December 31, 2020.

### PROFIT FORECASTS OR ESTIMATES

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

**05** As the BTT indication is based on temporary use of the Carmat device, obtaining the DT indication would also enable Carmat to target patients who are not eligible for a heart transplant and would remain reliant on the Carmat device for a longer period.

## 3.1.6 FIVE-YEAR FINANCIAL SUMMARY

### STATEMENT OF RESULTS FOR THE PAST FIVE FINANCIAL YEARS

| (in euros) | 2020 | 2019 | 2018 | 2017 | 2016 |
|---|---|---|---|---|---|
| Share capital at year end | | | | | |
| Share capital | 520,499.36 | 504,385.96 | 371,036.76 | 360,661.76 | 241,277.76 |
| Number of existing ordinary shares | 12,980,789 | 12,609,649 | 9,275,919 | 9,016,544 | 6,031,944 |
| Number of priority dividend shares | - | - | - | - | - |
| Maximum number of future shares to be created | | | | | |
| - by conversion of bonds | - | - | - | - | - |
| - by exercise of subscription or conversion rights | 1,032,285 | 1,314,700 | 1,246,750 | 943,025 | 852,140 |
| Operations and earnings | | | | | |
| Revenue excluding tax | 0 | 0 | 0 | 0 | 0 |
| Net profit (loss) before tax, profit sharing, depreciation/amortization and provisions | (30,257,474) | (43,339,319) | (42,784,848) | (30,020,856) | (25,378,370) |
| Income tax | 1,710,979 | 1,636,019 | 1,983,916 | 2,334,690 | 2,817,116 |
| Employee profit sharing | - | - | - | - | - |
| Net profit (loss) after tax, profit sharing, depreciation/amortization and provisions | (36,963,432) | (42,648,672) | (41,729,066) | (29,227,910) | (22,980,178) |
| Distributed earnings | - | - | - | - | - |
| Earnings per share | | | | | |
| Earnings (loss) after tax and profit sharing, but before depreciation/amortization and provisions | (2.20) | (3.31) | (4.40) | (3.07) | (3.74) |
| Earnings (loss) after tax, profit sharing, depreciation/amortization and provisions | (2.85) | (3.38) | (4.50) | (3.25) | (3.81) |
| Dividend per share | - | - | - | - | - |
| Personnel | | | | | |
| Headcount at year end (including temporary staff) | 130 | 107 | 90 | 70 | 56 |
| Total payroll for the year | 10,184,964 | 8,364,741 | 6,819,510 | 5,220,243 | 4,371,200 |
| Total payroll taxes for the year | 4,832,053 | 4,453,860 | 3,906,890 | 2,163,452 | 1,803,184 |

## 3.1.7 DIVIDEND PAYMENT HISTORY

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

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

## 3.1.8 PROPERTY, PLANT AND EQUIPMENT

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

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

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

Premises used by the Company as at December 31, 2020

| Lessee | Address | Nature of premises | Surface area | Lease start date | Lease expiration date |
|---|---|---|---|---|---|
| Carmat SA | 36, avenue de l'Europe<br>Immeuble l'Étendard Energy III<br>78140 Vélizy-Villacoublay | Business premises | 1,053 sq.m | Feb. 1, 2009 | Jan. 31, 2027 |
| Carmat SA | 36, avenue de l'Europe<br>Immeuble l'Étendard Energy III<br>78140 Vélizy-Villacoublay | Business premises | 595 sq.m | Oct. 1, 2010 | Sept. 30, 2028 |
| Carmat SA | 36, avenue de l'Europe<br>Immeuble l'Étendard Energy III<br>78140 Vélizy-Villacoublay | Business premises | 595 sq.m | July 1, 2011 | March 31, 2022 |
| Carmat SA | 9, rue René Clair<br>Bâtiment G<br>Sis parc Spirit Meliès III<br>78390 Bois d'Arcy | Business premises | 1,558 sq.m | Dec. 7, 2017 | Dec. 6, 2027 |
| Carmat SA | 9, rue René Clair<br>Lot F1<br>Sis parc Spirit Meliès III<br>78390 Bois d'Arcy | Business premises | 668 sq.m | March 10, 2020 | March 9, 2030 |

### ENVIRONMENTAL ISSUES

As part of the search for hemocompatible materials, Carmat decided to adopt an original approach by using chemically treated animal pericardium to make the device inert and biologically stable, which avoids rejection by the human body.

In the design, manufacture and distribution of the bioprosthetic artificial heart, the Company is subject to chemical and biological risks. Both in this respect and when explanting its artificial heart, Carmat also has to manage various types of waste, including biological and electronic waste.

Carmat therefore takes all necessary measures to protect its staff and other people exposed to these risks, and to efficiently manage waste in accordance with the regulations in force.

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

## 3.1.9 INFORMATION ON PAYMENT TERMS

### INFORMATION ON PAYMENT TERMS FOR ACCOUNTS RECEIVABLE

Not applicable.

## INFORMATION ON PAYMENT TERMS FOR ACCOUNTS PAYABLE

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

As at December 31, 2020, accounts payable totaled €2,591,755. A comparison of the figures from the financial statements is set out below:

| (in euros) | Dec. 31, 2020 | Dec. 31, 2019 |
|---|---|---|
| Trade notes and accounts payable shown under liabilities | 8,006,213 | 5,345,899 |
| Less: Amounts receivable from suppliers shown under assets | 0 | 0 |
| Less: Accrued expenses included in this item | (5,414,457) | (2,968,394) |
| Amounts payable on non-current assets and other | 0 | 0 |
| Accrued expenses included in this item | 0 | 0 |
| **TOTAL** | **2,591,755** | **2,377,505** |

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

| (in euros) | Dec. 31, 2020 | Dec. 31, 2019 |
|---|---|---|
| Due (including amounts receivable from suppliers) | 513,718 | 316,519 |
| Falling due on January 31 | 2,078,038 | 2,060,987 |
| Falling due on February 28 | 0 | 0 |
| Falling due on or after March 31 | 0 | 0 |

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

**Article D.441 I.-1°: Invoices received and due but not settled at the end of the period**

| (in euros) | 0 days | 1 to 30 days | 31 to 60 days | 61 to 90 days | > 90 days | Total |
|---|---|---|---|---|---|---|
| (A) Days late | | | | | | |
| Number of invoices | | 144 | | | | |
| Total amount of invoices (incl. taxes) | | 513,718 | 0 | 0 | 0 | 0 |
| Percentage of total purchases for the period (incl. taxes) | | 1.43% | 0 | 0 | 0 | 0 |
| (B) Invoices excluded from (A) relating to contested payables | | | | | | |
| Number of invoices | | | 0 | | | |

# 3.1.10 MATERIAL CONTRACTS

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

- a royalties agreement signed on June 24, 2008 and amended on February 5, 2010, between Carmat, Professor Alain Carpentier and Matra Défense (an Airbus Group subsidiary): please refer to section 5.6 "Related-party agreements";
- an exclusive license agreement with the Pierre and Marie Curie University relating to patent no. 8800381: please refer to section 1.5.5 "Innovation and R&D management";
- an agreement with Edwards Lifesciences initially concluded in the fourth quarter of 2010 between Carmat and Edwards Lifesciences, world leader in the segment

of heart valves and in hemodynamic monitoring, for the use and the supply of Carpentier-Edwards biological heart valves in the Carmat bioprosthetic artificial heart project;

- a 12-year agreement with Invibio Limited concluded in the third quarter of 2012 between Carmat and Invibio Limited for the supply and use of PEEK-OP-TIMA® polymeric material. This material is used by Carmat for its biocompatibility characteristics, which are certified as long-lasting implantable, and for its mechanical properties. The structural subsets of the prosthesis are processed with this material;
- a framework aid agreement for the Carmat Industrial Strategic Innovation (ISI) project and an agreement in support of the Carmat project entered into on July 24, 2009 for a total sum of €33 million granted by Bpifrance;
- a non-dilutive financing agreement concluded in December 2018 with the European Investment Bank for an amount of €30 million;
- a government-guaranteed loan agreement with BNP Paribas in the fourth quarter of 2020 for an amount of €5 million;
- a government-guaranteed loan agreement with Bpifrance in the fourth quarter of 2020 for an amount of €5 million.

These last four agreements are detailed below:

### FRAMEWORK AGREEMENT WITH BPIFRANCE

Initial conditions of the agreement

On July 24, 2009, the Company signed a framework agreement with Bpifrance to secure aid for the Carmat Industrial Strategic Innovation (ISI) project. Under the terms of the agreement, Bpifrance undertook to pay a total amount of €33 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 total amount of €33 million had already been received at December 31, 2019, as the remaining €1.5 million balance of the repayable advance was received in June 2019.

Accounting and financial conditions

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

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

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

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

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

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

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

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

| | |
|---|---|
| Year 1 | €184,000 |
| Year 2 | €368,000 |
| Year 3 | €1,472,000 |
| Year 4 | €2,784,000 |
| Year 5 | €8,316,000 |
| Year 6 | €11,300,000 |

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

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

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

Conversely, 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, provided that Carmat has complied with all its obligations.

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 revenue, subject to a maximum financial return of €50 million at nominal value, if achieved within 8 years.

### EUROPEAN INVESTMENT BANK (EIB) FINANCING AGREEMENT

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

The first tranche was drawn down on January 31, 2019 and the second tranche on May 4, 2020.

The third and final €10 million tranche can be drawn down at any time until December 17, 2021, as the draw down conditions have already been met.

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

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

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

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

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

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

### BNP PARIBAS GOVERNMENT-GUARANTEED LOAN

BNP Paribas has granted Carmat a €5 million loan, which is 90% guaranteed by the French government and was drawn down on October 27, 2020.

It is a bullet loan with an initial term of 12 months and bears interest at a fixed rate of 0.25%. The Company has the option to extend the repayment period for a further one to five years and intends to exercise this option.

The loan is not secured.

### BPIFRANCE GOVERNMENT-GUARANTEED LOAN

Bpifrance has granted Carmat a €5 million loan, which is 90% guaranteed by the French government and was drawn down on November 12, 2020.

It is a bullet loan with an initial term of 12 months and bears interest at a fixed rate of 1.75%. The Company has the option to extend the repayment period for a further one to five years and intends to exercise this option.

The loan is not secured.

## 3.1.11 PROPOSED APPROPRIATION OF NET PROFIT (LOSS)

We propose the approval of the annual financial statements (balance sheet, income statement and notes) as presented. These financial statements show a net loss of €36,963,432.

We propose the appropriation of this loss to "Losses carried forward", taking the balance of that item to negative €36,963,432.

# 3.2 2020 FINANCIAL STATEMENTS

## 3.2.1 FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2020

### INCOME STATEMENT

| Income statement | Year ended Dec. 31, 2020 | | | Year ended Dec. 31, 2019 |
|---|---|---|---|---|
| (in euros) | France | Export | Total | Total |
| OPERATING INCOME | | | | |
| Sale of goods for resale | | | | |
| Production sold - goods | | | | |
| Production sold - services | | | | |
| Net revenue | | | | |
| Inventoried production | | | 11,824,742 | |
| Capitalized production | | | | |
| Operating subsidies (note 3.2.2.5) | | | 9,333 | 14,000 |
| Reversals of impairment, depreciation/amortization and provisions, expense transfers | | | 410,615 | 688,472 |
| Other income | | | | |
| TOTAL OPERATING INCOME (I) | | | 12,244,690 | 702,472 |
| OPERATING EXPENSES | | | | |
| Purchases of goods for resale | | | 1,194,769 | |
| Change in inventories (goods for resale) | | | (944,092) | |
| Purchases of raw materials and other supplies | | | 8,420,267 | 7,397,143 |
| Change in inventories (raw materials and other supplies) | | | (4,647,106) | |
| Other purchases and external expenses | | | 20,375,426 | 20,901,665 |
| Taxes, duties and other levies | | | 319,268 | 365,293 |
| Wages and salaries | | | 10,184,964 | 8,364,741 |
| Social security contributions | | | 4,832,053 | 4,453,860 |
| Depreciation/amortization and impairment | | | | |
| - of non-current assets: depreciation/amortization (note 3.2.2.4.2) | | | 931,758 | 1,163,537 |
| - of non-current assets: impairment | | | | |
| - of current assets: impairment | | | 7,514,141 | |
| Additions to provisions (note 3.2.2.4.4) | | | 381,653 | 382,592 |
| Other expenses | | | 93,094 | 67,452 |
| TOTAL OPERATING EXPENSES (II) | | | 48,656,196 | 43,096,284 |
| 1 - NET OPERATING INCOME (EXPENSE) (I - II) | | | (36,411,506) | (42,393,812) |
| SHARE IN INCOME FROM JOINT VENTURES | | | | |
| Income allocated or loss transferred (III) | | | | |
| Loss incurred or income transferred (IV) | | | | |
| FINANCIAL INCOME | | | | |
| Investment income | | | | |
| Income from other marketable securities and non-current asset receivables | | | | |
| Other interest income | | | | |
| Reversals of impairment and provisions, expense transfers | | | | |
| Foreign exchange gains | | | 140,802 | 40,786 |
| Net income on sales of marketable securities | | | | |
| TOTAL (V) | | | 140,802 | 40,786 |

| Income statement | Year ended Dec. 31, 2020 | | | Year ended Dec. 31, 2019 |
|---|---|---|---|---|
| (in euros) | France | Export | Total | Total |
| FINANCIAL EXPENSES | | | | |
| Depreciation/amortization, impairment and provisions | | | | |
| Interest expense | | | 2,525,555 | 1,782,149 |
| Foreign exchange losses | | | 78,539 | 45,572 |
| Net expenses on sales of marketable securities | | | | |
| TOTAL (VI) | | | 2,604,094 | 1,827,721 |
| 2 - NET FINANCIAL INCOME (EXPENSE) (V - VI) | | | (2,463,292) | (1,786,935) |
| 3 - RECURRING INCOME (EXPENSE) BEFORE TAX (I-II+III-IV+V-VI) | | | (38,874,799) | (44,180,747) |
| NON-RECURRING INCOME (NOTE 3.2.2.5) | | | | |
| Non-recurring income on management transactions | | | 145,894 | |
| Non-recurring income on corporate actions | | | 115,748 | 46,794 |
| Reversals of impairment and provisions, expense transfers | | | | |
| TOTAL (VII) | | | 261,642 | 46,794 |
| NON-RECURRING EXPENSES (NOTE 3.2.2.5) | | | | |
| Non-recurring expenses on management | | | | 2,513 |
| Non-recurring expenses on corporate actions | | | 61,255 | 60,767 |
| Depreciation/amortization, impairment and provisions | | | | 87,458 |
| TOTAL (VIII) | | | 61,255 | 150,738 |
| 4 - NET NON-RECURRING INCOME (EXPENSE) | | | 200,387 | (103,944) |
| Employee profit-sharing (IX) | | | | |
| Income tax (X) (note 3.2.2.5) | | | (1,710,979) | (1,636,019) |
| TOTAL INCOME (I+III+V+VII) | | | 12,647,133 | 790,052 |
| TOTAL EXPENSES (II+IV+VI+VIII+IX+X) | | | 49,610,566 | 43,438,724 |
| 5 - NET PROFIT (LOSS) (total income - total expenses) | | | (36,963,432) | (42,648,672) |

## BALANCE SHEET

| Assets | Dec. 31, 2020 | | | Dec. 31, 2019 |
|---|---|---|---|---|
| (in euros) | Gross | Depreciation, amortization and impairment | Net | Net |
| UNCALLED SUBSCRIBED CAPITAL (TOTAL I) | | | | |
| Non-current assets | | | | |
| Intangible assets (notes 3.2.2.4.1 and 3.2.2.4.2) | | | | |
| - Start-up costs | | | | |
| - Development costs | | | | |
| - Licenses, patents and similar rights | 1,913,138 | 1,896,056 | 17,082 | 27,718 |
| - Goodwill* | | | | |
| - Intangible assets not yet available for use | | | | |
| - Advances and downpayments | | | | |
| Property, plant and equipment (notes 3.2.2.4.1 and 3.2.2.4.2) | | | | |
| - Land | | | | |
| - Buildings | | | | |
| - Technical plant, equipment and tooling | 9,760,745 | 7,241,917 | 2,518,828 | 3,080,224 |
| - Other property, plant and equipment | 2,841,775 | 1,586,918 | 1,254,857 | 1,415,737 |
| - Property, plant and equipment in progress | 2,639,980 | | 2,639,980 | 614,209 |
| - Advances and downpayments | | | | |
| Financial assets** (notes 3.2.2.4.1 and 3.2.2.4.2) | | | | |
| - Equity-accounted investments | | | | |
| - Other equity interests | | | | |
| - Other long-term investments | | | | |
| - Loans | | | | |
| - Other financial assets | 545,525 | | 545,525 | 473,503 |
| TOTAL II | 17,701,162 | 10,724,890 | 6,976,272 | 5,611,392 |
| Current assets | | | | |
| Inventories and work in progress (note 3.2.2.4.3) | | | | |
| - Raw materials, supplies | 4,647,106 | 115,057 | 4,532,049 | |
| - Work in progress – goods | 1,005,574 | 544,119 | 461,455 | |
| - Semi-finished and finished goods | 10,819,168 | 6,444,560 | 4,374,608 | |
| - Goods for resale | 944,092 | 410,405 | 533,687 | |
| Advances and downpayments on orders | 2,676,338 | | 2,676,338 | 494,132 |
| Receivables*** | | | | |
| - Trade notes and accounts receivable | | | | |
| - Other receivables (note 3.2.2.4.5) | 4,108,333 | | 4,108,333 | 2,943,016 |
| Share capital subscribed, called and unpaid | | | | |
| Marketable securities | | | | |
| Cash instruments | | | | |
| Cash | 35,984,388 | | 35,984,388 | 55,505,492 |
| Prepaid expenses*** (note 3.2.2.4.11) | 188,039 | | 188,039 | 121,610 |
| TOTAL III | 60,373,038 | 7,514,141 | 52,858,897 | 59,064,250 |
| ACCRUAL ACCOUNTS | | | | |
| Deferred loan issuance costs (IV) | | | | |
| Bond redemption premiums (V) | | | | |
| Unrealized foreign exchange losses (VI) | | | | |
| GRAND TOTAL (I+II+III+IV+V+VI) | 78,074,200 | 18,239,032 | 59,835,169 | 64,675,643 |
| * Including lease rights. | | | | |
| ** Of which are due in less than one year. | | | 181,880 | 127,386 |
| *** Of which are due in more than one year. | | | | |

| Equity and liabilities<br>(in euros) | Dec. 31, 2020 | Dec. 31, 2019 |
|---|---|---|
| EQUITY (note 3.2.2.4.6) | | |
| Share capital (of which paid-up: 520,499) | 520,499 | 504,386 |
| Additional paid-in capital | 29,704,317 | 254,053,133 |
| Revaluation adjustments | | |
| Reserves | | |
| - Legal reserve | | |
| - Statutory or contractual reserves | | |
| - Untaxed reserves | | |
| - Other reserves | 50,308 | 38,476 |
| Retained earnings (losses carried forward) | | (187,480,075) |
| Net profit (loss) for the year | (36,963,432) | (42,648,672) |
| Investment subsidies | | |
| Tax-driven provisions | | |
| TOTAL I | (6,688,308) | 24,467,248 |
| OTHER EQUITY | | |
| Proceeds from issues of equity securities | | |
| Conditional advances (note 3.2.2.4.11) | 14,507,309 | 14,507,309 |
| TOTAL II | 14,507,309 | 14,507,309 |
| PROVISIONS | | |
| Provisions for contingencies | 80,000 | |
| Provisions for losses (notes 3.2.2.4.4 and 3.2.2.5) | 576,598 | 685,560 |
| TOTAL III | 656,598 | 685,560 |
| LIABILITIES* | | |
| Debt | | |
| - Convertible bonds | | |
| - Other bonds | | |
| - Bank loans and borrowings | 32,130,333 | 10,733,333 |
| - Bank overdrafts | | |
| - Sundry loans and borrowings (note 3.2.2.4.5) | 6,810,075 | 5,681,519 |
| Advances and downpayments received on orders in progress | | |
| Accounts payable (note 3.2.2.4.5) | | |
| - Trade notes and accounts payable | 8,006,213 | 5,345,899 |
| - Tax and social security payables | 4,412,949 | 3,254,774 |
| Amounts payable on non-current assets and other | | |
| Other payables | | |
| ACCRUAL ACCOUNTS | | |
| Prepaid income* | | |
| TOTAL IV | 51,359,569 | 25,015,525 |
| Unrealized foreign exchange gains | | |
| TOTAL V | - | - |
| GRAND TOTAL (I+II+III+IV+V) | 59,835,169 | 64,675,643 |
| * Liabilities and prepaid income due in less than one year: | 12,498,606 | 8,600,673 |

## CASH FLOW STATEMENT

| Cash flow statement<br>(in euros) | Year ended Dec. 31, 2020 | Year ended Dec. 31, 2019 |
|---|---|---|
| Net profit (loss) | (36,963,432) | (42,648,672) |
| Depreciation/amortization and provisions | 8,827,551 | 1,546,129 |
| Reversals of depreciation/amortization and provisions | (410,615) | (688,472) |
| Gains or losses on disposals of assets | | |
| Investment subsidies transferred to income | | |
| Other income and expenses with no cash impact | 2,525,555 | 1,763,219 |
| CASH FLOW FROM OPERATIONS BEFORE CHANGE IN WORKING CAPITAL | (26,020,940) | (40,027,796) |
| Tax and social security payables | 1,158,175 | 268,867 |
| Trade accounts payable | 2,660,314 | (2,269,648) |
| Other payables | | (46,544) |
| Prepaid income | | |
| Inventories and work in progress | (17,415,940) | |
| Advances and downpayments on orders | (2,182,206) | (118,411) |
| Other receivables | (1,165,317) | 1,636,856 |
| Trade receivables | | |
| Prepaid expenses | (66,429) | 311,708 |
| CHANGE IN WORKING CAPITAL | (17,011,403) | (217,172) |
| NET CASH FROM (USED IN) OPERATING ACTIVITIES | (43,032,343) | (40,244,968) |
| Acquisition of property, plant and equipment | (2,325,730) | (613,158) |
| Acquisition of intangible assets | 101,115 | (35,568) |
| Acquisition of financial assets | (72,022) | 12,374 |
| Proceeds from disposals of financial assets | | |
| NET CASH FROM (USED IN) INVESTING ACTIVITIES | (2,296,637) | (636,352) |
| Capital increase | 16,113 | 133,349 |
| Bonds redeemable in shares/share warrants | | |
| Share premium and reserves | 5,791,763 | 59,501,072 |
| Capitalization of current accounts | | |
| Borrowings and conditional advances | 20,000,000 | 11,450,732 |
| NET CASH FROM (USED IN) FINANCING ACTIVITIES | 25,807,876 | 71,085,154 |
| CHANGE IN CASH AND CASH EQUIVALENTS | (19,521,103) | 30,203,834 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR | 55,505,492 | 25,301,658 |
| CASH AND CASH EQUIVALENTS AT END OF YEAR | 35,984,389 | 55,505,492 |

# 3.2.2 NOTES TO THE 2020 FINANCIAL STATEMENTS

**Notes to the balance sheet for the year ended December 31, 2020, which shows total assets of €59,835,169, and to the income statement for the year ended December 31, 2020, presented in list form and showing zero revenue resulting in a net loss of €36,963,432.**

The financial statements cover the 12-month period to December 31, 2020, and the comparative 12-month period to December 31, 2019.

The notes and tables presented below are an integral part of the financial statements for the year ended December 31, 2020 as approved by the Board of Directors on February 8, 2021. They are presented in euros unless otherwise stated.

## 3.2.2.1 SIGNIFICANT EVENTS DURING THE YEAR

During 2020, the Company continued to develop its artificial heart and, on December 22, 2020, obtained CE marking enabling it to market the device as a bridge to transplant in all countries that recognize CE marking, including the whole of the European Union.

In 2020, Carmat felt the effects of the Covid-19 pandemic from a regulatory viewpoint (with delays in its talks with the French Health Ministry regarding the EFICAS), although its timetable has not been pushed back by more than three to six months. The Company has also suffered from supply chain issues and difficulties in access to hospitals, which has slowed down patient enrollment in the pivotal study and put a brake on the pace of production and therefore on stockbuilding of devices. However, despite these challenges, the Company obtained CE marking for the bridge to transplant indication for its device in December 2020 and did not halt production at any point during the year.

In April 2020, the Haute Autorité de Santé (HAS) gave its final opinion in favor of the reimbursement of Carmat's artificial heart exceptionally within the framework of a multicentric study (EFICAS) on 52 patients to be conducted in France. In October, the Ministry of Health and Solidarity granted Carmat €13.0 million of funding for the study, covering two-thirds of its total cost. The funds will be received as and when patients receive their implants. Carmat expects to begin implantation under the EFICAS study in the second quarter of 2021.

As part of the flexible equity financing agreement entered into with Kepler-Cheuvreux in September 2018, Kepler-Cheuvreux exercised 251,000 share warrants (BSA) in 2020, thus increasing the capital by €10,040 via the issuance of 251,000 ordinary shares each with a par value of €0.04, issued at an average price of €23.57 per share, with a gross share premium of €5,906,280. Taking into account the costs related to the capital increase, amounting to €108,444, which are deducted from the share premium in accordance with the preferential accounting method, the net amount of the share premium for this capital increase is €5,797,836.

During the year, 3,610 AGAP 2017 (320 AGAP 2017-01, 2,000 AGAP 2017-02 and 1,290 AGAP 2017-03) were converted into 137,250 ordinary shares each with a par value of €0.04, thus increasing the capital by a net amount of €5,345.60 after cancellation of the converted AGAP 2017.

Lastly, 370 AGAP 2018-03 and 17,825 AGAP 2019 (7,260 AGAP 2019-01, 7,260 AGAP 2019-02 and 3,305 AGAP 2019-03) awarded in 2019 vested during the year, thus increasing the capital by €727.80.

All of the capital increases carried out during the financial year therefore made it possible to increase the share capital by an amount of €16,113.4, by creating 406,445 new shares and canceling 3,610 converted shares. The Company's share capital was thus increased in total from €504,385.96 to €520,499.36 and additional paid-in capital was increased from €254,053,133 to €259,833,084, net of costs related to the capital increases.

The Shareholders' Meeting of October 28, 2020 resolved to transfer the negative retained earnings of €230,128,747 to additional paid-in capital, which was therefore reduced to €29,704,317.

In May 2020, the Company drew down the second tranche of €10 million from the loan granted under conditions by the European Investment Bank (EIB) in December 2018. The loan was for a total of €30 million made available in three €10 million tranches. The third and final tranche can be drawn down at any time until December 17, 2021 as the draw down conditions have already been met.

In the fourth quarter of 2020, Carmat obtained government-guaranteed loans totaling €10 million from a banking syndicate comprising BNP Paribas and Bpifrance,

which were drawn down in full in October and November. The loans are 90%-guaranteed by the French government and have an initial maturity of 12 months with an option for Carmat to extend the repayment period for up to five more years.

Furthermore, for the first time, the Company has recognized its inventories and work in progress as an asset on its balance sheet, for a gross amount of €17,415,940 and a net amount of €9,901,799 (see note 3.2.2.3 to the financial statements).

The Company maintains the option for the Research Tax Credit for the year 2020. The first option was exercised for the calendar year 2009 and renewed each year until 2020. The Research Tax Credit relating to the year 2020 has been recognized for €1,649,976 on the "Income tax" line in the income statement (details in note 3.2.2.5) and appears on the "Other receivables" line of the balance sheet. An Innovation Tax Credit has also been recognized on the "Income tax" line of the income statement (details in note 3.2.2.5) and on the "Other receivables" line of the balance sheet for an amount of €68,938 in respect of 2020.

### 3.2.2.2 SIGNIFICANT EVENTS AFTER THE REPORTING DATE

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

### 3.2.2.3 SIGNIFICANT ACCOUNTING POLICIES

General principles and conventions

The Company's financial statements have been prepared in accordance with French generally accepted accounting rules and principles as set out in the French General Chart of Accounts (ANC Standard 2014-03 on the Chart of Accounts issued by the French accounting standards-setter – Autorité des Normes Comptable [ANC]). The historical cost method is used as the basis for measuring accounting items.

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

The financial statements for the year ended December 31, 2020 have been prepared in accordance with French generally accepted accounting principles, including the principles of prudence and accrual-based accounting. They are presented on a going concern basis and accounting methods have been applied consistently from one year to the next.

- Going concern basis:

The Company's available financial resources will enable it to finance its activities until August 2021 without additional funding, based on its current business plan.

Available resources comprise:

- €36.0 million of available cash and cash equivalents at December 31, 2020;

- the third and final €10 million tranche of the EIB loan granted in September 2018, which can be drawn down by Carmat at any time until December 17, 2021, as the draw down conditions have already been met;

- €13 million of French government funding intended to partially finance the EFICAS* study;

- a total of €1.7 million in research and innovation tax credits for 2020, receivable in 2021.

The Company's business plan:

- does not include any repayment of the principal amount of the EIB loan (i.e, €20 million at December 31, 2020), in accordance with the terms of the loan agreement, or any repayment of the Bpifrance repayable advance, during 2021;

- includes a maturity extension of the government-guaranteed loans obtained in the fourth quarter of 2020 (i.e., €10 million) beyond the initial term of 12 months; therefore no repayment will be made in 2021.

Furthermore:

- Carmat can draw down on the Kepler-Cheuvreux flexible equity financing line obtained in September 2018 until September 27, 2021, the available balance of which stood at €16 million at December 31, 2020. If the entire balance of €16 million were to be drawn down in full, Carmat would be able to finance its business activities until November 2021.

- Carmat also has the capacity to reduce its variable operating expenses if needed (consulting expenses, purchases of raw materials and components, etc.).

Lastly, Carmat has an ongoing active investor relations and fund-seeking policy and, having obtained CE marking at the end of 2020, is therefore confident in its ability to raise the financial resources needed to finance its future development.

Based on these factors, the Board of Directors believes that the going concern basis is appropriate.

* These funds will be received as and when patients receive their implants during the study, over an estimated period of two years. Implantation is expected to begin in the second quarter of 2021.

The Company's clinical, industrial and commercial development will continue to generate additional financial needs over the coming years, including financing of recurring operations, continuation of R&D efforts, commercial launch, clinical trials, and working capital required to develop sales, investments, etc. Fundraising or other types of financing will therefore be required in the future.

Additional information

- Applied research and development costs

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

- Intangible assets

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

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

- Property, plant and equipment

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

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

- Financial assets

OTHER LONG-TERM INVESTMENTS

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

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

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

The gains or losses on disposals of treasury shares are recognized in non-recurring income or expense.

OTHER FINANCIAL ASSETS

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

- Receivables and payables

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

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

- Inventories

According to the French Commercial Code and Chart of Accounts (Article 211-7), inventories are assets that meet the following criteria:

- they are identifiable items that will generate future economic benefits, are controlled by the company, and their cost can be measured reliably;

- they are held for sale in the ordinary course of business or in the form of materials or supplies to be consumed in the production process or in the rendering of services.

The Company's inventories and work in progress comprise goods, raw materials and other supplies, semi-finished and finished goods, and work in progress in the production process.

Inventories and work in progress were recognized as an asset on Carmat's balance sheet for the first time on December 31, 2020. They were previously expensed in the year in which they were purchased or produced, as the Company was still in the clinical phase and could not expect them to generate any future economic benefits.

At December 31, 2020, inventories and work in progress complied with all the criteria for recognition as an asset:

- They are identifiable items;

- CE marking was obtained for Carmat's artificial heart on December 22, 2020, enabling the Company to market its product in many countries, including the whole of the European Union. In addition, as of 2021, the device will be billed to the hospitals taking part in some of the Company's clinical trials; therefore most of the inventories held

by Carmat at December 31, 2020 will generate future economic benefits;

- Their cost can be measured reliably.

Inventories and work in progress are measured at the year-end using the standard cost method. Measurement of inventory costs using the standard cost method gives a comparable result as measurement using the methods set out in the French Chart of Accounts. Items are monitored individually and are clearly identifiable. An impairment provision is taken if their realizable value falls below their carrying amount.

Impairment is calculated taking the following factors into account:

- the life cycle of items of inventory and work in progress (obsolete or short shelf-life items, damaged items or items that do not meet the requisite quality standards, etc.);

- inventory use prospects between items intended for sale and items intended for other activities (clinical trials, training, R&D tests). Inventories intended for other activities are fully impaired.

When the recoverable amount at year-end (market value for finished goods and goods for resale and value in use for work in progress and raw materials) is less than the carrying amount, a provision for impairment is recognized for the difference. Impairment provisions are recognized by inventory category. A breakdown is provided in note 3.2.2.4.3.

- Cash in euros

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

- Cash in foreign currencies

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

- Cash and cash equivalents

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

- Repayable advances made by public bodies

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

- Operating subsidies

Subsidies received are recorded under income as soon as they are granted, taking into account, if necessary, the corresponding rate of expenditure in order to adhere to the principle of matching expenses with revenue.

- Retirement benefits

Future payments for benefits to members of staff are measured according to an actuarial method (ANC recommendation 2013-02) based on assumptions concerning changes in salaries, retirement age and mortality; the resulting valuations are then discounted to their present value. These obligations are covered by provisions in the balance sheet liabilities. The calculation method used is the method 1 set out in the former CNC recommendation 2003-R.01.

- Sub-contracting expenses

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

- Share issue costs

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

- Borrowing Costs

Borrowing costs are expensed as incurred.

## 3.2.2.4 ADDITIONAL INFORMATION ON THE BALANCE SHEET

- 3.2.2.4.1 Movements in non-current assets

| (in euros) | Gross value at start of period | Increases | |
|---|---|---|---|
| | | Line to line transfers | Acquisitions |
| Licenses, patents and similar rights* | 2,014,252 | | 14,234 |
| Intangible assets not yet available for use | | | |
| TOTAL | 2,014,252 | | 14,234 |
| Technical plant, equipment and industrial tooling** | 9,670,508 | 166,893 | 49,627 |
| General plant, sundry fixtures and fittings | 2,430,861 | | 2,875 |
| Office and IT equipment, furniture | 379,360 | 4,965 | 40,852 |
| Property, plant and equipment in progress | 614,209 | 80,599 | 2,117,029 |
| TOTAL | 13,094,938 | 252,456 | 2,210,383 |
| Other financial assets*** | 473,503 | | 3,247,367 |
| TOTAL | 473,503 | | 3,247,367 |
| GRAND TOTAL | 15,582,693 | 252,456 | 5,471,984 |

| (in euros) | Decreases | | Gross value at end of year | Revaluation of original value at end of year |
|---|---|---|---|---|
| | Line to line transfers | Disposals | | |
| Licenses, patents and similar rights* | | 115,348 | 1,913,139 | |
| Intangible assets not yet available for use | | | | |
| TOTAL | | 115,348 | 1,913,139 | |
| Technical plant, equipment and industrial tooling** | 80,599 | 45,682 | 9,760,746 | |
| General plant, sundry fixtures and fittings | | | 2,433,736 | |
| Office and IT equipment, furniture | | 17,138 | 408,039 | |
| Property, plant and equipment in progress | 171,857 | | 2,639,980 | |
| TOTAL | 252,456 | 62,820 | 15,242,501 | |
| Other financial assets*** | | 3,175,345 | 545,525 | |
| TOTAL | | 3,175,345 | 545,525 | |
| GRAND TOTAL | 252,456 | 3,353,513 | 17,701,162 | |

* This item includes a sum of €411,284, recognized in respect of the share of the contribution in kind made on September 30, 2008, with a total value of €960,000, corresponding to the contribution of patents.
** This item includes the commissioning of the clean room at a total cost of €943,582. The item also includes a sum of €548,716 recognized in respect of the share of the contribution in kind of €960,000 made on September 30, 2008, corresponding to the contribution of equipment and tooling.
*** This item includes the 4,773 treasury shares held in connection with the liquidity agreement, valued at €134,002, and (i) the liquidities not invested in treasury shares as at the end of the period under the liquidity agreement for €47,878 and (ii) guarantee deposits of €363,645, mainly comprising deposits under premises lease contracts.

- 3.2.2.4.2 Movements in depreciation and amortization

| Positions and movements for the year (in euros) | Value at start of period | Additions for the period | Decreases Reversals | Value at end of period |
|---|---|---|---|---|
| Licenses, patents and similar rights | 1,986,534 | 24,870 | 115,348 | 1,896,056 |
| TOTAL | 1,986,534 | 24,870 | 115,348 | 1,896,056 |
| Technical plant, equipment and industrial tooling | 6,590,691 | 696,908 | 45,682 | 7,241,917 |
| General plant, sundry fixtures and fittings | 1,056,126 | 186,539 | | 1,242,665 |
| Office and IT equipment, furniture | 337,950 | 23,441 | 17,138 | 344,253 |
| TOTAL | 7,984,767 | 906,888 | 62,821 | 8,828,835 |
| GRAND TOTAL | 9,971,301 | 931,758 | 178,169 | 10,724,890 |

- 3.2.2.4.3 Movements in inventories

| Inventories - gross value (in euros) | Value at start of period | Increases | Decreases | Value at end of period |
|---|---|---|---|---|
| Goods for resale | | 944,092 | | 944,092 |
| Raw materials | | 4,647,106 | | 4,647,106 |
| Work in progress – goods | | 1,005,574 | | 1,005,574 |
| Semi-finished and finished goods | | 10,819,168 | | 10,819,168 |
| TOTAL | | 17,415,940 | | 17,415,940 |

| Inventories - impairment[1] (in euros) | Value at start of period | Additions for the period | Decreases Reversals | Value at end of period |
|---|---|---|---|---|
| Goods for resale | | 115,057 | | 115,057 |
| Raw materials | | 544,119 | | 544,119 |
| Work in progress – goods | | 6,444,559 | | 6,444,559 |
| Semi-finished and finished goods | | 410,405 | | 410,405 |
| TOTAL | | 7,514,141 | | 7,514,141 |

(1) Impairment breaks down as follows by type:
- Impairment related to the life cycle of items of inventory (€3.9 million),
- Impairment related to use prospects (€3.5 million),
- Impairment related to net realizable value (€0.1 million).

A 10-point change in the portion of inventories classified as intended for “other activities” (clinical trials, training, R&D tests, etc.) would have a €0.9 million impact on impairment related to use prospects. A 10% decrease in the estimated commercial selling price would have a €0.3 million impact on impairment related to net realizable value.

- 3.2.2.4.4 Movements in provisions

| Provisions (in euros) | Value at start of period | Increases Additions | Decreases Utilized amounts | Decreases Surplus amounts | Value at end of period |
|---|---|---|---|---|---|
| Sundry risks | | 80,000 | | | 80,000 |
| Pension and similar obligations* | 413,906 | 128,617 | | | 542,523 |
| Payroll taxes on AGAP free preference shares** | 271,654 | 173,036 | 410,615 | | 34,075 |
| TOTAL | 685,560 | 381,653 | 410,615 | | 656,599 |
| Impairment of inventories and work in progress | | 7,514,141 | | | 7,514,141 |
| TOTAL | | 7,514,141 | | | 7,514,141 |
| GRAND TOTAL | 685,560 | 7,895,794 | 410,615 | | 8,170,740 |
| Of which operational additions and reversals: | | 7,895,794 | 410,615 | | |
| Of which financial additions and reversals: | | | | | |

* See note 3.2.2.6.
** See note 3.2.2.4.8.

- 3.2.2.4.5 Receivables and payables by maturity

| Receivables (in euros) | Gross amount | Due within 1 year | Due beyond 1 year |
|---|---|---|---|
| Social security receivables | 42,074 | 42,074 | |
| Income tax* | 1,790,336 | 1,790,336 | |
| Value-added tax | 2,204,140 | 2,204,140 | |
| Other taxes, duties and levies | 22,590 | 22,590 | |
| Sundry receivables | 49,193 | 49,193 | |
| TOTAL | 4,108,333 | 4,108,333 | |

* The receivable corresponds to: - the French research tax credit (CIR) for 2020 for an amount of €1,649,976;
- the French innovation tax credit for 2020 for an amount of €68,938;
- the balance on the CIR for 2018 for a net amount of €71,421 (gross amount of €79,357 with an impairment of €7,936 - collective deduction of 4% collected by Predirec as part of the CIR 2018 mobilization).

| Payables (in euros) | Gross amount | Due within 1 year | Due in 2 to 5 years | Due beyond 5 years |
|---|---|---|---|---|
| Bank loans and borrowings* | 32,130,333 | 79,445 | 30,050,888 | 2,000,000 |
| Sundry loans and borrowings** | 6,810,075 | | 1,324,000 | 5,486,075 |
| Trade notes and accounts payable | 8,006,213 | 8,006,213 | | |
| Staff and related payables | 2,425,774 | 2,425,774 | | |
| Social security payables | 1,810,503 | 1,810,503 | | |
| Value-added tax | 31,717 | 31,717 | | |
| Other taxes, duties and levies | 144,956 | 144,956 | | |
| TOTAL | 51,359,569 | 12,498,606 | 31,374,888 | 7,486,075 |

* See breakdown below.
** This amount corresponds to the accrued interest expected at year-end on the repayable advances from Bpifrance (details in section 3.2.2.6).

| Breakdown of bank loans* (in euros) | Gross amount | Due within 1 year | Due beyond 1 year |
|---|---|---|---|
| EIB loan - principal | 20,000,000 | | 20,000,000 |
| EIB loan - accrued interest | 2,116,443 | 65,555 | 2,050,888 |
| Bpifrance government-guaranteed loan - principal | 5,000,000 | | 5,000,000 |
| Bpifrance government-guaranteed loan - accrued interest | 11,667 | 11,667 | |
| BNP Paribas government-guaranteed loan - principal | 5,000,000 | | 5,000,000 |
| BNP Paribas government-guaranteed loan - accrued interest | 2,223 | 2,223 | |
| TOTAL | 32,130,333 | 79,445 | 32,050,888 |

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

- 3.2.2.4.6 Share capital

Composition of the share capital

| Classes of shares | Par value in euros | Number of shares | | | | |
|---|---|---|---|---|---|---|
| | | Opening | Created | Canceled | Redeemed | Closing |
| Ordinary shares | 0.04 | 12,592,539 | 388,250 | | | 12,980,789 |
| Preference shares | 0.04 | 17,110 | 18,195 | 3,610 | | 31,695 |
| TOTAL | | 12,609,649 | 406,445 | 3,610 | | 13,012,484 |

The capital increase further to the exercise of share warrants (BSA) by Kepler-Cheuvreux in 2020 resulted in the creation of 251,000 ordinary shares, with a par value of €0.04.

The capital increase resulting from the conversion during 2020 of 320 AGAP 2017-01, 2,000 AGAP 2017-02 and 1,290 AGAP 2017-03 gave rise to the issuance of 137,250 ordinary shares each with a par value of €0.04 and the cancellation of 3,610 preference shares each with a par value of €0.04.

The capital increases resulting from the vesting during the year of 370 AGAP 2018-03, and 17,825 AGAP 2019 (7,260 AGAP 2019-01, 7,260 AGAP 2019-02 and 3,305 AGAP 2019-03) gave rise to the issuance of 18,195 preference shares each with a par value of €0.04.

Changes in equity

| Changes in equity | Capital Number of shares | Capital | Additional paid-in capital | Reserves | Retained earnings (losses carried forward) | Profit (loss) | Equity |
|---|---|---|---|---|---|---|---|
| At December 31, 2019 | 12,609,649 | 504,386 | 254,053,133 | 38,476 | (187,480,075) | (42,648,672) | 24,467,248 |
| Allocation of 2019 net loss | | | | | (42,648,672) | 42,648,672 | 0 |
| Net profit (loss) for the year | | | | | | (36,963,432) | (36,963,432) |
| Transfer of retained earnings to additional paid-in capital* | | | (230,128,747) | | 230,128,747 | | 0 |
| Capital increases | 406,445 | 16,258 | 5,888,375 | 11,832 | | | 5,916,465 |
| Cost of capital increases | | | (108,444) | | | | (108,444) |
| Cancellation of preference shares | (3,610) | (144) | | | | | (144) |
| At December 31, 2020 | 13,012,484 | 520,499 | 29,704,317 | 50,308 | - | (36,963,432) | (6,688,308) |

* Transfer of negative retained earnings of €230,128,747 to additional paid-in capital, decided at the Shareholders' Meeting of October 28, 2020

- 3.2.2.4.7 Stock options

2018 stock options

On the authorization of the Combined Shareholders' Meeting of April 5, 2018, the Board of Directors decided, on December 3, 2018, to grant 46,000 options to subscribe to ordinary shares, breaking down as follows: 23,000 A options and 23,000 B options. These options entitle holders to subscribe to 46,000 new shares, following the achievement of attendance and/or performance criteria, representing 0.35% of the existing capital as of December 31, 2020, at a price of €20.35 per share, share premium included.

2019 stock options

On the authorization of the Combined Shareholders' Meeting of March 28, 2019, the Board of Directors decided, on April 1, 2019, to grant 46,000 options to subscribe to ordinary shares. These options entitle holders to subscribe to 46,000 new shares, following the achievement of attendance and/or performance criteria, representing 0.35% of the existing capital as of December 31, 2020, at a price of €22.70 per share, share premium included.

- 3.2.2.4.8 Preference shares (AGAP)

The tables in section 5.2.5 summarize the AGAP 2017, AGAP 2018, AGAP 2019 and AGAP 2020 awarded, lapsed, vested and yet to vest, as well as the AGAP already converted into ordinary shares, those not yet converted and the maximum number of new ordinary shares that could be issued upon their conversion.

The performance conditions associated with each class of AGAP are also described in that section.

AGAP 2017

On the authorization of the Combined Shareholders' Meeting of April 27, 2017, the Board of Directors' meeting decided, on May 15, 2017, to allocate provisionally 5,250 preference shares, breaking down as follows: 270 AGAP 2017-01, 1,800 AGAP 2017-02, 3,180 AGAP 2017-03, then on September 25, 2017; to allocate provisionally 560 preference shares, breaking down as follows: 50 AGAP 2017-01, 200 AGAP 2017-02, 310 AGAP 2017-03; These preference shares may be converted based on the achievement of the performance criteria into a maximum of 421,000 ordinary shares: 32,000 ordinary shares under AGAP 2017-01, 40,000 ordinary shares under AGAP 2017-02, and 349,000 ordinary shares under AGAP 2017-03.

In 2020, 3,610 AGAP 2017 (320 AGAP 2017-01, 2,000 AGAP 2017-02 and 1,290 AGAP 2017-03) were converted into ordinary shares via the issuance of 137,250 ordinary shares each with a par value of €0.04 and the cancellation of 3,610 AGAP 2017 each with a par value of €0.04.

At December 31, 2020, all of the AGAP 2017-01 and 2017-02 had been converted into ordinary shares. There were 180 AGAP 2017-02 not convertible into ordinary shares and 2,020 AGAP 2017-03 convertible into 111,100 ordinary shares.

AGAP 2018

On the authorization of the Combined Shareholders' Meeting of April 5, 2018, the Board of Directors' meeting decided, on April 16, 2018, to allocate provisionally 12,080 preference shares, breaking down as follows: 580 AGAP 2018-01 and 11,500 AGAP 2018-02; then on September 27, 2018, to allocate provisionally 370 preference shares (AGAP 2018-03); then on February 11, 2019, to allocate provisionally 370 preference shares (AGAP 2018-03). These preference shares may be converted based on the achievement of the performance criteria into a maximum of 301,500[(1)] ordinary shares: 58,000 ordinary shares under AGAP 2018-01, 169,500 ordinary shares under AGAP 2018-02, and 74,000 ordinary shares under AGAP 2018-03.

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

AGAP 2019

On the authorization of the Combined Shareholders' Meeting of March 28, 2019, the Board of Directors' meeting decided, on April 1, 2019, to allocate provisionally 11,900 preference shares, breaking down as follows: 4,760 AGAP 2019-01, 4,760 AGAP 2019-02 and 2,380 AGAP 2019-03; then on September 23, 2019, to allocate provisionally 4,700 preference shares, breaking down as follows: 2,240 AGAP 2019-01, 2,240 AGAP 2019-02 and 220 AGAP 2019-03; then on December 2, 2019, to allocate provisionally 3,000 preference shares, breaking down as follows: 1,000 AGAP 2019-01, 1,000 AGAP 2019-02 and 1,000 AGAP 2019-03. These preference shares may be converted based on the achievement of the performance criteria into a maximum of 193,000[(2)] ordinary shares: 78,800 ordinary shares under AGAP 2019-01, 78,800 ordinary shares under AGAP 2019-02, and 35,400 ordinary shares under AGAP 2019-03.

(2) These figures take into account the departure of an AGAP 2019-01, 2019-02 and 2019-03 beneficiary.

AGAP 2020

On the authorization of the Combined Shareholders' Meeting of March 30, 2020, the Board of Directors' meeting decided, on December 2, 2020, to allocate provisionally 3,140 preference shares on December 18, 2020, breaking down as follows: 2,240 AGAP 2020-01 and 900 AGAP 2020-02. These preference shares may be converted based on the achievement of the performance criteria into a maximum of 314,000 ordinary shares: 224,000 ordinary shares under AGAP 2020-01 and 90,000 ordinary shares under AGAP 2020-02.

- 3.2.2.4.9 Share warrants (BSA)

BSA 2009-1

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

Kepler-Cheuvreux BSA

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

By decision of the Board of Directors on September 27, 2018, as authorized by the Combined Shareholders' Meeting of April 5, 2018, 400,000 BSA share warrants were issued, of which 139,000 BSA warrants were exercised on December 31, 2019 and 251,000 in 2020. The 10,000 BSA warrants not exercised on the same date confer subscription rights to 10,000 new shares, representing 0.08% of the existing capital as at December 31, 2020, at a price per share defined contractually between Carmat and Kepler-Cheuvreux, the holder of the BSA warrants, as being equal to the average share price at the time of the drawdown, less a discount of not more than 6%.

BSA 2017

By decision of the Board of Directors dated May 15, 2017, 12,000 share warrants were issued as authorized by the Combined Shareholders' Meeting of April 27, 2017, none of which had been exercised as at December 31, 2020. The 12,000 BSA warrants not exercised on the same date confer subscription rights for 12,000 new shares, representing 0.09% of the existing capital as at December 31, 2020, at a price of €30.10 per share.

BSA 2018

By decision of the Board of Directors dated June 11, 2018, 10,000 BSA share warrants were issued pursuant to a delegation of authority granted by the Combined Shareholders' Meeting of April 5, 2018, none of which had been exercised as at December 31, 2020. The 10,000 BSA warrants not exercised on the same date entitle them to subscribe to 10,000 new shares, representing 0.08% of the existing capital as at December 31, 2020, at a price of €20.93 per share.

BSA 2019

By decision of the Board of Directors dated June 24, 2019, 6,000 BSA share warrants were issued pursuant to a delegation of authority granted by the Combined Shareholders' Meeting of March 28, 2019, none of which had been exercised as at December 31, 2020. The 6,000 BSA warrants not exercised on the same date entitle them to subscribe to 6,000 new shares, representing 0.05% of the existing capital as at December 31, 2020, at a price of €20.21 per share.

SUMMARY TABLE OF BSA SHARE WARRANTS

| | Issued | Sub-scribed | Expired | Reserve | Exercised | Balance | Expiry date |
|---|---|---|---|---|---|---|---|
| BSA 2009-1 (SM of July 8, 2009) | 3,096 | 3,096 | 556 | 0 | 2,540 | 0 | July 8, 2019 |
| Kepler-Cheuvreux BSA (old tranches - SM of June 28, 2016) | 900,000 | 900,000 | 157,400 | 0 | 742,600 | 0 | July 20, 2018 |
| Kepler-Cheuvreux BSA (old tranches - SM of April 5, 2018) | 400,000 | 400,000 | 0 | 0 | 390,000 | 10,000 | Sept. 27, 2021 |
| BSA 2017 (SM of April 27, 2017) | 12,000 | 12,000 | 0 | 0 | 0 | 12,000 | May 15, 2027 |
| BSA 2018 (SM of April 5, 2018) | 10,000 | 10,000 | 0 | 0 | 0 | 10,000 | June 11, 2028 |
| BSA 2019 (SM of March 28, 2019) | 6,000 | 6,000 | 0 | 0 | 0 | 6,000 | June 24, 2029 |

- 3.2.2.4.10 Company founder share warrants (BCE)

BCE 2009-1

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

BCE 2009-2

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

SUMMARY TABLE OF BCE SHARE WARRANTS

BCE-2012-1

In accordance with the Board of Directors' decision of June 27, 2012, as authorized by the Combined Shareholders' Meeting of April 26, 2012, 56,500 fully assigned and subscribed BCE 2012-1 company founder share warrants were issued, of which 49,000 have expired and been canceled. The 7,500 BCE 2012-1 warrants subscribed and not exercised as at December 31, 2020 confer subscription rights to 7,500 new shares, representing 0.06% of the existing capital as at December 31, 2020, at a price of €108.483 per share.

BCE 2012-2

In accordance with the Board of Directors' decision of November 8, 2012, as authorized by the Combined Shareholders' Meeting of April 26, 2012, 6,700 fully assigned and subscribed BCE 2012-2 company founder share warrants have been issued. The 6,700 BCE 2012-2 warrants subscribed and not exercised as at December 31, 2020 confer subscription rights to 6,700 new shares, representing 0.05% of the existing capital as at December 31, 2020, at a price of €122.003 per share.

| | Issued | Subscribed | Expired | Exercised | Balance | Expiry date |
|---|---|---|---|---|---|---|
| BCE 2009-1 SM of July 8, 2009 | 3,108 | 3,108 | 0 | 3,108 | 0 | Sept. 9, 2019 |
| BCE 2009-2 SM of July 8, 2009 | 7,566 | 7,566 | 3,091 | 4,475 | 0 | July 8, 2019 |
| BCE 2012-1 SM of April 26, 2012 | 56,500 | 56,500 | 49,000 | 0 | 7,500 | June 27, 2022 |
| BCE 2012-2 SM of April 26, 2012 | 6,700 | 6,700 | 0 | 0 | 6,700 | Nov. 8, 2022 |

- 3.2.2.4.11 Other balance sheet details

Conditional advances

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

They are interest-bearing at the contracted rate of 5.59%. The interest accrued, calculated using the capitalization method, stood at €6,810,075 at the year-end and appears in liabilities under "Sundry loans and borrowings".

Accrued income

| Value of accrued income included in the following balance sheet items | Value |
|---|---|
| Other receivables | 60,495 |
| Total | 60,495 |

Accrued expenses

| Value of accrued expenses included in the following balance sheet items | Value |
|---|---|
| Bank loans and borrowings | 2,130,333 |
| Sundry loans and borrowings | 6,810,075 |
| Trade notes and accounts payable | 5,414,457 |
| Tax and social security payables | 3,679,328 |
| Total | 18,034,193 |

Prepaid expenses and deferred income

| Prepaid expenses | Value |
|---|---|
| Operating expenses | 188,039 |
| Total | **188,039** |

Prepaid expenses comprise the share of subscriptions, software license royalties and insurance premiums for the period after December 31, 2020, totaling €188,039.

| Prepaid income | Value |
|---|---|
| Operating income | None |
| Total | **None** |

Information on related companies

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

| | |
|---|---|
| Trade notes and accounts payable | 46,922 |

The related companies taken into account, which are all part of Airbus Group, are as follows:

- Matra Electronique;
- Airbus Group Aeroassurances.

Provisions for losses

One preference share allocation plan, approved on December 18, 2020, allowed for the provisional allocation of 3,260 preference shares, which can be converted based on the achievement of the performance criteria to a maximum of 203,000 ordinary shares. The vesting date for these preference shares is December 18, 2021.

At the end of the year, the Company booked a €34,075 provision for losses corresponding to the amount of the employer contributions of 20% to be due in 2020, on a pro rata basis of the vesting period and based on the estimate of the value of the ordinary shares that could be converted at the end of the vesting period.

The calculation assumptions made were as follows:
- determination of a percentage of achievement of each of the performance criteria;
- value of a ordinary share of €28.30;
- employer contribution rate of 20%.

### 3.2.2.5 ADDITIONAL INFORMATION ON THE INCOME STATEMENT

- Operating subsidies

The Company received an operating subsidy of €9,333 from the Association nationale de la recherche et de la technologie (national research and technology association) to employ one PhD student. This sum has been recognized in the income statement under the line "Operating subsidies".

- Applied research and development costs

Research and development costs are recognized under expenses. They amounted to €22,098,809 in 2020, compared to €29,368,163 in the previous year.

- Research tax credit and innovation tax credit

The income statement for the year shows a tax credit amounting to €1,710,979, corresponding to:

- the research tax credit in respect of 2020, i.e., €1,649,976;

- the innovation tax credit in respect of 2020, i.e., €68,938;

- an impairment provision of €7,935 against the receivable corresponding to the 4% collective deduction collected by Predirec as part of the CIR 2018 mobilization mechanism.

- Statutory Auditors' fees

The total amount of Statutory Auditors' fees paid over the year was €165,124 excluding taxes and disbursements and breaks down as follows:

| Total amount excl. taxes (in euros) | PwC | LCA | Total |
|---|---|---|---|
| Statutory Auditors' fees | 57,850 | 44,150 | 102,000 |
| Non-audit services fees | | | |
| - Non-audit services required | 7,500 | 10,750 | 18,250 |
| - Other non-audit services | 44,874 | 0 | 44,874 |
| Total | **110,224** | **54,900** | **165,124** |

- Non-recurring income and expenses

| Type | 2020 | 2019 |
|---|---|---|
| Non-recurring income | | |
| - Various adjustments | 145,894 | |
| - Disposal of assets | | |
| - Disposal of treasury shares | 115,748 | 46,794 |
| Total | 261,642 | 46,794 |
| Non-recurring expenses | | |
| - Disposal of assets | | |
| - Disposal of treasury shares | 61,255 | 60,767 |
| - Fines and penalties | | 2,513 |
| - Non-recurring depreciation | | 87,458 |
| Total | **61,255** | **150,738** |

Non-recurring items relate to:

- disposals of treasury shares carried out under the liquidity agreement;

- settlement of a trade payable in respect of a prior year.

- Information on related companies

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

| | |
|---|---|
| Other purchases and external expenses | 473,395 |

The related companies taken into account, which are all part of Airbus Group, are as follows:

- Matra Electronique.

### 3.2.2.6 FINANCIAL COMMITMENTS AND OTHER INFORMATION

- Financial commitments

Commitments given

- Bpifrance repayable advance

A repayable advance totaling €14,507,309 was received from Bpifrance, of which the final €1,450,732 tranche was received in June 2019. The corresponding accrued interest amounts to €6,810,075 at the end of the financial year. This amount is repayable subject to achieving cumulative revenue of at least €38,000,000. The Bpifrance agreement provides for supplementary payments if certain conditions are met, so that the total amount repayable could exceed the amount of the advance initially granted, up to a ceiling of €50,000,000.

- Royalties agreement with Professor Alain Carpentier and Matra Défense

On June 24, 2008 the Company signed a royalties agreement with Professor Alain Carpentier and Matra Défense, who still held shares as at December 31, 2020. Under this Agreement, the Company undertakes to pay to Professor Alain Carpentier and Matra Défense 2% of the net sales proceeds of the Carmat artificial heart manufactured and distributed by Carmat SA, 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 six months within 30 days of the end of each six-month period, commencing after the first marketing of the Carmat artificial heart post-CE marking in Europe and FDA marketing authorization in the United States, and ending upon expiration of the patents shown in the appendices to the agreement.

The Company is also authorized to repurchase at any time the right to benefit from these royalties for a sum of €30,000,000 less any royalties already paid under the agreement, with this total sum being shared between the two beneficiaries in proportion to their respective shares in the capital of the Company on the date it was established. This amount of €30,000,000 is indexed to the Producer Price Index of the Business Services Industry – euro zone orthopedic and orthopedic equipment.

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

As at December 31, 2020, since the marketing of the Carmat artificial heart had not started, no royalties had been paid by the Company under the agreement.

- Royalties agreement with the European Investment Bank (EIB)

In addition, the Company has signed a royalties agreement with the EIB providing for the payment of additional compensation to the EIB depending on the commercial performance of the Company. This agreement is valid for 13 years from the year during which the cumulative sales of Carmat reach €500,000. The royalty rate varies from 0.25% to 1.50% depending on the Company's annual sales. The Company can decide to terminate the royalties agreement at any time by paying a lump sum (net of any royalties already paid), based on the amount borrowed and the year during which the decision is taken.

Upon the occurrence of certain events (in particular should the EIB demand the early repayment of the loan or should a new shareholder reach 33% of the voting rights of Carmat), the EIB could, if deemed necessary, demand from Carmat an advance payment of royalties up to a certain percentage of the amount of the loan effectively used (this percentage would range from 100% of the borrowed

amount if the event occurs during the first four years of the financial contract to 160% if the event occurs after the eleventh year).

Commitments received

None.

Pension and retirement obligations

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

In application of the reference method 1 in ANC recommendation 2013-02, the provision for retirement obligations has been booked as at December 31, 2020.

The calculation assumptions made were as follows:
- time-apportioned rights method in accordance with CNC Regulation 2003 R-01;
- retirement on the initiative of the member of staff, at 62 years (non-management) or 65 years (management);
- salary increases of 2% per annum;
- low staff turnover;
- discount rate of 0.34% per annum (versus the rate of 0.77% used at December 31, 2019).

The overall amount of the provision was €542,523 at the end of the period, an increase of €128,617 on the previous period.

- Other information

Information on executives

ADVANCES AND LOANS TO MANAGEMENT

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

MANAGEMENT COMPENSATION

Total directors' compensation recognized in respect of 2020 amounted to €83,003 (amounts entered under "Other expenses" in the income statement).

The total compensation paid to the Chairman of the Board of Directors and the Chief Executive Officer of the Company was €773,014 for the financial year and breaks down as follows:

| Type | 2020 | 2019 |
|---|---|---|
| Gross salaries | 564,283 | 465,396 |
| Benefits in kind | 6,462 | 7,793 |
| Bonuses | 202,269 | 176,946 |
| Total compensation | **773,014** | **650,135** |

Increases and decreases in future tax liabilities

| Type of temporary differences | Value |
|---|---|
| Tax loss carryforwards | 307,002,768 |

This amount comprises:

- the tax loss carried forward made during previous periods and available as at January 1, 2020, in the sum of €268,500,634;

- the tax loss made in the 2020 financial year in the sum of €38,502,134.

Headcount at year end

| Salaried staff | 2020 | 2019 |
|---|---|---|
| Managers | 96 | 80 |
| Supervisors and technicians | 18 | 17 |
| Administrative employees | 5 | 6 |
| Total | **119*** | **103*** |

* Excluding temporary workers.

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

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

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

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

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

The Company's objectives in this area are:

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

## PRODUCTION OF ACCOUNTING INFORMATION

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

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

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

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

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

As Carmat is not yet self-financing, particular attention is paid to the Company's financing plan, cash flow forecasts and liquidity risk. In this context, the Company's multi-year business plan is updated and presented to the Board of Directors, at least once a year (and more frequently if necessary), and the financing strategy and options are regularly shared and discussed with the Board of Directors.

## PUBLICATION OF ACCOUNTING AND FINANCIAL INFORMATION

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

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

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

of Directors.

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

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

Carmat is assisted as needed by specialized advisers to ensure that the information it publishes complies with the legal and regulatory requirements.

# 3.4 STATUTORY AUDITORS' REPORT ON THE 2020 FINANCIAL STATEMENTS

This is a translation into English of the statutory auditors' report on the financial statements of the Company issued in French and it is provided solely for the convenience of English-speaking users. This statutory auditors' report includes information required by European regulation and French law, such as information about the appointment of the statutory auditors or verification of the management report and other documents provided to shareholders. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

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

## OPINION

In compliance with the engagement entrusted to us by your annual general meeting, we have audited the accompanying financial statements of CARMAT for the year ended December 31, 2020.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and of the financial position of the Company as at December 31, 2020 and of the results of its operations for the year then ended in accordance with French accounting principles.

## BASIS FOR OPINION

Audit framework

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

Our responsibilities under those standards are further described in the Statutory Auditors 'Responsibilities for the Audit of the Financial Statements section of our report.

Independence

We conducted our audit engagement in compliance with independence requirements of the French Commercial Code (code de commerce) and the French Code of Ethics (code de déontologie) for statutory auditors, for the period from January 1, 2020 to the date of our report.

Emphasis of matter

We draw attention to the following matter described in the paragraph "general principles and conventions" of Note 3.2.2.3 "Significant accounting policies" to the financial statements relating to the assumptions underlying the application of the going concern principle. Our opinion is not modified in respect of this matter.

## JUSTIFICATION OF OUR ASSESSMENTS

Due to the global crisis related to the Covid-19 pandemic, the financial statements of this period have been prepared and audited under specific conditions. Indeed, this crisis and the exceptional measures taken in the context of the state of sanitary emergency have had numerous consequences for companies, particularly on their operations and their financing, and have led to greater uncertainties on their future prospects. Those measures, such as travel restrictions and remote working, have also had an impact on the companies' internal organization and the performance of the audits.

It is in this complex and evolving context that, in accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code (code de commerce) relating to the justification of our assessments, we inform you of the following assessments that, in our professional judgment, were of most significance in our audit of the financial statements of the current period.

These assessments were addressed in the context of our audit of the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the financial statements.

Accounting estimates

For the first time at December 31, 2020, the Company recognized its inventories and work in progress as an asset on the balance sheet. Impairment provisions were recorded to write down the value of the inventories to their realizable value, as described in the "Inventories" section of note 3.2.2.3 "Significant accounting policies" to the financial statements. We assessed the methods used by the Company, based on information available at the date hereof, and performed tests, using sampling techniques, to verify the application of those methods.

As part of our assessments, we verified that the estimates were reasonable.

## SPECIFIC VERIFICATIONS

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by laws and regulations.

Information given in the management report and in the other documents with respect to the financial position and the financial statements provided to the Shareholders

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 with respect to the financial position and the financial statements provided to the Shareholders.

We attest the fair presentation and the consistency with the financial statements of the information relating to the payment deadlines mentioned in Article D.441-4 of the French Commercial Code (code de commerce).

Information relating to corporate governance

We attest that the section of the management report devoted to corporate governance sets out the information required by Article L. 225-37-4 of the French Commercial Code (code de commerce).

Other information

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

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

Management is responsible for the preparation and fair presentation of the financial statements in accordance with French accounting principles and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

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

The financial statements were approved by the Board of Directors.

## STATUTORY AUDITORS' RESPONSIBILITIES FOR THE AUDIT OF THE FINANCIAL STATEMENTS

Our role is to issue a report on the financial statements. Our objective is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As specified in Article L.823-10-1 of the French Commercial Code (code de commerce), our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.

- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the financial statements.
- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.
- Evaluates the overall presentation of the financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

Lyon and Paris, February 24, 2021

The Statutory Auditors

| | |
|---|---|
| PricewaterhouseCoopers<br>Audit<br>Gonzague Van Royen | Lison Chouraki<br>Audit<br>Lison Dahan 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 Board of Directors consists of ten members, including six independent directors. Jean-Pierre Garnier is Chairman.

The Company is not required to have directors representing employees or directors representing employee shareholders on the Board of Directors.

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

| | Personal information | | | | Experience | Position on the Board | | | | Committees |
|---|---|---|---|---|---|---|---|---|---|---|
| | Year of birth | Gender | Citizenship | Number of shares* | Number of directorships in listed companies (including Carmat) | Independent | First appointed | Term of office ends** | Number of years' service on the Board | Committee membership |
| Jean-Pierre Garnier (Chairman of the Board) | 1947 | M | French and American | 0 | 4 | No | Dec. 3, 2018 | 2021 | 3 years | |
| Stéphane Piat (Chief Executive Officer and director) | 1971 | M | French | 58,070 | 1 | No | April 27, 2017 | 2022 | 4 years | |
| Matra Défense, represented by Karl Hennessee | 1974 | M | German and American | 0 | 1 | No | May 20, 2015 | 2021 | 6 years | Member of the Appointments & Compensation Committee |
| Henri Lachmann | 1938 | M | French | 0 | 1 | Yes | Dec. 23, 2010 | 2021 | 11 years | Chairman of the Audit Committee |
| Truffle Capital, represented by Philippe Pouletty | 1958 | M | French | 0 | 5 | No | May 7, 2010 | 2021 | 11 years | Chairman of the Appointments & Compensation Committee |
| Pierre Bastid | 1954 | M | French | 0 | 3 | Yes | April 5, 2018 | 2023 | 3 years | |
| Santé Holdings SRL, represented by Antonino Ligresti | 1938 | M | Italian | 0 | 1 | Yes | April 12, 2016 | 2021 | 5 years | Member of the Appointments & Compensation Committee |
| Jean-Luc Lemercier | 1957 | M | French | 0 | 1 | Yes | January 2, 2017 | 2021 | 4 years | Member of the Appointments & Compensation Committee |
| Michal Mack | 1947 | M | American | 0 | 1 | Yes | January 2, 2017 | 2021 | 4 years | |
| André Muller | 1963 | M | French | 0 | 1 | Yes | March 30, 2020 | 2024 | 1 year | Member of the Audit Committee |

* For companies represented by an individual, the number of shares held by the individual.
** Shareholder's Meeting held to approve the financial statements for the year ended December 31...

| Full name or registered name of the member and business address | Term of office | Functions fulfilled within the Company | Other positions currently held in other companies | Previous other positions and functions in other companies over the last five years |
|---|---|---|---|---|
| **Jean-Pierre Garnier**<br>(French & US citizenship)<br><br>Carmat<br>36, avenue de l'Europe<br>78 941 Velizy Villacoublay, France | First appointed: Dec. 3, 2018<br>Term of office ends: SM held to approve the financial statements for year ending Dec. 31, 2021 | Chairman of the Board of Directors | - Director of Radius Health*<br>- Director of Carrier Corp*<br>- Director of Fondation Paul Newman<br>- Chairman of Cellectis* | - Chairman of Actelion* (until its acquisition by Johnson and Johnson in 2017)<br>- Chairman of Idorsia* (until May 2020) |
| **Stéphane Piat**<br>(French citizenship)<br><br>Carmat<br>36, avenue de l'Europe<br>78 941 Velizy Villacoublay, France | First appointed: April 27, 2017<br>Term of office ends: SM held to approve the financial statements for year ending Dec. 31, 2022 | Chief Executive Officer**<br>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**<br><br>**Represented by Karl Hennessee**<br>(German and US citizenship)<br><br>Airbus Group<br>2 rond-point Emile Dewoitine<br>31700 Blagnac, France | First appointed: March 20, 2015<br>Term of office ends: SM held to approve the financial statements for year ending Dec. 31, 2021 | Director | - Chairman of Projic 9<br>- Chairman of Matra Défense<br>- Managing Director of Matra Holding GmbH<br>- Director of Perpetual Ltd, Fast<br>- Director of Express Investment Ltd<br>- Director of Aeropart<br>- Director of China World Aviation Leasing Co. Limited<br>- Chief Executive Officer of Mimme Fze | - Member of the Executive Committee of Projic 9<br>- Director of Shiny T BV and Sunny T BV (until November 2020) |

** In accordance with the Articles of Association, the Board of Directors appoints the Chief Executive Officer, sets the term of his office, determines his compensation and defines the limits of his powers if necessary.

| Full name or registered name of the member and business address | Term of office | Functions fulfilled within the Company | Other positions currently held in other companies | Previous other positions and functions in other companies over the last five years |
|---|---|---|---|---|
| **Henri Lachmann**<br>(French citizenship)<br><br>Association Marie Lannelongue<br>133, avenue de la Résistance<br>92 350 Le Plessis Robinson, France | First appointed:<br>Dec. 23, 2010<br><br>Term of office ends:<br>SM held to approve the financial statements for year ending Dec. 31, 2021 | Independent director | - | - Director of various companies in the Schneider Electric Group*<br>- Honorary Vice-Chairman of the supervisory board at Vivendi SA*<br>- Vice-Chairman and treasurer of the Institut Montaigne (non-profit organization)<br>- Member of the supervisory board of Norbert Dentressangle SA*<br>- Chairman of the Board of Directors of the Marie Lannelongue Hospital (non-profit organization)<br>- Chairman of the Institut Télémaque (non-profit organization)<br>- Director of the Fondation Entreprendre<br>- Chairman of the campaign committee of the Strasbourg University Foundation |
| **Truffle Capital**<br><br>**Represented by Dr. Philippe Pouletty**<br>(French citizenship)<br><br>Truffle Capital<br>5, rue de la Baume<br>75 008 Paris, France | First appointed:<br>May 7, 2010<br><br>Term of office ends:<br>SM held to approve the financial statements for year ending Dec. 31, 2021 | Director | In a personal capacity:<br>- Chairman of the Board of Directors of Abivax SA*<br>- Manager at Nakostech SARL<br>- Chief Executive Officer and director of Truffle Capital<br>- Honorary Chairman and director of France Biotech (non-profit organization)<br>As representative of Truffle Capital:<br>- Director of Biokinesis SAS<br>- Director of Pharnext SA*<br>- Director of Deinove SA*<br>- Director of Carbios SA*<br>- Director of Affluent Medical SA<br>- Chairman of Skinosive SASU<br>- Director of Holistick Medical SASU<br>- Director of Artedrone SASU<br>- Chairman of Diaccurate SASU<br>- Director of Bariatek SASU<br>- Chairman of the Board of Directors of Caranx SASU | - Director of Vexim SA* until 2017<br>- Director of Neovacs SA* until 2014<br>- Director of Plasmaprime SAS until 2015<br>- Director of Immune Targeting Systems Ltd (UK) until 2015<br>- Director of Altimmune, Inc. (United States) until December 2016 |

| Full name or registered name of the member and business address | Term of office | Functions fulfilled within the Company | Other positions currently held in other companies | Previous other positions and functions in other companies over the last five years |
|---|---|---|---|---|
| **Pierre Bastid**<br>(French citizenship)<br><br>Hougou<br>480, avenue Louise<br>1050 Brussels,<br>Belgium | First appointed:<br>April 5, 2018<br><br>Term of office ends:<br>SM held to approve the financial statements for year ending Dec. 31, 2023 | Independent director | - Director of Hougou Finance SA<br><br>- Director of Cellectis* and Pharnext*<br><br>- Director of Shango SA, Hebioso SA and Nepteam SAS<br><br>- Director of Louise 342-344 SA<br><br>- Director of Batuque Hotelaria e Turismo SA, Casino Royal SA and East West SA<br><br>- Director of Hougou SA Développement SA<br><br>- Manager of Hougou SA and permanent representative of Hesobio SA at Hougou SA | None |
| **Santé Holdings SRL**<br><br>**Represented by Antonino Ligresti**<br>(Italian citizenship)<br><br>NCTM<br>Via Agnello 12<br>20121 Milan,<br>Italy | First appointed:<br>April 12, 2016<br><br>Term of office ends:<br>SM held to approve the financial statements for year ending Dec. 31, 2021 | Independent director | - Sole shareholder of Immobiliare Cosio SRL, Iniziative Immobiliari Due SRL and Iniziative Immobiliari Tre SRL | None |
| **Jean-Luc Lemercier**<br>(French citizenship)<br><br>Edwards Lifesciences<br>Route de l'Etraz 70<br>1260 Nyon,<br>Switzerland | First appointed:<br>Jan. 2, 2017<br><br>Term of office ends:<br>SM held to approve the financial statements for year ending Dec. 31, 2021 | Independent director | - Corporate officer<br>Edwards Lifesciences | None |
| **Dr. Michael Mack**<br>(US citizenship)<br><br>The Heart Hospital<br>Baylor Plano<br>1100 Allied Drive<br>4708 Alliance - S. 500<br>TX 75093 Plano,<br>United States | First appointed:<br>Jan. 2, 2017<br><br>Term of office ends:<br>SM held to approve the financial statements for year ending Dec. 31, 2021 | Independent director | None | None |
| **André Muller**<br>(French citizenship)<br><br>Riedmattstrasse 26<br>6052 Hergiswil,<br>Switzerland | First appointed:<br>March 30, 2020<br><br>Term of office ends:<br>SM held to approve the financial statements for year ending Dec. 31, 2024 | Independent director | - Director and Executive Vice President of Idorsia Pharmaceuticals Ltd* responsible for finance, information systems and group purchasing<br><br>- Director of Idorsia Pharmaceuticals Japan (Japan)<br><br>- Director of Idorsia Pharmaceuticals US Inc. (United States)<br><br>- Chairman of Chiron Investments AG (Switzerland) | - Director of various subsidiaries of Actelion Ltd (Switzerland) (until 2017) |

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, or had a company placed into administration, in the last five years;
- no director has been accused of any offense or received 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 act together with others in relation to Carmat.

## 4.1.2 BIOGRAPHIES OF THE MEMBERS OF THE BOARD OF DIRECTORS

### KARL HENNESSEE

Karl Hennessee, Chairman of Matra Défense, has 25 years of experience in law, economics and regulation. He worked, in Europe and in the United States, as a business lawyer on some of the most important cases for a very large company in the energy sector, then as Secretary General of this same company.

In addition to his management functions at Airbus Group, Karl Hennessee is the Chairman of the Board of Directors of the International Arbitration Tribunal within the International Chamber of Commerce. He also sits on the Board of Directors of many other non-profit organizations. He also lectures and regularly publishes articles on law and regulations.

### DR. JEAN-PIERRE GARNIER

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

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

The Best Practice Institute has named Jean-Pierre Garnier as one of the world's top 20 CEOs. He is a French Officier de la Légion d'Honneur (Officer of the Legion of Honor) and Knight Commander of the Order of the British Empire.

### DR. PHILIPPE POULETTY

Dr. Philippe Pouletty is a pioneer in biotechnology and medical devices. He founded SangStat in 1988, a company specializing in organ transplants, listed on the NASDAQ, then Conjuchem in 1993, a biotech firm specialized in developing next-gen medicines from therapeutic peptides, listed on the Toronto Stock Exchange. Among other things, he is the co-founder and CEO of Truffle Capital, founder and Chairman of Deinove, a biotech company that develops and produces 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 the founder of Carbios, a green chemical company developing innovative enzyme processes to reshape the life cycle of plastics, and co-founder and Board member of Pharnext, a leading biopharma company in combinatorial medicine.

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 current Honorary Chairman of France Biotech, the French biotech industry association, 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 became a member of the Board at Schneider Electric in 1996 and the company's CEO in 1999. He also held the position of Chairman of the Supervisory Board from 2006. In addition, he has served as director and Vice-President of the Saint Joseph hospital/Marie Lannelongue hospital foundation.

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

### PIERRE BASTID

Former manager at Schneider Electric then Valeo, Pierre Bastid became Vice President of Thomson Television Components France (Thomson Multimedia Group) in 1998. In 2004, via the Magenta Participations structure, he successfully participated in the acquisition of Alstom Power Conversion, a group that later became Converteam Group, sold to General Electric in 2011.

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

### DR. ANTONINO LIGRESTI

Dr. Antonino Ligresti began his career in the Medical Clinic at the University of Milan 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, renowned 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 Institute of Oncology.

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

### JEAN-LUC LEMERCIER

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

Jean-Luc Lemercier graduated in pharmacy from Claude Bernard Lyon 1 University.

### DR. MICHAEL MACK

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

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

### ANDRÉ MULLER

André Muller is a graduate of EM Lyon business school. He began his career with audit firm KPMG from 1987 to 1990 before moving to the venture capital industry with Siparex from 1990 to 1994. From 1994 to 2011, he held various financial positions in pharmaceutical and cosmetics group Pierre Fabre. From 2012 to 2013, he was a financial consultant (fund raising, financial restructuring, etc.) and co-founded the company Nasabe SAS, an OTC business.

In mid-2013, he joined Swiss pharmaceutical group Actelion Ltd as Executive Vice President responsible for finance, information systems and group purchasing. He played an active role in negotiating Actelion's acquisition by US pharmaceutical group Johnson & Johnson, a $30 billion deal, while at the same time setting up Idorsia Ltd, a spin-off of Actelion's clinical research and development business, which was subsequently floated on the stock exchange.

Since mid-2017, he has been Executive Vice President responsible for finance, information systems and group purchasing at Swiss biotech company Idorsia Ltd, which is listed on the Swiss stock exchange.

### STEPHANE PIAT

Stéphane Piat is a renowned 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 Johnson & Johnson Cordis, where he spent five years in several management positions ranging from Business Director France to European Marketing Director for Cardiology. In 2007, he joined Abbott Vascular as General Manager for Mid-Size Europe, then was appointed General Manager for 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
### CHIEF EXECUTIVE OFFICER

See above.

### DR. PIET JANSEN
### CHIEF MEDICAL OFFICER

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 a Doctor of Medicine from Radboud University Nijmegen, both in the Netherlands.

### ÉRIC RICHEZ
### SALES & BUSINESS DEVELOPMENT DIRECTOR

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

He has over 13 years' experience in sales and marketing with Thoratec, a global leader in ventricular assist 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 is professionally trained in Business & Management and Sales Force Management.

### PASCALE D'ARBONNEAU
### CHIEF FINANCIAL OFFICER

A graduate of the ESCP Business School and holder of a DEA in Management Control and a Postgraduate Diploma in Finance and Accounting, Pascale d'Arbonneau is also a lecturer at Paris Diderot University.

She began her career as an auditor at Coopers & Lybrand (now PwC) before entering the pharmaceutical industry as Head of Finance & IT, France at Johnson & Johnson – MSD (1995-1999). She spent most of her career (1999-2016) at pharmaceutical company GlaxoSmithKline (GSK). She joined as Director, Head of Controlling & Finance Partnering, and then held a number of senior positions within the Group (Vice President & Finance Controller, Pharma Europe from 2006 to 2010, Vice President & Area Finance Director, Western Europe from 2010 to 2014) before becoming Vice President Finance, Compliance & Control Integration for all business units worldwide. Before joining Carmat at the end of 2018, Pascale d'Arbonneau was Executive Director of the Econocom International B.V. family office.

### MARC GRIMMÉ
### RESEARCH & DEVELOPMENT DIRECTOR

Since 1996, Marc Grimmé has been responsible for all technical studies related to Carmat's artificial heart development program. He began his career in 1991 at MBDA France, where he was in charge of all activities related to the development of mission-critical electronics, from upstream studies and the design phase to production commissioning.

Marc Grimmé is a graduate of the Institute Supérieur d'Electronique et du Numérique (ISEN).

### THIERRY DUPOUX
### QUALITY & REGULATORY AFFAIRS DIRECTOR

Thierry Dupoux is a seasoned medical device professional with a strong and in-depth expertise in Quality Assurance/Regulatory Affairs and R&D. An engineering graduate from Ecole Centrale de Lyon (France), he has worked most of his career in Life Sciences companies such as General Electric, where he was appointed Supply Chain Quality & Compliance Manager for the plant in Buc (France) in his final position at the company. In 2006, he joined Sorin Group, now LivaNova, a world leader in heart surgery and neuromodulation. In 12 years at LivaNova, he held several senior positions in Quality Assurance, Regulatory Affairs and R&D. Prior to joining Carmat, he was Vice President of Quality Assurance at LivaNova where he led the integration of the Quality Systems following the merger between Sorin Group and Cyberonics. He joined Carmat in July 2018 as Director of Quality.

### ALEXANDRE ELEONORE
### MANUFACTURING DIRECTOR

Alexandre Eleonore is a proven industry expert with a strong background in operational management. He graduated from the Sevenans Polytechnic Institute, now UTBM (Université de Technologie Belfort-Montbéliard), and spent the first part of his career in leading automotive equipment manufacturers such as Faurecia and Plastic Omnium. After

ten years in this sector, he joined Sorin Group in 2009, which became Microport CRM, one of the world's leading players in the treatment of cardiac rhythm disorders. He became Vice President Operations & Customer Service and implemented cost improvement plans, thanks to his expertise in lean manufacturing and industrial process automation. He joined Carmat as Director of Manufacturing in November 2019.

### FRANCESCO ARECCHI
### MARKETING MANAGER

A marketing professional with extensive experience in leading global companies within the healthcare industry, Francesco Arecchi joined Carmat in September 2017. Francesco Arecchi spent most of his career in Life Sciences companies such as Johnson & Johnson and Abbott, where he held a number of positions from sales to marketing in cardiology breakthrough technology products such as Cypher and MitraClip.

Prior to joining Carmat, he served as Product Manager EMEA Structural Heart at Abbott. Francesco Arecchi is a biomedical engineer and a graduate of Politecnico di Milano (Italy) with an MBA from Rotterdam School of Management (Netherlands).

### RAOUIA BOUYANZER
### HUMAN RESOURCES MANAGER

Raouia Bouyanzer has more than 20 years of experience in payroll and human resources management. She began her career in an accounting firm in 1998. In 2001, Raouia Bouyanzer joined Morgan Stanley, where she served for more than seven years in several positions in social management control, payroll and human resources. Raouia Bouyanzer joined Carmat at the Company's 'development' stage in February 2011 as an Administrative, Financial and Human Resources Manager, and has focused on human resources since 2012.

Raouia Bouyanzer holds a master's degree in HR from ESSEC Business School and holds a degree in accounting and finance (2001).

# 4.2 CONFLICTS OF INTEREST IN THE GOVERNING, MANAGEMENT AND SUPERVISORY BODIES AND EXECUTIVE MANAGEMENT

## 4.2.1 POTENTIAL CONFLICTS OF INTEREST

At the date of this Universal Registration Document and as far as the Company is aware, there are no current or potential conflicts of interest between the private interests and other duties of the Company's Board of Directors and the interests of the Company.

Similarly, as at the same date, the Company has no knowledge of any current or potential conflicts of interest between the private interests or other duties of the members of the Audit Committee or the Compensation Committee and the interests of the Company.

The Board of Directors' Internal Rules set out the duties and obligations of the Board members (see section 4.4.2 of this document). These duties and obligations include preventing any conflict of interest situations and inappropriate use of inside information.

As at the date of this Universal Registration Document, there were no service contracts linking the members of the Board of Directors and Executive Management of the Company, nor any business relationship binding the independent directors and the Company.

All related-party agreements are disclosed in section 5.6.1 of this document. Financial information about related companies is disclosed in the notes to the financial statements (see section 3.2.2 of this document).

## 4.2.2 COMMITMENTS OF THE DIRECTORS AND EXECUTIVE MANAGEMENT TO PRESERVE SHAREHOLDINGS

No commitment to preserve shareholdings by directors or Executive Management was in force on December 31, 2020, with the exception of the obligation for the CEO, Stéphane Piat, to hold, in registered form, a certain percentage of ordinary shares which have resulted or which will result, where applicable, from the conversion of the free preference shares ("AGAP") granted in 2017, 2018, 2019 and 2020 (see section 4.5.1 of this document).

# 4.3 BOARD COMMITTEES

As at the date of this Universal Registration Document, the Company had set up the committees presented below.

## 4.3.1 AUDIT COMMITTEE

By decision of the Board of Directors of July 8, 2009 the Company set up an Audit Committee for an unlimited duration.

Under the exclusive and collective responsibility of the members of the Board of Directors of the Company and in order to ensure the quality of internal control and the reliability of the information provided to shareholders and financial markets, the Committee oversees matters relating to the preparation and control of accounting and financial information and, to this end, shall in particular:

- follow-up on the process of developing information and financial communication;
- monitor the effectiveness of the internal control and risk management systems and in particular:

  - evaluate the internal control procedures and any measures taken to remedy any significant internal control dysfunctions;

  - review the annual work programs of the auditors;

  - evaluate the adequacy of the risk monitoring procedure;
- monitor the statutory audit of the annual and consolidated financial statements by the auditors and in particular:

  - review the assumptions used for the preparation of the annual financial statements of the Company and the half-yearly and, where applicable, quarterly financial statements before their examination by the Board of Directors, after reviewing the financial position, cash position and commitments of the Company;

  - evaluate, in consultation with the auditors, the appropriateness of the choice of accounting principles and methods;

  - consult the members of the Board responsible for the financial aspects as well as the administrative and financial director if he/she is not a member of the Board, between the end of any financial year and the date on which the Committee decides on the draft annual financial statements, with regard to the adequacy of the accounting principles and methods used, the effectiveness of the accounting control procedures and any other appropriate matters;

  - issue a recommendation on the auditors proposed for appointment by the Shareholders' Meeting and review their fees;
- monitor the independence of the auditors and in particular:

  - propose the establishment of rules for recourse to auditors for work other than auditing in order to guarantee the independence of the audit services provided by auditors in accordance with the laws, regulations and recommendations applicable to the Company, and verify proper application;

  - authorize the use of auditors for work other than auditing;
- examine the conditions of use of derivatives;
- execute periodic reviews of the status of significant litigation;
- review the Company's procedures for the receipt, retention and treatment of claims relating to accounting matters and accounting internal controls, audit matters and documents transmitted by employees on an 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.

The Audit Committee met twice in 2020, in particular to review the financial statements for 2019 and the first half of 2020 and to analyze the Company's cash needs and financing options.

As at the date of this Universal Registration Document, the

Audit Committee comprises Henri Lachmann, independent director and Chairman of the Audit Committee, and André Muller, independent director.

## 4.3.2 APPOINTMENTS & COMPENSATION COMMITTEE

The Company has also established an Appointments & Compensation Committee which as at the date of this Universal Registration Document is comprised of four members, including two independent members, appointed by the Board of Directors for an unlimited term:

- Truffle Capital, represented by Dr. Philippe Pouletty, director and Chairman of the Appointments & Compensation Committee;
- Matra Défense, represented by Karl Hennessee;
- Jean-Luc Lemercier, independent director;
- Santé Holdings SRL, represented by Antonino Ligresti, independant director.

The main objectives of the Appointments & Compensation Committee are to:

- recommend to the Board of Directors the persons who should be appointed to Executive Management, the Board of Directors and the main functions of the Company, as the case may be;
- review the compensation policies for executives and high-potential staff within Carmat, propose the compensation of executives and, where applicable, the members of the Board of Directors and prepare any report that the Company must present on these subjects.

It reports to the Board of Directors on its activities at regular intervals.

## 4.3.3 BOARD OBSERVERS

Article 17-VI of the Articles of Association gives the Ordinary Shareholders' Meeting the power to appoint, at its discretion, up to three persons or legal entities, who may or may not be shareholders, for a term of office of one year expiring at the Shareholders' Meeting held to approve the financial statements for the year just ended and held during the year in which their terms of office expire. This term of office may be renewed an unlimited number of times. The duty of the observers (censeurs) is to ensure the strict application of the Articles of Association and to present their observations at the meetings of the Board of Directors. The observers perform a general and permanent role of advice and monitoring within the Company. In connection with their role they may make observations to the Board of Directors.

Observers must be invited to each meeting of the Board of Directors in the same way as directors. Observers have only consultative powers on an individual or joint basis and have no voting rights on the Board.

As at the date of this Universal Registration Document, no observer has been appointed.

# 4.4 STATEMENT ON CORPORATE GOVERNANCE

## 4.4.1 CORPORATE GOVERNANCE

The Company refers to the recommendations of the AFEP-MEDEF Corporate Governance Code for listed companies, to the extent that these principles are compatible with the organization, the size, the resources and the ownership structure of the Company.

To this end, the Company regularly reviews its corporate governance in respect of the recommendations of the AFEP-MEDEF Code, as updated in January 2020.

The principal recommendations not applied are presented hereafter.

| Exclusions | Reasons |
|---|---|
| Assessment of the Board of Directors | There is no formal system to measure the individual contribution of each director.<br>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 AFEP-MEDEF recommends a limit of four years.<br>Reason: When the Company was established, it was deemed that a longer term would ensure the stability of the Company's governance.<br>It is proposed to reduce the term to no more than four years within the next few years. |
| Composition of the Appointments & Compensation Committee | The Appointments & Compensation Committee does not comprise two-thirds of independent directors. The Chairman of the Committee is not an independent director.<br>Reason: In each of the 2018 and 2019 financial years, an independent director was added to the committee, so that independent directors now represent 50% of the committee.<br>In the future, the Company intends to continue increasing this share and complying with recommendations on committee chairs. |
| Evaluation of the work of the Board of Directors and committees | Within the Board of Directors, a debate on its functioning and that of the committees is not systematically carried out every year.<br>Reason: Special attention will be given to this point in the coming years. |
| Desirable balance in Board composition in terms of diversity (representation of women and men, nationalities, etc.) | The Company, which is not bound by the diversity obligations provided for by the French Commercial Code as its shares are not listed on a regulated market, intends in the long term to further diversify the composition of its Board, particularly in terms of female representation. |
| Executive compensation | The quantifiable conditions on which the annual variable compensation of the executive corporate officers is based on are not always preponderant.<br>Reason: Given the Company's development stage, it was considered that a preponderance of qualitative conditions could be more appropriate in certain years. |
| Long-term executive compensation | The resolutions authorizing performance share award plans, put to the vote at the shareholders' meeting, do not refer to the maximum percentage of the total award that can be awarded to the executive corporate officers.<br>Reason: It was considered that the Board of Directors is more qualified to determine the appropriate number of preference shares to be awarded to the Company's Chief Executive Officer. |
| Conclusion of a non-compete agreement with executive corporate officers | To the extent that the contracts concluded between the Company and its employees do not include non-compete clauses, the Company wished to align the condition of executive corporate officers with that of its employees. The Company therefore does not benefit from the protection of this type of clause, even if it also intends to maintain and develop a retention policy by allocating securities giving access to capital to its executive corporate officers. |

In addition to setting up the Audit Committee and the Appointments & Compensation Committee, and in order to meet the standards of corporate governance that the Company has set itself, the elements described below have been put in place.

## 4.4.2 INTERNAL RULES OF THE BOARD OF DIRECTORS

In 2011, the Board of Directors adopted internal rules, the purpose of which is to define the ways in which it is organized and operates over and above the legal and statutory provisions in force. These internal rules were reviewed in 2016. They are available on request from the registered office of the Company.

In addition to respecting the legal, regulatory and statutory provisions applicable to the Board, the Board of Directors, in accordance with these rules:

- determines the Company's business strategy and ensures its implementation. Subject to the powers expressly granted by Shareholders' Meetings and within the scope of the Company's purpose, the Board shall consider any matter affecting the proper functioning of the Company and shall, by its deliberations, resolve matters affecting it;

- appoints the Chairman of the Board, the Chief Executive Officer and the Deputy Chief Executive Officers, and determines their duties and compensation;
- authorizes the agreements and commitments referred to in Articles L.225-38 et seq. of the French Commercial Code;
- authorizes the decisions and commitments listed in the Appendix to the internal rules;
- ensures the quality of information provided to shareholders and the markets.

The Board of Directors' Internal Rules also set out the directors' duties and obligations, which include general obligations, duty of loyalty, duty of disclosure, duty to refrain from trading in the Company's shares during certain black-out periods, duty regarding inside information, duty regarding holding financial instruments issued by the Company, duty of care and duty to provide and right to obtain information. These duties and obligations include preventing any conflict of interest situations and inappropriate use of inside information.

## 4.4.3 WORK OF THE BOARD OF DIRECTORS

During the 2020 financial year, the Board of Directors met five times. In addition to its traditional governance missions, including the approval of the 2019 financial statements and those of the first half of 2020, the Board focused in particular on:

- steering and monitoring of the artificial heart development project;
- the Company's strategic plan;
- the Company's manufacturing plan;
- the commercial launch plan for the artificial heart;
- the financial forecasts and the financing strategy of the Company;
- changes in the composition of the Board of Directors.

Board meetings are subject to an annual provisional calendar defined at the latest in January of each year. Each meeting is prepared in advance by the Chairman and the Chief Executive Officer.

The table below summarizes the effective presence of the directors at the various Board meetings.

| Effective presence at Board meetings (2020) | Number of meetings applicable | Effective presence at meetings |
|---|---|---|
| Jean-Pierre Garnier - Chairman of the Board | 5 | 5 |
| Stéphane Piat - Chef Executive Officer and director | 5 | 5 |
| Truffle Capital - Director | 5 | 4 |
| Matra Défense - Director | 5 | 4 |
| Henri Lachmann - Director | 5 | 5 |
| Pierre Bastid - Director | 5 | 4 |
| Santé Holdings SRL - Director | 5 | 4 |
| Jean Luc Lemercier - Director | 5 | 5 |
| Michael Mack - Director | 5 | 5 |
| André Muller - Director | 4 | 4 |

## 4.4.4 SEPARATION OF THE OFFICES OF CHAIRMAN OF THE BOARD OF DIRECTORS AND CHIEF EXECUTIVE OFFICER

When the Company converted to a société anonyme, the Board of Directors opted for a separation of the offices of Chairman of the Board of Directors and of Chief Executive Officer.

The Board of Directors must approve in advance the following decisions and commitments, it being specified that the thresholds mentioned below in these decisions will be assessed (i) individually for each operation and (ii) annually:

A. Corporate life of the Company:

(a) any amendment to the articles or other documents constituting the Company or its subsidiaries;

(b) liquidation, amicable dissolution or other similar proceedings relating to the Company and/or the companies or entities controlled by the Company (the "Subsidiaries") and withdrawal from the Company.

B. Strategic decisions:

(a) definition of strategic, economic, social, financial and scientific priorities for the Company;

(b) operations outside the strategy announced by the Company;

(c) significant development of related or derivative activities, directly within the Company, or through subsidiaries controlled or not;

(d) the change in the normal business of the Company and its development strategy;

(e) any significant agreement to use patents or production licenses granted to third parties outside the ordinary course of business;

(f) any transfer, acquisition, contribution or exchange of assets of a unit amount exceeding three hundred thousand euros (€300,000);

(g) any investment in excess of three hundred thousand euros (€300,000);

(h) mergers, spin-offs, contributions, partnerships, joint ventures or similar significant transactions;

(i) transfer and relocation of the Company's registered office outside France, cross-border mergers or conversion of the Company into a European company;

(j) additional indebtedness, modification, refinancing of a loan amounting to more than three hundred thousand euros (€300,000);

(k) significant change in the accounting rules and principles applied by the Company;

(l) hiring, dismissal and alteration of employment contracts (including the compensation) of any employee who has an executive function (i.e., medical director, director of operations, sales manager and administrative director and financial director);

(m) selection of advisers and intermediaries in strategic decision-making and compensation.

C. Related-party agreements (approval and annual review of contracts in progress).

D. Securities:

(a) issue of any securities giving access, immediately or in the future, to 5% or more of the share capital of the Company;

(b) transfer of securities of subsidiaries to third parties or subscription or acquisition of securities issued by an entity other than a subsidiary.

E. Any proposal to the Shareholders' Meeting relating to the policy of dividend distribution, redemption of shares or other payments or distribution to shareholders.

F. Adoption and modification of the annual budget, approval and modification of the business plan.

G. Any commitment exceeding three hundred thousand euros (€300,000).

H. Compensation and profit-sharing of executives in respect of their office or employment contract (including any stock option plans, performance shares or other similar arrangements) on the proposal of the Appointments & Compensation Committee.

I. Appointment and dismissal of executive corporate officers, the administrative and financial director, the scientific director and the medical director.

J. Decision regarding commitments or transactions relating to a dispute of more than two hundred and fifty thousand euros (€250,000).

K. Site closure; adoption of a plan to safeguard employment.

L. Appointment of Statutory Auditors and alternates.

M. Subscription of any loan or advance to acquire securities of any subsidiary company except in the event that such subsidiary is wholly or partly owned by the Company.

N. Granting of guarantees, deposits of endorsements for the benefit of third parties (including a subsidiary) or granting of security rights to guarantee debts of the Company.

It is specified that:

- one of the aforementioned decisions foreseen within the annual budget in a precise manner shall not have to be approved again when implemented; and

- decisions A to E shall be adopted by a majority of (i) half of the directors on first call and (ii) half of the directors present or represented on second call.

For a detailed description of the provisions governing the functioning of the Board of Directors and Executive Management, see section 5.4.2 "Provisions of the Articles of Association, charter or bylaws of the Company concerning the members of the Board of Directors and Executive Management".

## 4.4.5 INDEPENDENT DIRECTORS

The Company has six independent directors: Henri Lachmann, Jean-Luc Lemercier, Michael Mack, André Muller, Pierre Bastid, and the company Santé Holdings SRL; the Company believes that since their appointment they have met the criteria of the AFEP-MEDEF Code of December 2008 (as amended in January 2020), that is:

- not be or have been in the past five years (criterion 1):

  - an employee or executive corporate officer of the Company;

  - an employee, executive corporate officer or director of a company consolidated by the Company;

  - an employee, executive corporate officer or director of the Company's parent company or another company consolidated by it;

- not be an executive corporate officer of a company in which the Company directly or indirectly holds a directorship or in which an employee appointed as such or an executive corporate officer of the Company (currently in office or having held such office in the last five years) holds a directorship (criterion 2);

- not be 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 (criterion 3);

- have no close family ties with a corporate officer (criterion 4);

- not have been the Company's Statutory Auditor during the last five years (criterion 5);

- not have been a director of the Company for more than 12 years (criterion 6);

- not have any particular relationships of interest with the Company, its management or its Group (significant shareholder, employee or other) that could compromise his/her freedom of judgment (criterion 7);

- for non-executive corporate officers, not receive variable compensation in cash or securities, or any compensation related to the Company's or the Group's performance (criterion 8);

- in addition, the Board of Directors may consider that a director who meets the above criteria should nonetheless not be regarded as independent given his/her particular position in the Company, having regard to its share ownership or for any other reason. Conversely, the Board of Directors may consider that a director who does not meet the above criteria is nonetheless independent. For example, major shareholders of the Company or its parent company may be considered as independent if they do not have any control over the Company (criterion 9).

The table below summarizes independence assessments for members of the Board of Directors.

| Criterion | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | Independence |
|---|---|---|---|---|---|---|---|---|---|---|
| Jean-Pierre Garnier - Chairman of the Board | | X | X | X | X | X | X | N/A | N/A | Not independent |
| Stéphane Piat - Chef Executive Officer and director | | X | X | X | X | X | X | N/A | N/A | Not independent |
| Matra Défense, represented by Karl Hennessee | X | X | X | X | X | X | | X | N/A | Not independent |
| Henri Lachmann | X | X | X | X | X | X | X | X | N/A | Independent |
| Truffle Capital, represented by Philippe Pouletty | X | X | X | X | X | X | | X | N/A | Not independent |
| Pierre Bastid | X | X | X | X | X | X | X | X | X | Independent |
| Santé Holdings SRL, represented by Antonino Ligresti | X | X | X | X | X | X | X | X | N/A | Independent |
| Jean-Luc Lemercier | X | X | X | X | X | X | X | X | N/A | Independent |
| Michael Mack | X | X | X | X | X | X | X | X | N/A | Independent |
| André Muller | X | X | X | X | X | X | X | X | N/A | Independent |

## 4.4.6 INTERNAL CONTROL

At the date of this Universal Registration Document, the Company had internal control procedures, in particular in the administrative, accounting, and financial areas, to guarantee the implementation of its strategic objectives and the quality of its financial information.

In January 2020, the Company also created a Risk Committee, which includes all members of its management team, whose role is to identify the Company's main risks and to define and implement appropriate risk mitigation plans. The Committee meets at least twice a year.

## 4.4.7 CODE OF ETHICS & BUSINESS CONDUCT

On September 7, 2020, the Board of Directors adopted a Code of Ethics & Business Conduct, which applies to all staff and directors of the Company. It came into effect on December 1, 2020 and is available on the Company's website. It sets out the corporate standards of behavior to be observed by all people working for or on behalf of Carmat and the disciplinary measures that may be taken in the event of non-compliance.

These standards cover compliance with laws, rules and regulations, conflicts of interest, protection and proper use of the Company's resources and assets, confidentiality and information management (including inside information), bribes, kickbacks and other improper payments or gifts, political contributions and activity, work environment, accuracy of records (including accounting and financial information), the quality of public disclosures, clinical and scientific integrity, and interactions with healthcare professionals.

# 4.5 COMPENSATION AND BENEFITS OF EXECUTIVES AND DIRECTORS

## 4.5.1 COMPENSATION AND BENEFITS IN KIND OF EXECUTIVE DIRECTORS

Table 1: Summary table of compensation and options, warrants and free shares awarded to each executive corporate officer (in euros)

| Jean-Pierre Garnier - Chairman of the Board of Directors (since December 3, 2018) | 2019 | 2020 |
|---|---|---|
| Compensation payable for the year (detailed in table 2) | 100,000 | 100,000 |
| Value of long-term variable compensation awarded during the year | - | - |
| Value of options and warrants awarded during the year (detailed in table 4) | * | - |
| Value of free shares awarded for the year (detailed in table 6) | - | - |
| TOTAL | 100,000 | 100,000 |

* 46,000 stock options awarded in April 2019, subject to conditions, with an exercise price of €22.70. Taking into account the price of the Carmat share at December 31, 2019, i.e., €19.28, the potential capital gain relating to these stock options was zero at December 31, 2019.

| Stéphane Piat - Chief Executive Officer | 2019 | 2020 |
|---|---|---|
| Compensation payable for the year (detailed in table 2)* | 621,805 | 686,898 |
| Value of long-term variable compensation awarded during the year | - | - |
| Value of options and warrants awarded during the year (detailed in table 4) | - | - |
| Value of free shares awarded for the year (detailed in table 6)** | 1,083,343 | 2,224,380 |
| TOTAL | 1,705,148 | 2,911,278 |

* Benefits in kind included. Stéphane Piat received a 2% increase in his fixed compensation in 2020. He also benefits from variable compensation (based on objectives approved by the Board of Directors), the maximum % of which was increased in 2019 from 45% to 50%. The percentage achievement of those objectives in 2020, as validated by the Compensation Committee, was 125% (versus 98% in 2019). Details of the objectives and their level of achievement are not disclosed publicly for reasons of confidentiality.

** The free shares awarded during the financial year are subject to performance conditions. Their values at December 31, 2019 and December 31, 2020 correspond to the share price on those respective dates and to the estimate made by the Company on those dates of the probability of achievement of the conditions. Stéphane Piat is required to hold at least 10% of the ordinary shares resulting from the conversion of the free preference shares granted to him in 2019 and at least 15% of the ordinary shares resulting from the conversion of the free preference shares granted to him in 2020 in registered form until the termination of his office as a corporate officer of the Company. To the best of the Company's knowledge, no hedging instrument has been put in place.

Table 2: Summary table of the compensation of each executive corporate officer (in euros)

| Jean-Pierre Garnier - Chairman of the Board of Directors (since December 3, 2018) | 2019 | | 2020 | |
|---|---|---|---|---|
| | Amounts due* | Amounts paid** | Amounts due* | Amounts paid** |
| Fixed compensation*** | 100,000 | 53,653 | 100,000 | 146,347 |
| Annual variable compensation*** | - | - | - | - |
| Special compensation | - | - | - | - |
| Directors' compensation | - | - | - | - |
| Benefits in kind | - | - | - | - |
| TOTAL | 100,000 | 53,653 | 100,000 | 146,347 |

* For the financial year. ** During the financial year, including for the previous year.
*** Under an employment contract as US Business Development Manager. Jean-Pierre Garnier receives fixed compensation but no variable compensation or any other benefits. His fixed compensation was not increased in either 2019 or 2020.

| Stéphane Piat - Chief Executive Officer | 2019 | | 2020 | |
|---|---|---|---|---|
| | Amounts due* | Amounts paid** | Amounts due* | Amounts paid** |
| Fixed compensation*** | 411,743 | 411,743 | 417,936 | 417,936 |
| Annual variable compensation*** | 202,269 | 176,946 | 262,500 | 202,269 |
| Special compensation | - | - | - | - |
| Directors' compensation | - | - | - | - |
| Benefits in kind**** | 7,793 | 7,793 | 6,462 | 6,462 |
| TOTAL | 621,805 | 596,482 | 686,898 | 626,667 |

* For the financial year. ** During the financial year, including for the previous year.
*** Stéphane Piat received a 2% increase in his fixed compensation in 2020. He benefits from variable compensation (based on objectives approved by the Board of Directors), the maximum % of which was increased in 2019 from 45% to 50%. The percentage achievement of those objectives in 2020, as validated by the Compensation Committee, was 125% (versus 98% in 2019). Details of the objectives and their level of achievement are not disclosed publicly for reasons of confidentiality.
**** Company car.

Table 3: Table of directors' compensation and other compensation received by non-executive corporate officers

| Table 3 - Part 1 | 2019 | 2020 |
|---|---|---|
| Professor Alain Carpentier - Director until March 28, 2019 | | |
| Directors' compensation* | 1,500 | 0 |
| Other compensation | - | - |
| Truffle Capital - Director | | |
| Directors' compensation* | 7,500 | 6,000 |
| Other compensation | - | - |
| Airbus Group - Director** | | |
| Directors' compensation* | 4,500 | 6,000 |
| Other compensation | - | - |
| Henri Lachmann - Director | | |
| Directors' compensation* | 7,500 | 7,500 |
| Other compensation | - | - |
| Pierre Bastid - Director | | |
| Directors' compensation* | 7,500 | 6,000 |
| Other compensation | - | - |
| Santé Holdings SRL - Director | | |
| Directors' compensation* | 6,000 | 6,000 |
| Other compensation | - | - |

* The term "Directors' compensation" replaces the term "Directors' fees" previously used.

** Karl Hennessee replaced Anne-Pascale Guédon as permanent representative of Airbus Group on the Carmat Board of Directors on June 6, 2019.

| Table 3 - Part 2 | 2019 | 2020 |
|---|---|---|
| Jean-Luc Lemercier - Director | | |
| Directors' compensation* | 12,500 | 12,500 |
| Other compensation | - | - |
| Michael Mack - Director | | |
| Directors' compensation* | 22,839 | 29,003 |
| Other compensation | - | - |
| André Muller - Director since March 30, 2020 | | |
| Directors' compensation* | - | 10,000 |
| Other compensation | - | - |

* The term "Directors' compensation" replaces the term "Directors' fees" previously used.

Table 4: Stock options awarded to each executive corporate officer during the year ended December 31, 2020

No stock options were awarded in 2020.

Table 5: Stock options exercised by each executive corporate officer during the year ended December 31, 2020

No stock options were exercised in 2020.

Table 6: Free shares awarded to each corporate officer during 2020

| Free shares awarded to each corporate officer by the issuer | Plan no. and date | Class and number of AGAP free preference shares awarded | Maximum number of ordinary shares to which the AGAP awarded give right | Value of shares* | Date of award | Vesting date | Exercise period | Performance conditions |
|---|---|---|---|---|---|---|---|---|
| Stéphane Piat<br>Chief Executive Officer | 2020 AGAP plan<br>Dec. 2, 2020 | | | | | | | |
| | of which AGAP 2020-01 | 800 | 80,000 | €1,516,880 | December 18, 2020 | December 18, 2021 | From Dec. 18, 2023 to March 18, 2029 | See section 5.2.5 |
| | of which AGAP 2020-02 | 500 | 50,000 | €707,500 | | | From Dec. 18, 2025 to March 18, 2029 | |
| TOTAL | | 1,300 | 130,000 | €2,224,380 | | | | |

* The free shares awarded during the financial year are subject to performance conditions. Their values at December 31, 2020 correspond to the Carmat share price on that date (i.e., €28.30) and to the estimate made by the Company of the probability of achievement of the conditions (i.e., 67% for the AGAP 2020-01 and 50% for the AGAP 2020-02). At least 15% of the number of ordinary shares resulting from the conversion of the preference shares granted without consideration to Stéphane Piat must be held in registered form until the termination of his office as a corporate officer of the Company. To the best of the Company's knowledge, no hedging instrument has been put in place.

Tables 7 and 7 bis: Free shares awarded to each executive corporate officer that vested during the year ended December 31, 2020

Table 7: Free shares that vested during the year

| Corporate officer name | Plan no. and date | Class and number of AGAP vested during the year* | | Maximum number of ordinary shares to which the AGAP vested give right** | Exercise conditions |
|---|---|---|---|---|---|
| Stéphane Piat<br>Chief Executive Officer | 2019 AGAP plan<br><br>April 1, 2019 | | | | |
| | | AGAP 2019-01 | 2,640 | 26,400 | See sections 5.2.5 and 5.4.3 |
| | | AGAP 2019-02 | 2,640 | 26,400 | |
| | | AGAP 2019-03 | 1,320 | 13,200 | |
| | 2019 AGAP Plan<br><br>Sept. 23, 2019 | | | | |
| | | AGAP 2019-01 | 1,800 | 18,000 | |
| | | AGAP 2019-02 | 1,800 | 18,000 | |
| | | AGAP 2019-03 | 150 | 1,500 | |
| TOTAL | | | 10,350 | 103,500 | |

* AGAP preference shares that vested during the 2020 financial year. These AGAP will be convertible into ordinary shares during the exercise period depending on the achievement of performance criteria (see sections 5.2.5 and 5.4.3).

** Assuming 100% achievement of the performance criteria.

Table 7 bis: Shares that became convertible during the year

| Corporate officer name | Plan no. and date | Class and number of AGAP that became convertible during the year | | Number of ordinary shares to which the convertible AGAP give right* | Exercise conditions |
|---|---|---|---|---|---|
| Stéphane Piat<br>Chief Executive Officer | 2017 AGAP plan<br><br>May 15, 2017 | | | | |
| | | AGAP 2017-01 | 180 | 18,000 | See sections 5.2.5 and 5.4.3 |
| | | AGAP 2017-02 | 1,000 | 20,000 | |
| | | AGAP 2017-03 | 1,720 | 94,600 | |
| TOTAL | | | 2,900 | 132,600 | |

* Taking into account the actual degree of achievement of the performance conditions on the convertibility date, as determined by the Board of Directors (i.e., 100% for the AGAP 2017-01, 100% for the AGAP 2017-02 and 55% for the AGAP 2017-03). At December 31, 2020, Stéphane Piat had converted all of his AGAP 2017-01 and 2017-02 into ordinary shares. At that date, he had not converted any of his AGAP 2017-03 into ordinary shares.

Table 8: History of stock option awards (for executive and non-executive directors)

| Part 1<br>Table 8 | BCE-2009-1 | BCE-2009-2 | BCE-2012-1 | BCE-2012-2 | BSA-2009-1 |
|---|---|---|---|---|---|
| Date of the Board meeting | Sept. 9, 2009 | July 8, 2009 | June 27, 2012 | Nov. 8, 2012 | July 8, 2009 |
| Number of shares that can be subscribed or acquired | 77,700 | 189,150 | 56,500 | 6,700 | 77,400 |
| Number of which can be subscribed or acquired by corporate officers (executive and non-executive) | 77,700 | 0 | 4,000 | 0 | 64,750 |
| Jean-Luc Lemercier* | | | | | |
| Michael Mack* | | | | | |
| Jean-Pierre Garnier* | | | | | |
| Marcello Conviti** | 77,700 | | 4,000 | | |
| Jean-Claude Cadudal** | | | | | 38,850 |
| Michel Finance** | | | | | 12,950 |
| André Ballester** | | | | | 12,950 |
| Starting point for exercising options | Sept. 9, 2009 | July 8, 2009 | June 27, 2012 | Nov. 8, 2012 | July 8, 2009 |
| Expiration date | Sept. 9, 2019 | July 8, 2019 | June 27, 2022 | Nov. 8, 2022 | July 8, 2019 |
| Subscription or purchase price | €8.00 | €8.00 | €108.483 | €122.003 | €8.00 |
| Exercise conditions (when the plan includes several tranches) | See note 3, on the next page | See section 5.2.5 | See section 5.2.5 | See section 5.2.5 | See section 5.2.5 |
| Number of shares subscribed as at Dec. 31, 2020 | 77,700 | 111,875 | 0 | 0 | 63,500 |
| Cumulative number of options canceled or expired | 0 | 3,091*** | 49,000 | 0 | 556**** |
| Number of options outstanding at year-end | 0 | 0 | 7,500 | 6,700 | 0 |

* Corporate officer on the date of publication of this document. ** Former corporate officer of the Company.

*** I.e., 77,275 ordinary shares after adjustment resulting from the capital increase with pre-emptive subscription rights performed in August 2011.

**** I.e., 13,900 ordinary shares after adjustment resulting from the capital increase with pre-emptive subscription rights performed in August 2011.

| Part 2 Table 8 | BSA-2017 - Board Members | Stock options - 2018 | Stock options - 2019 |
|---|---|---|---|
| Date of the Board meeting | May 15, 2017 | Dec. 3, 2018 | April 1, 2019 |
| Number of shares that can be subscribed or acquired | 12,000 | 46,000 | 46,000 |
| Number of which can be subscribed or acquired by corporate officers (executive and non-executive) | 12,000 | 46,000 | 46,000 |
| Jean-Luc Lemercier* | 6,000 | | |
| Michael Mack* | 6,000 | | |
| Jean-Pierre Garnier* | | 46,000 | 46,000 |
| Marcello Conviti** | | | |
| Jean-Claude Cadudal** | | | |
| Michel Finance** | | | |
| André Ballester** | | | |
| Starting point for exercising options | May 15, 2017 | Jan. 1, 2019 | Jan. 1, 2019 |
| Expiration date | May 15, 2027 | Dec. 2, 2028 | March 31, 2029 |
| Subscription or purchase price | €30.10 (1) | €20.35 (2) | €22.70 (2) |
| Exercise conditions (when the plan includes several tranches) | See section 5.2.5 | See section 5.2.5 | See section 5.2.5 |
| Number of shares subscribed as at Dec. 31, 2020 | 0 | 0 | 0 |
| Cumulative number of options canceled or expired | 0 | 0 | 0 |
| Number of options outstanding at year-end | 12,000 | 46,000 | 46,000 |

* Corporate officer on the date of publication of this document. ** Former corporate officer of the Company.

Note 1: Price corresponding to the average weighted volume of the share prices quoted over the 20 trading days preceding the date of the Board of Director's decision.

Note 2: Share price (closing price) on Euronext Growth on the day preceding the Board of Director's decision.

Note 3: Information relating to BCE-2009-1.

| Exercise conditions applicable | BCE-2009-1 |
|---|---|
| Exercise conditions | - 25% of the BCE-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 in the Company at that date;<br>- 75% of BCE-2009-1 warrants may be exercised on the basis of monthly periods in tranches of 1/36 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 in the Company at that date.<br>Early exercise in the event of a share transfer agreement being entered into, with or without conditions precedent, resulting in a change in control of the Company to the benefit of the transferee on the basis of a valuation in excess of €100 million.<br>As a result of the success of the initial listing of the Company on the Alternext market of Euronext Paris, according to the assessment of the meeting of the Board of Directors of September 8, 2010, 20% of BCE-2009-1 warrants that were not exercisable as at the date of the initial listing may be exercised early. |

* After adjustments resulting from the increase in capital with pre-emptive subscription rights performed in August 2011.

Table 9: Dilutive instruments granted to the top ten employees who are not corporate officers, and options exercised by these grantees during 2020

| Dilutive instruments granted to the top ten employees who are not corporate officers, and options exercised by these beneficiaries, including BSA, BSAR, BSPCE, etc. | Total number of options awarded/ shares subscribed or purchased | Weighted average subscription price for one new share |
|---|---|---|
| Dilutive instruments granted during the year by the issuer to the top ten employees having been granted the highest number of such instruments (comprehensive information) | None | None |
| Dilutive instruments held on the issuer exercised during the year by the top ten employees having purchased or subscribed to the highest number of such instruments (comprehensive information) | None | None |

Table 10: History of free share awards (comprehensive information)

2017 AGAP plans

| 2017 AGAP plans | | | | | | |
|---|---|---|---|---|---|---|
| Class of AGAP | AGAP 2017-01 | AGAP 2017-02 | AGAP 2017-03 | AGAP 2017-01 | AGAP 2017-02 | AGAP 2017-03 |
| Date of the Board meeting | May 15, 2017 | | | Sept. 25, 2017 | | |
| Total number of free AGAP awarded | 270 | 1,800 | 3,180 | 50 | 200 | 310 |
| Of which number of AGAP awarded to corporate officer beneficiaries | 180 | 1,000 | 1,720 | 0 | 0 | 0 |
| Stéphane Piat - Chief Executive Officer and director | 180 | 1,000 | 1,720 | 0 | 0 | 0 |
| AGAP vesting date | May 15, 2018 | | | Sept. 25, 2018 | | |
| Exercise period to convert into ordinary shares* | From May 15, 2020 to May 15, 2025 | | | From Sept. 25, 2020 to Dec. 25, 2025 | | |
| End date of lock-up period | May 15, 2020 | | | Sept. 25, 2020 | | |
| Number of shares (AGAP) vested as at Dec. 31, 2020 | 270 | 1,800 | 3,180 | 50 | 200 | 310 |
| Cumulative number of shares (AGAP) expired or canceled (total) | 0 | 0 | 0 | 0 | 0 | 0 |
| Cumulative number of shares (AGAP) expired or canceled (corporate officers) | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of shares (AGAP) outstanding as at Dec. 31, 2020 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of ordinary shares issued | 27,000 | 36,000 | 53,900 | 5,000 | 4,000 | 11,350 |
| Number of ordinary shares yet to be issued ** | 0 | 0 | 111,100 | 0 | 0 | 0 |

* See section 5.2.5 for the conversion ratios into ordinary shares, and the associated performance conditions.
** Assuming all performance conditions are achieved.

| 2018 AGAP plans<br>Class of AGAP | AGAP 2018-01 | AGAP 2018-02 | AGAP 2018-03 | AGAP 2018-01 | AGAP 2018-02 | AGAP 2018-03 | AGAP 2018-01 | AGAP 2018-02 | AGAP 2018-03 |
|---|---|---|---|---|---|---|---|---|---|
| Date of the Board meeting | April 16, 2018 | | | Sept. 27, 2018 | | | Feb. 11, 2019 | | |
| Total number of free AGAP awarded | 580 | 11,500 | 0 | 0 | 0 | 370 | 0 | 0 | 370 |
| Of which number of AGAP awarded to corporate officer beneficiaries | 580 | 7,500 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stéphane Piat - Chief Executive Officer and director | 500 | 7,500 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| AGAP vesting date | April 16, 2019 | | | Sept. 27, 2019 | | | Feb. 11, 2020 | | |
| Exercise period to convert into ordinary shares* | From April 16, 2021 to April 16, 2026 | | | From Sept. 27, 2021 to Dec. 27, 2026 | | | From Feb. 11, 2022 to May 11, 2027 | | |
| End date of lock-up period | April 16, 2021 | | | Sept. 27, 2021 | | | Feb. 11, 2022 | | |
| Number of shares (AGAP) vested as at Dec. 31, 2020 | 580 | 10,350 | 0 | 0 | 0 | 370 | 0 | 0 | 370 |
| Cumulative number of shares (AGAP) expired or canceled (total) | 0 | 200 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cumulative number of shares (AGAP) expired or canceled (corporate officers) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of shares (AGAP) outstanding as at Dec. 31, 2020 | 0 | 950 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of ordinary shares issued | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of ordinary shares yet to be issued ** | 58,000 | 169,500 | 0 | 0 | 0 | 37,000 | 0 | 0 | 37,000 |

* See section 5.2.5 for the conversion ratios into ordinary shares, and the associated performance conditions.
** Assuming all performance conditions are achieved.

| 2019 AGAP plans | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Class of AGAP** | **AGAP 2019-01** | **AGAP 2019-02** | **AGAP 2019-03** | **AGAP 2019-01** | **AGAP 2019-02** | **AGAP 2019-03** | **AGAP 2019-01** | **AGAP 2019-02** | **AGAP 2019-03** |
| Date of the Board meeting | April 1, 2019 | | | Sept. 23, 2019 | | | Dec. 2, 2019 | | |
| Total number of free AGAP awarded | 4,760 | 4,760 | 2,380 | 2,240 | 2,240 | 220 | 1,000 | 1,000 | 1,000 |
| Of which number of AGAP awarded to corporate officer beneficiaries | 2,640 | 2,640 | 1,320 | 1,800 | 1,800 | 150 | 0 | 0 | 0 |
| Stéphane Piat - Chief Executive Officer and director | 2,640 | 2,640 | 1,320 | 1,800 | 1,800 | 150 | 0 | 0 | 0 |
| AGAP vesting date | April 1, 2020 | | | Sept. 23, 2020 | | | Dec. 2, 2020 | | |
| Exercise period to convert into ordinary shares* | From April 1, 2022 to June 30, 2027 | | | From Sept. 23, 2022 to Oct. 31, 2027 | | | From Dec. 2, 2022 to Jan. 1, 2028 | | |
| End date of lock-up period | April 1, 2022 | | | Sept. 23, 2022 | | | Dec. 2, 2022 | | |
| Number of shares (AGAP) vested as at Dec. 31, 2020 | 4,240 | 4,240 | 2,120 | 2,020 | 2,020 | 185 | 1,000 | 1,000 | 1,000 |
| Cumulative number of shares (AGAP) expired or canceled (total) | 120 | 120 | 60 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cumulative number of shares (AGAP) expired or canceled (corporate officers) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of shares (AGAP) outstanding as at Dec. 31, 2020 | 400 | 400 | 200 | 220 | 220 | 35 | 0 | 0 | 0 |
| Number of ordinary shares issued | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of ordinary shares yet to be issued ** | 46,400 | 46,400 | 23,200 | 22,400 | 22,400 | 2,200 | 10,000 | 10,000 | 10,000 |

* See section 5.2.5 for the conversion ratios into ordinary shares, and the associated performance conditions.
** Assuming all performance conditions are achieved.

2020 AGAP plans

| 2020 AGAP plans<br>Class of AGAP | AGAP 2020-01 | AGAP 2020-02 |
|---|---|---|
| Date of the Board meeting | December 2, 2020 | |
| Total number of free AGAP awarded | 2,240 | 900 |
| Of which number of AGAP awarded to corporate officer beneficiaries | 800 | 500 |
| Stéphane Piat - Chief Executive Officer and director | 800 | 500 |
| AGAP vesting date | December 18, 2021 | |
| Exercise period to convert into ordinary shares* | From Dec. 18, 2023 to March 18, 2029 | From Dec. 18, 2025 to March 18, 2029 |
| End date of lock-up period | Dec. 17, 2023 | Dec. 17, 2025 |
| Number of shares (AGAP) vested as at Dec. 31, 2020 | 0 | 0 |
| Cumulative number of shares (AGAP) expired or canceled (total) | 0 | 0 |
| Cumulative number of shares (AGAP) expired or canceled (corporate officers) | 0 | 0 |
| Number of shares (AGAP) outstanding as at Dec. 31, 2020 | 2,240 | 900 |
| | | |
| Number of ordinary shares issued | 0 | 0 |
| Number of ordinary shares yet to be issued ** | 224,000 | 90,000 |

* See section 5.2.5 for the conversion ratios into ordinary shares, and the associated performance conditions.
** Assuming all performance conditions are achieved.

Table 10 bis: Information about the free shares awarded to Stéphane Piat

The following table summarizes the AGAP awarded to Stéphane Piat, Director and Chief Executive Officer of the Company, since he was first appointed Chief Executive Officer on September 1, 2016. Stéphane Piat has not received any other instruments (BSA share warrants, BCE company founder share warrants, stock options, etc.) giving access to the Company's share capital.

| Table 10 bis - Part 1 | 2017 AGAP plan | | | 2018 AGAP plan | |
|---|---|---|---|---|---|
| Class of AGAP | AGAP 2017-01 | AGAP 2017-02 | AGAP 2017-03 | AGAP 2018-01 | AGAP 2018-02 |
| Date of award | May 15, 2017 | | | April 16, 2018 | |
| Number of free AGAP awarded | 180 | 1,000 | 1,720 | 500 | 7,500 |
| Maximum number of ordinary shares to which the AGAP give right* | 18,000 | 20,000 | 172,000 | 50,000 | 150,000 |
| AGAP vesting date | May 15, 2018 | | | April 16, 2019 | |
| AGAP convertibility date | May 15, 2020 | | | April 16, 2021 | |
| Exercise period to convert into ordinary shares | From May 15, 2020 to May 15, 2025 | | | From April 16, 2021 to April 16, 2026 | |
| Number of shares (AGAP) vested as at Dec. 31, 2020 | 180 | 1,000 | 1,720 | 500 | 7,500 |
| Cumulative number of shares (AGAP) expired or canceled | 0 | 0 | 0 | 0 | 0 |
| Cumulative number of shares (AGAP) that have become convertible as at Dec. 31, 2020 | 180 | 1,000 | 1,720 | | |
| % achievement of performance conditions on the convertibility date | 100% | 100% | 55% | | |
| Number of ordinary shares to which the convertible AGAP give right | 18,000 | 20,000 | 94,600 | | |
| Number of ordinary shares actually issued at December 31, 2020 | 18,000 | 20,000 | 0 | | |
| Number of ordinary shares yet to be issued at December 31, 2020* | 0 | 0 | 94,600 | 50,000 | 150,000 |

* For the AGAP not yet converted at December 31, 2020, assuming that the relevant performance conditions are 100% achieved.

Summary:

The AGAP 2017 awarded to Stéphane Piat in 2017 became convertible in 2020 into 132,600 ordinary shares (corresponding to a value of €3.75 million based on Carmat's share price at December 31, 2020, i.e., €28.30).

The AGAP 2018, AGAP 2019 and AGAP 2020 awarded to Stéphane Piat in 2018, 2019 and 2020, respectively, will become convertible in 2021, 2022 and 2023/2025, respectively, into a maximum of 433,500 ordinary shares assuming that all the performance conditions are fully met. Based on Carmat's closing share price on December 31, 2020, i.e., €28.30. these 433,500 ordinary shares would be worth €12.27 million.

Table 10 bis (cont.): Information about the free shares awarded to Stéphane Piat

| Table 10 bis - Part 2 | 2019 AGAP plan | | | 2019 AGAP plan | | | 2020 AGAP plan | |
|---|---|---|---|---|---|---|---|---|
| Class of AGAP | AGAP 2019-01 | AGAP 2019-02 | AGAP 2019-03 | AGAP 2019-01 | AGAP 2019-02 | AGAP 2019-02 | AGAP 2020-01 | AGAP 2020-02 |
| Date of award | April 1, 2019 | | | Sept. 23, 2019 | | | Dec. 18, 2020 | |
| Number of free AGAP awarded | 2,640 | 2,640 | 1,320 | 1,800 | 1,800 | 150 | 800 | 500 |
| Maximum number of ordinary shares to which the AGAP give right* | 26,400 | 26,400 | 13,200 | 18,000 | 18,000 | 1,500 | 80,000 | 50,000 |
| AGAP vesting date | April 1, 2020 | | | Sept. 23, 2020 | | | Dec. 18, 2021 | |
| AGAP convertibility date | April 1, 2022 | | | Sept. 23, 2022 | | | Dec. 18, 2023 | Dec. 18, 2025 |
| Exercise period to convert into ordinary shares | From April 1, 2022 to June 30, 2027 | | | From Sept. 23, 2022 to Oct. 31, 2027 | | | From Dec. 18, 2023 to March 18, 2029 | From Dec. 18, 2025 to March 18, 2029 |
| Number of shares (AGAP) vested as at Dec. 31, 2020 | 2,640 | 2,640 | 1,320 | 1,800 | 1,800 | 150 | 0 | 0 |
| Cumulative number of shares (AGAP) expired or canceled | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cumulative number of shares (AGAP) that have become convertible as at Dec. 31, 2020 | | | | | | | | |
| % achievement of performance conditions on the convertibility date | | | | | | | | |
| Number of ordinary shares to which the convertible AGAP give right | | | | | | | | |
| Number of ordinary shares actually issued at December 31, 2020 | | | | | | | | |
| Number of ordinary shares yet to be issued at December 31, 2020* | 26,400 | 26,400 | 13,200 | 18,000 | 18,000 | 1,500 | 80,000 | 50,000 |

* For the AGAP not yet converted at December 31, 2020, assuming that the relevant performance conditions are 100% achieved.

Table 10 ter: Free share awards to the top ten employees who are not corporate officers, and shares that vested to these beneficiaries

| Free shares awarded to the top ten employees who are not corporate officers, and shares that vested to these beneficiaries | Total number of shares (AGAP) awarded/shares (AGAP) vested | of which AGAP-2020-01 | of which AGAP-2020-02 | of which AGAP-2019-01 | of which AGAP-2019-02 | of which AGAP-2019-03 | of which AGAP-2018-03 |
|---|---|---|---|---|---|---|---|
| Free shares (AGAP)* awarded during the year by the issuer to the top ten employees having been granted the highest number of shares (comprehensive information) | 1,675 *** | 1,275 | 400 | | | | |
| Free shares (AGAP)** on the issuer that vested during the year, for the top ten employees with the highest number of shares vested (comprehensive information) | 7,845 **** | | | 2,820 | 2,820 | 1,835 | 370 |

* See sections 5.2.5 and 5.4.3 for the characteristics and performance conditions attached to the AGAP shares.
** AGAP preference shares that vested during the financial year. These AGAP will be convertible into ordinary shares during the exercise period depending on the achievement of performance criteria (see sections 5.2.5 and 5.4.3).
*** I.e., a maximum of 167,500 ordinary shares assuming all performance conditions are achieved.
**** I.e., a maximum of 111,750 ordinary shares assuming all performance conditions are achieved.

Table 11: Clarifications regarding the terms of compensation and other benefits awarded to executive corporate officers

The directors and the Chief Executive Officer do not enjoy any particular retirement benefits, compensation for loss of office, or non-compete indemnities.

| Executive corporate officer | Employment contract | | Supplementary pension plan | | Allowances or benefits due or likely to be due upon loss of office or change in role | | Non-compete indemnities | |
|---|---|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| Jean-Pierre Garnier, Chairman of the Board | X* | | | X | | X | | X |
| Start date of office | | | | | | | | Dec. 3, 2018 |
| End date of office | | | | At the close of the Annual Shareholders' Meeting held to approve the financial statements for the year ending December 31, 2021 | | | | |
| Stéphane Piat, Chief Executive Officer | | X | | X | | X | | X |
| Start date of office | | | | | | | | April 27, 2017 |
| End date of office | | | | At the close of the Annual Shareholders' Meeting held to approve the financial statements for the year ending December 31, 2022 | | | | |

* Employment contract as US Business Development Manager since December 3, 2018. Jean-Pierre Garnier receives fixed compensation but no variable compensation, Directors' fees or other benefits. His fixed compensation was not increased in either 2019 or 2020.

Table 12: Share warrants (BSA), company founder share warrants (BCE) and stock options awarded by the Company to the corporate officers, still valid but not exercised at December 31, 2020

| Holder/Number of shares* | BSA-2017 - Board members | Stock options - 2018 | Stock options - 2019 | BSA-2019 - Consultant |
|---|---|---|---|---|
| Jean-Pierre Garnier Chairman of the Board of Directors since December 3, 2018 | - | 46,000 | 46,000 | - |
| Jean-Luc Lemercier Director | 6,000 | - | - | - |
| Michael Mack Director | 6,000 | - | - | - |
| André Muller Director since March 30, 2020 | - | - | - | 6,000 |

* See section 5.2.5 for details of the conditions attached to these BSA share warrants and stock options.

On June 24, 2019, André Muller, director of the Company since March 30, 2020, was awarded 6,000 BSA share warrants for his services as consultant (see section 5.2.5 – Table "BSA-2019-Consultant").

## 4.5.2 BOARD OF DIRECTORS COMPENSATION POLICY

On December 2, 2020, the Board of Directors determined the compensation policy for Board members in respect of their directorship, applicable as of January 1, 2021:

- For independent directors: €8,000 per meeting attended whether in person or remotely, plus €4,000 per meeting for directors based in the United States to compensate for travel time in the case of meetings attended in person;
- For other directors: €2,000 per meeting attended whether in person or remotely.

However, the Chairman of the Board and the Chief Executive Officer will not receive any compensation in respect of their directorship.

Members of the Audit Committee and the Compensation Committee will each receive, in addition to the above amounts:

- €4,000 per year for independent directors;
- €1,000 per year for other directors.

However, the Chairman of the Board and the Chief Executive Officer will not receive any compensation in respect of their Committee membership.

Should new independent directors be appointed, they will each receive 6,000 BSA share warrants when they take up office, which are exercisable in tranches of one third per year over three years.

## 4.5.3 AMOUNTS PROVISIONED OR RECOGNIZED BY THE COMPANY FOR THE PAYMENT OF PENSIONS, RETIREMENT OR OTHER BENEFITS FOR EXECUTIVES AND DIRECTORS

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

In application of the reference method 1 in ANC recommendation 2013-02, a provision for retirement obligations has been booked as at December 31, 2020.

See note 3.2.2.6 to the financial statements in section 3 of this document.

The total amount of the provision for executives stood at €33,651 at the end of the 2020 reporting period.

## 4.5.4 STATEMENT ON SERVICE CONTRACTS

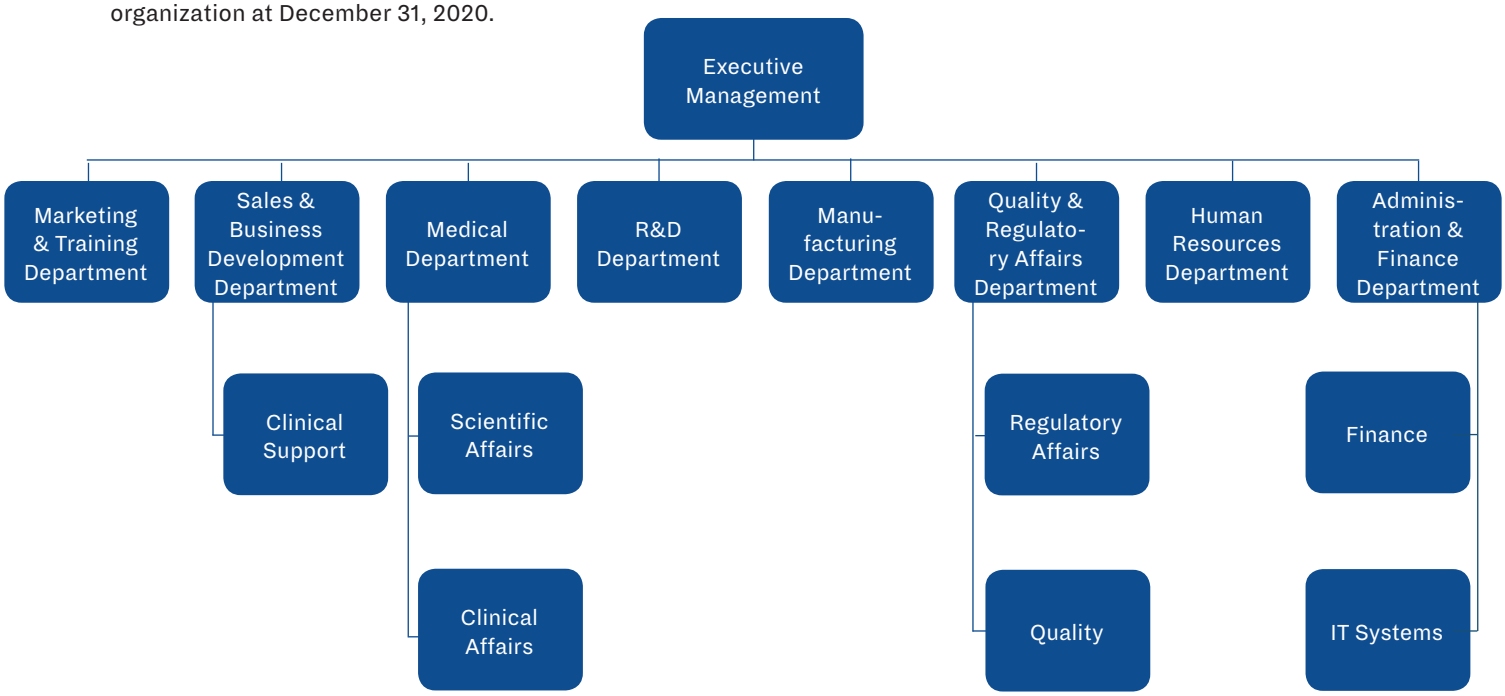
There are no service contracts binding the members of the Board of Directors or management of the Company and providing for the granting of benefits under such contracts, with the exception of those mentioned in section 5.6 “Related-party agreements”.

# 4.6 EMPLOYEES AND ORGANIZATION

## 4.6.1 HUMAN RESOURCES

### FUNCTIONAL ORGANIZATIONAL CHART

The chart below presents the Company's functional organization at December 31, 2020.




### NUMBER AND BREAKDOWN OF EMPLOYEES

At December 31, 2020, the Company's workforce amounted to 130 people, including eleven temporary workers; most members of staff are employed under permanent employment contracts. The Company's workforce thus increased by 23 people in 2020.

| Headcount | Dec. 31, 2020 | Dec. 31, 2019 | Dec. 31, 2018 |
|---|---|---|---|
| Managers | 96 | 80 | 66 |
| Non-management | 23 | 23 | 21 |
| Temporary | 11 | 4 | 3 |
| TOTAL | 130 | 107 | 90 |

The Company also uses various outside service providers for specific services. At December 31, 2020, there were 61 service providers, mainly in R&D, Production and Quality.

### HUMAN RESOURCES POLICY

Human resources management is of major importance to the Company, as a qualified, highly-skilled workforce is essential to its business.

The headcount at December 31, 2020 was made up of 44 women and 86 men. The average age of salaried employees was 39. In 2020, the Company financed approximately 750 hours of training.

The Company applies the following French National Collective Agreements: "Metallurgical Industries: workers, administrative employees, technicians and supervisors" and "Metallurgical Industries: engineers and managers". It also applies the French Regional Collective Agreement "Metallurgical Industries: workers, administrative employees, technicians and supervisors in the Paris Region". There are no company agreements other than the internal rules.

Standard employment contracts do not contain clauses relating to contract termination or to non-compete and non-solicitation (staff and/or customers) requirements.

All Company employees benefit, in addition to their basic salary, from a potential annual bonus subject to achieving quantitative and qualitative targets set in advance. The amount of this bonus is limited to a percentage of the gross annual salary.

Working times at the Company are 35 hours per week for non-managers and 218 days per year for non-executive managers.

## 4.6.2 INTERESTS AND STOCK OPTIONS HELD BY MEMBERS OF THE MANAGEMENT AND SUPERVISORY BODIES AND BY EMPLOYEES

The history of stock option and share warrant awards to the various corporate officers of the Company, as well as the options and warrants that they exercised in 2020, are detailed in section 4.5.1.

The history of free share (preference shares subject to performance conditions) awards to the various corporate officers, as well as the free shares that vested in 2020, are detailed in section 4.5.1.

At December 31, 2020, to the knowledge of the Company, Stéphane Piat (Chief Executive Officer and director) held 58,070 Company shares (i.e., 0.45% of the share capital). The other current executive directors of Carmat do not, to the Company's knowledge, hold any Carmat shares.

Certain employees of the Company are beneficiaries of stock options, share warrants (BSA and BSPCE) and free shares (preference shares subject to performance conditions), detailed in section 5.5.1.

Table 9 in section 4.5.1 specifies the number of stock options granted to the top ten employees who are not corporate officers, and the options exercised by these beneficiaries during the 2020 financial year.

Table 10 ter in section 4.5.1 specifies the number of free shares (subject to performance conditions) awarded to the top ten employees who are not corporate officers, and the free shares that vested to them during the 2020 financial year.

At December 31, 2020, to the Company's knowledge, Carmat employees held 98,048 Company shares (i.e., 0.76% of the share capital).

## 4.6.3 STATUTORY AND DISCRETIONARY PROFIT SHARING

As at the date of this Universal Registration Document, the Company had not set up any statutory or discretionary profit-sharing plans.

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# 5

# INFORMATION ABOUT THE COMPANY AND THE SHARE CAPITAL

# 5.1 LEGAL STRUCTURE

## 5.1.1 REGISTERED NAME

The Company's registered name is: "Carmat".

## 5.1.2 PLACE AND NUMBER OF REGISTRATION

The Company is registered in the Versailles Trade and Companies Register under number 504 937 905.

Its LEI (Legal Entity Identifier) number is 96 95 0 0 ARXAC M0P0 KH333.

## 5.1.3 DATE OF INCORPORATION AND TERM

The Company was incorporated on June 25, 2008 and registered on June 30, 2008 for a term of 99 years, unless said term is extended or the Company is wound up in advance.

## 5.1.4 REGISTERED OFFICE, LEGAL FORM AND APPLICABLE LAW

The Company's registered office is located at 36, avenue de l'Europe – Immeuble l'Etendard-Energy III – 78140 Vélizy-Villacoublay (phone number: +33 1 39 45 64 50). The Company is a French joint-stock corporation (société anonyme) with a Board of Directors. It is governed by French law, especially the provisions of Book II of the French Commercial Code (*Code de commerce*).

## 5.1.5 ORGANIZATION OF THE GROUP

The Company is not part of a group.

## 5.1.6 SUBSIDIARIES AND INVESTMENTS

The Company has no subsidiaries or investments.

# 5.2 SHARE CAPITAL

## 5.2.1 VALUE OF THE SHARE CAPITAL AND EQUITY

Share capital

As at December 31, 2020, the fully paid-up share capital amounted to €520,499.36, divided into 13,012,484 shares with a par value of €0.04 each, including:
- 12,980,789 ordinary shares,
- 2,200 preference shares of class 2017-03,
- 580 preference shares of class 2018-01,
- 10,350 preference shares of class 2018-02,
- 740 preference shares of class 2018-03,
- 7,260 preference shares of class 2019-01,
- 7,260 preference shares of class 2019-02,
- 3,305 preference shares of class 2019-03.

The Shareholders' Meeting of April 27, 2017 decided to add three classes of preference shares convertible into ordinary shares and governed by Articles L.228-11 *et seq*. of

the French Commercial Code to Article 12.2 of the Company's Articles of Association, respectively named "AGAP 2017-01", "AGAP 2017-02" and "AGAP 2017-03" (hereinafter together referred to as the "2017 Preference Shares").

The Shareholders' Meeting of April 5, 2018 then decided to add three new classes of preference shares convertible into ordinary shares to Article 12.2 of the Company's Articles of Association, respectively named "AGAP 2018-01", "AGAP 2018-02" and "AGAP 2018-03" (hereinafter together referred to as the "2018 Preference Shares").

Similarly, the Shareholders' Meeting of March 28, 2019 decided to add three new classes of preference shares to Article 12.2 of the Company's Articles of Association, respectively called "AGAP 2019-01", "AGAP 2019-02" and "AGAP 2019-03" (hereinafter together referred to as the "2019 Preference Shares").

Lastly, the Shareholders' Meeting of March 30, 2020 decided to add two new classes of preference shares to Article 12.2 of the Company's Articles of Association, respectively called "AGAP 2020-01" and "AGAP 2020-02" (hereinafter together referred to as the "2020 Preference Shares").

The 2017, 2018, 2019 and 2020 Preference Shares will also be convertible into Ordinary Shares subject to vesting and lock-up periods and to performance criteria, as described in section 5.2.6 of this document.

The awards of the 2017, 2018, 2019 and 2020 Preference Shares are detailed in section 4.5 of this document.

Equity

At December 31, 2020, equity amounted to a negative €6,688,308 and represent less than half the share capital.

## 5.2.2 SECURITIES NOT REPRESENTING CAPITAL

As at the date of this Universal Registration Document, there were no securities not representing capital.

## 5.2.3 PLEDGES, GUARANTEES AND COLLATERAL

As at the date of this Universal Registration Document, and to the best of the Company's knowledge, no shares have been pledged or used as guarantee or collateral.

## 5.2.4 ACQUISITION BY THE COMPANY OF ITS OWN SHARES

At December 31, 2020, the Company held 4,773 treasury shares, representing 0.037% of its share capital. The carrying amount of these shares was €135,075.90 at December 31, 2020.

The Combined Shareholders' Meeting of March 30, 2020 authorized the Board of Directors to implement a share buyback program for a period of 18 months from the date of the meeting, pursuant to the provisions of Article L.225-209 of the French Commercial Code and in compliance with the General Regulation of the French Financial Markets Authority (Autorité des marchés financiers – AMF).

5.2.4.1: Characteristics of the authorization

The main terms of this authorization are the following:

Number of shares that may be purchased: 10% of the share capital at the date of the buyback. When shares are acquired in order to promote trading in and the liquidity of the shares, the number of shares taken into account to determine the above-mentioned 10% limit corresponds to the number of shares purchased, less the number of shares sold during the period of the authorization.

Objectives of the share buyback program

- To ensure the liquidity of the shares of the Company under a liquidity agreement with an investment services provider that complies with a code of ethics recognized by the AMF.
- To honor obligations under stock purchase option programs, bonus share allocations, employee savings plans or other share allocations to employees and executives of the Company or related companies.
- To deliver shares upon exercise of the rights attached to securities giving access to the share capital.
- To hold shares in treasury for subsequent delivery as payment or exchange for external growth transactions.
- To cancel all or some of the shares bought back.
- Or more generally, to carry out transactions for any purposes subsequently authorized by law or to implement any market practices subsequently authorized by the market authorities. In such event, the Company will inform the shareholders in a press release.

Maximum purchase price: €240, excluding fees and commissions and any adjustments made in order to account for corporate actions.

It is specified that the number of shares acquired by the Company for the purpose of being held in treasury for subsequent delivery as payment or exchange as part of a merger, demerger or contribution may not exceed 5% of the share capital.

Maximum amount of funds that may be allocated to the share buyback program: €5,000,000.

The shares bought back may be canceled up to a limit of 10% of the share capital per 24-month period.

5.2.4.2: Liquidity agreement entered into with Gilbert Dupont

The liquidity agreement entered into for a period of 12 months, renewable each year by tacit agreement, covers the Company's shares listed on the Euronext Growth market in Paris. Upon the signing of the liquidity agreement, €123,414.37 and 3,160 Company shares were allocated to the liquidity account.

5.2.4.3: Employee share allocations

In the year ended December 31, 2020, the Company did not buy back any of its own shares with a view to allocating them to employees under a stock option plan, free share allocation plan, employee savings plan or other share allocations to employees and executives of the Company or related companies.

5.2.4.4: Overview of share buybacks

The share buyback program authorized by the Combined Shareholders' Meeting of March 30, 2020 was used exclusively for the liquidity agreement entered into with Gilbert Dupont.

At December 31, 2020, the resources in the liquidity account set up for this agreement represented €47,878.22 and 4,773 Company shares, i.e., 0.037% of the current share capital.

An overview of share buybacks between December 31, 2019 and December 31, 2020 can be found in section 5.5.2 of this document.

## 5.2.5 OTHER SECURITIES GIVING ACCESS TO THE SHARE CAPITAL

At December 31, 2020, the exercise or conversion of all the securities giving access to the share capital would result in the issuance of 1,032,285 shares of the Company (of which 10,000 in respect of the Kepler-Cheuvreux share warrants and 1,022,285 in respect of incentive tools), representing 7.93% of the current share capital (7.86% taking into account only the incentive tools) and 7.35% of the share capital after issuance of these new shares (7.28% taking into account only the incentive tools) .

Thus, a shareholder holding 1% of the current share capital would subsequently hold 0.926% if all the securities were exercised and 0.927% if only the incentive tools were exercised.

| Type of instrument | Number of new shares that may be created (as at December 31, 2020) |
|---|---|
| Incentive instruments for Management, Consultants and Board members | |
| - BCE-2009-2 | 0 |
| - BCE-2012-1 | 7,500 |
| - BCE-2012-2 | 6,700 |
| - BSA-2009-1 | 0 |
| - BSA-2017 - Board members | 12,000 |
| - BSA-2018 - Consultant | 10,000 |
| - BSA-2019 - Consultant | 6,000 |
| - Stock options - 2018 | 46,000 |
| - Stock options - 2019 | 46,000 |
| - Preference shares - 2017 | 109,080 |
| - Preference shares - 2018 | 289,830 |
| - Preference shares - 2019 | 175,175 |
| - Preference shares - 2020 | 314,000 |
| Total incentive instruments | 1,022,285 |
| Financing tool | |
| - BSA Kepler Cheuvreux Tranches 1 & 2 | 10,000 |
| Total financing instruments | 10,000 |

The tables below present all the securities giving access to the issued share capital of the Company that have been granted and remain in effect as at December 31, 2020 and would result in the subscription of 1,032,285 new ordinary shares.

## COMPANY FOUNDER SHARE WARRANTS (BCE)

| Security | BCE-2009-2 |
|---|---|
| Number of BCE warrants issued and allocated | 7,566* |
| Number of BCE warrants expired | 3,091* |
| Number of BCE warrants exercised | 4,475* |
| Balance of BCE warrants to be exercised | 0 |
| Date of the Shareholders' Meeting | July 8, 2009 |
| Date of the Board meeting | July 8, 2009 |
| Exercise price per new share subscribed | €8 |
| BCE warrant expiration date | Ten years from the date of the allocation of the BCE warrants |
| Ratio | One BCE-2009-2 warrant for 25 new Carmat shares |
| Exercise conditions | - 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;<br>- 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;<br>- 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;<br>- 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;<br>- 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;<br>- 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;<br>- 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 Executive Management and approved by the Board of Directors, subject to the actual and continued presence of the beneficiary within the Company at that date. |
| Number of new shares that may be subscribed | 0 |

* After adjustments resulting from the increase in capital with pre-emptive subscription rights performed in August 2011.

| Security | BCE-2012-1 |
|---|---|
| Number of BCE warrants issued and allocated | 56,500 |
| Number of BCE warrants expired | 49,000 |
| Number of BCE warrants exercised | 0 |
| Balance of BCE warrants to be exercised | 7,500 |
| Date of the Shareholders' Meeting | April 26, 2012 |
| Date of the Board meeting | June 27, 2012 |
| Exercise price per new share subscribed | €108.483 |
| BCE warrant expiration date | Ten years from the date of the allocation of the BCE warrants |
| Ratio | One BCE-2012-1 warrant for 1 new Carmat share |
| Exercise conditions | - 50% of BCE-2012-1 warrants may be exercised on the basis of monthly periods in tranches of 1/48th 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;<br>- 16.25% of the BCE-2012-1 warrants may be exercised after the successful outcome of the pivotal clinical trials of the Carmat total artificial heart (report from the scientific advisory committee), subject to his/her actual and continued presence within the Company at that date;<br>- 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;<br>- 17.5% of the BCE-2012-1 warrants may be exercised after completion at December 31 of the first year of marketing of the Carmat total artificial heart, confirmed by the Board of Directors, in accordance with the expectations in terms of revenue and gross profit margin set out in the business plan drawn up by Executive Management and approved by the Board of Directors, subject to the actual and continued presence of the beneficiary within the Company at that date. |
| Number of new shares that may be subscribed | 7,500 |

| Security | BCE-2012-2 |
|---|---|
| Number of BCE warrants issued and allocated | 6,700 |
| Number of BCE warrants expired | 0 |
| Number of BCE warrants exercised | 0 |
| Balance of BCE warrants to be exercised | 6,700 |
| Date of the Shareholders' Meeting | April 26, 2012 |
| Date of the Board meeting | November 8, 2012 |
| Exercise price per new share subscribed | €122.003 |
| BCE warrant expiration date | Ten years from the date of the allocation of the BCE warrants |
| Ratio | One BCE-2012-2 warrant for 1 new Carmat share |
| Exercise conditions | - 50% of BCE-2012-2 warrants may be exercised on the basis of monthly periods in tranches of 1/48th 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;<br>- 16.25% of the BCE-2012-2 warrants may be exercised after the successful outcome of the pivotal clinical trials of the Carmat total artificial heart (report from the scientific advisory committee), subject to his/her actual and continued presence within the Company at that date;<br>- 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;<br>- 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 Executive Management and approved by the Board of Directors, subject to the actual and continued presence of the beneficiary within the Company at that date. |
| Number of new shares that may be subscribed | 6,700 |

## SHARE WARRANTS (BSA)

| Security | BSA-2009-1 |
|---|---|
| Number of BSA warrants issued and allocated | 3,096* |
| Number of BSA warrants expired | 556* |
| Number of BSA warrants exercised | 2,540* |
| Balance of BSA warrants to be exercised | 0 |
| Date of the Shareholders' Meeting | July 8, 2009 |
| Date of the Board meeting | July 8, 2009 |
| Exercise price per new share subscribed | €8 |
| BSA warrant expiration date | Ten years from the date of allocation of the BSA warrants |
| Ratio | One BSA-2009-1 warrant for 25 new Carmat shares |
| Exercise conditions | - 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;<br>- 75% of BSA-2009-1 warrants may be exercised on the basis of monthly periods in tranches of 1/36$^{th}$ from the date of the first anniversary of the beneficiary joining the Company, subject to his/her actual and continued presence within the Company at that date.<br>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.<br>As a result of the success of the initial listing of the Company on the Euronext Paris Alternext market, according to the assessment of the meeting of the Company's Board of Directors on September 8, 2010, 20% of the BSA-2009-1 warrants that were not exercisable as at the date of the initial listing may be exercised early. |
| Number of new shares that may be subscribed | 0 |

* After adjustments resulting from the increase in capital with pre-emptive subscription rights performed in August 2011.

The Board of Directors meeting of December 3, 2018, acting on the departure of Jean Claude Cadudal, modified the conditions of exercise of the BSA-2009-1, which remained exercisable until July 8, 2019, even after the departure of its holder.

| Security | BSA Kepler Cheuvreux - Tranches 1 & 2 (all exercisable by Kepler Cheuvreux) |
|---|---|
| Number of BSA warrants issued and allocated | 400,000 |
| Number of BSA warrants expired | 0 |
| Number of BSA warrants exercised | 390,000 |
| Balance of BSA warrants to be exercised | 10,000 |
| Date of the Shareholders' Meeting | April 5, 2018 |
| Date of CEO's decision | Sept. 27, 2018 |
| Exercise price per new share subscribed | 94% of the average volume-weighted trading price |
| BSA warrant expiration date | September 27, 2021 |
| Ratio | One Kepler BSA warrant for one new Carmat share |
| Number of new shares that may be subscribed | 261,000 |

The Company has put in place a new flexible equity financing arrangement with Kepler Cheuvreux, as the previous one expired in July 2018. Signed in September 2018, this new framework agreement comprises up to two consecutive 12-month tranches, namely a first €12 million tranche beginning on the date the agreement is signed followed by a second tranche making the total amount (Tranche 1 + Tranche 2) €25 million.

Under this framework, Kepler Cheuvreux has made a firm and definitive commitment to purchase new shares under Tranches 1 and 2 for €25 million, at times and intervals of its own choosing, no later than September 27, 2021, subject to compliance with the terms agreed upon by the parties. The Company may terminate the agreement at any time. Kepler Cheuvreux does not intend to retain the shares subscribed under these arrangements, and will subsequently sell them to investors or on the open market.

| Security | BSA-2017 - Board members |
|---|---|
| Number of BSA warrants issued and allocated for free | 12,000 |
| Number of BSA warrants expired | 0 |
| Number of BSA warrants exercised | 0 |
| Balance of BSA warrants to be exercised | 12,000 |
| Date of the Shareholders' Meeting | April 27, 2017 |
| Date of the Board meeting | May 15, 2017 |
| Exercise price per new share subscribed | €30.10 |
| BSA warrant expiration date | May 15, 2027 |
| Ratio | One BSA - Board members warrant for one new Carmat share |
| Exercise conditions | - up to 1,500 warrants will be exercisable as from January 2, 2018;<br>- up to 94 additional warrants will be exercisable from each month starting on January 2, 2018, i.e., from February 2, 2018 for the first tranche, it being specified that the last tranche will be limited to 82 warrants. |
| Number of new shares that may be subscribed | 12,000 |

| Security | BSA-2018 - Consultant |
|---|---|
| Number of BSA issued and subscribed at €3.14/BSA | 10,000 |
| Number of BSA warrants expired | 0 |
| Number of BSA warrants exercised | 0 |
| Balance of BSA warrants to be exercised | 10,000 |
| Date of the Shareholders' Meeting | April 5, 2018 |
| Date of the Board meeting | June 11, 2018 |
| Exercise price per new share subscribed | €20.93 |
| BSA warrant expiration date | June 11, 2028 |
| Ratio | One BSA - Consultant warrant for one new Carmat share |
| Exercise conditions | - up to 2,500 warrants will be exercisable after each 12-month period (i.e., until June 12, 2019 for the first tranche);<br>- June 11, 2028, at the latest. |
| Number of new shares that may be subscribed | 10,000 |

At its meeting of December 2, 2020, the Board of Directors revised the terms of exercise of the BSA-2018-Consultant, authorizing the beneficiary to exercise all of his/her BSA warrants notwithstanding the termination of his/her consulting contract, provided that he/she joined Carmat as an employee no later than April 1, 2021. Otherwise, the revised terms of the BSA warrants would become null and void.

| Security | BSA-2019 - Consultant |
|---|---|
| Number of BSA issued and subscribed at €3.03/BSA | 6,000 |
| Number of BSA warrants expired | 0 |
| Number of BSA warrants exercised | 0 |
| Balance of BSA warrants to be exercised | 6,000 |
| Date of the Shareholders' Meeting | March 28, 2019 |
| Date of the Board meeting | June 24, 2019 |
| Exercise price per new share subscribed | €20.21 |
| BSA warrant expiration date | June 24, 2029 |
| Ratio | One BSA - Consultant warrant for one new Carmat share |
| Exercise conditions | - up to 166 warrants per full calendar month that has elapsed from the first day of the calendar month following the decision of the Board of Directors;<br>- June 24, 2029, at the latest. |
| Number of new shares that may be subscribed | 6,000 |

## STOCK OPTIONS

| Security | Stock options - 2018 |
|---|---|
| Number of options issued and allocated | 46,000 |
| Number of options expired | - |
| Number of options exercised | - |
| Balance of options to be exercised | 46,000 |
| Date of the Shareholders' Meeting | April 5, 2018 |
| Date of the Board meeting | Dec. 3, 2018 |
| Exercise price per new share subscribed | €20.35 |
| Option expiration date | Ten years from the date of allocation of the options |
| Ratio | One stock option for one new Carmat share |
| Exercise conditions | - 50% of the options may be exercised in increments of 1/36th each month elapsed from January 1, 2019, and in any event no later than 10 years after their date of allocation to the beneficiary;<br>- 50% of the options are exercisable when the Company succeeds in successfully raising additional financing (excluding Equity Line financing and EIB type loans) for an amount of at least €100 million between the date of allocation and December 31, 2021, and in any event no later than 10 years after their date of allocation to the beneficiary. |
| Number of new shares that may be subscribed | 46,000 |

At its meeting of June 22, 2020, the Board of Directors revised the terms of the 2018 stock options to postpone the deadline for achieving the performance condition (additional funding of at least €100 million) from December 31, 2020 to December 31, 2021.

| Security | Stock options - 2019 |
|---|---|
| Number of options issued and allocated | 46,000 |
| Number of options expired | - |
| Number of options exercised | - |
| Balance of options to be exercised | 46,000 |
| Date of the Shareholders' Meeting | March 28, 2019 |
| Date of the Board meeting | April 1, 2019 |
| Exercise price per new share subscribed | €22.70 |
| Option expiration date | Ten years from the date of allocation of the options |
| Ratio | One stock option for one new Carmat share |
| Exercise conditions | - the options can be exercised in increments of 1/36th each month elapsed from January 1, 2019;<br>- March 31, 2029, at the latest. |
| Number of new shares that may be subscribed | 46,000 |

### PREFERENCE SHARES (FREE PREFERENCE SHARES SUBJECT TO PERFORMANCE CRITERIA OVER A 3 TO 5-YEAR PERIOD)

The AGAP (AGAP 2017, AGAP 2018, AGAP 2019 and AGAP 2020) are preference shares subject to performance conditions over a period of 3 to 5 years. The general mechanism of the AGAP is as follows:

- On date T, the beneficiary is awarded a number of AGAP subject to performance conditions. Each AGAP is convertible into a maximum number of ordinary shares (e.g., 100).
- On date T+12 months, the AGAP vest in the beneficiary provided that the beneficiary is still with the Company on that date. This is known as the vesting date. If the beneficiary is no longer with the Company on the vesting date, the AGAP will lapse.
- On date T+36 months (or T+60 months for the AGAP 2020-02), which is the convertibility date, the AGAP become convertible into a number of ordinary shares based on the degree of achievement of the preset performance conditions. The degree of achievement is determined by the Board of Directors. If all the conditions are met, the AGAP will be convertible into the maximum number of shares (in our example: 100). If none of the conditions are met, the AGAP will not be convertible into ordinary shares. If some conditions are met but not others, the AGAP will be convertible into a number of ordinary shares based on the degree of achievement of the objectives (in our example, if the degree of achievement is 60%, then each AGAP may be converted into 60 ordinary shares).
- The AGAP may be converted into ordinary shares at the beneficiary's request during the convertibility period, i.e., for about five years (three years for the AGAP 2020-02) after their convertibility date.

For more information on the rights attached to preference shares issued by the Company, see Article 12.2 of the Articles of Association, reproduced in section 5.4.3 of this document.

AGAP 2017:

| AGAP 2017 (free preference shares subject to performance conditions) | Tranche 1 | Tranche 2 | Tranche 3 |
|---|---|---|---|
| Number of preference shares awarded | 320 | 2,000 | 3,490 |
| Number of preference shares lapsed | 0 | 0 | 0 |
| Number of preference shares vested | 320 | 2,000 | 3,490 |
| - of which number of preference shares already converted into ordinary shares*** | 320 | 2,000 | 1,290 |
| - of which number of preference shares yet to be converted into ordinary shares | 0 | 0 | 2,020 |
| - of which number of preference shares not convertible into ordinary shares | 0 | 0 | 180 |
| Number of preference shares | 0 | 0 | 0 |
| Maximum number of ordinary shares that may be created as at December 31, 2020* | 0 | 0 | 111,100 |
| Maximum net** number of shares that may be created as at December 31, 2020 | 0 | 0 | 109,080 |

* Based on the applicable conversion ratios and performance conditions described in the table below.
** Maximum number of ordinary shares that may be created, net of the number of preference shares canceled upon their conversion
*** During 2020, 320 AGAP 2017-01 were converted into 32,000 ordinary shares, 2,000 AGAP 2017-02 were converted into 40,000 ordinary shares and 1,290 AGAP 2017-03 were converted into 65,250 ordinary shares, i.e., a total of 3,610 AGAP 2017 converted into 137,250 ordinary shares.

| AGAP 2017<br><br>Preference share tranches | Performance criteria | Maximum conversion ratio applicable for each performance criteria |
|---|---|---|
| Tranche 1 | Definition of the Company's industrial development plan | 100 |
| Tranche 2 | Successful implantation of the bioprosthesis evaluated on 10 patients in total worldwide | 20 |
| Tranche 3 | Filing of the clinical module of the bioprosthesis' CE marking | 15 |
| | Bioprosthesis CE marking | 20 |
| | Obtaining additional financing for the Company for an aggregate amount, between the allocation date and the convertibility date, of €100 million | 25 |
| | Implementation of a production process meeting certain criteria | 15 |
| | Effective commercialization of bioprostheses at 15 European implantation centers | 10 |
| | Successful implantation of the bioprosthesis evaluated on 10 patients in the United States | 10 |
| | Successful implantation of the bioprosthesis evaluated on 100 patients in total worldwide | 10 |
| | Increase in the ordinary share price according to specific criteria | 10 |
| | Maximum number of ordinary shares that may be created, regardless of the number of performance criteria achieved for Tranche 3 | 100 |

In 2020, the Board of Directors noted that, at the AGAP 2017 convertibility date:

- for the AGAP 2017-01, the sole performance condition had been achieved and each AGAP 2017-01 may therefore be converted into 100 ordinary shares;
- for the AGAP 2017-02, the sole performance condition had been achieved and each AGAP 2017-02 may therefore be converted into 20 ordinary shares;
- for the AGAP 2017-03, the performance conditions had been 55% achieved and each AGAP 2017-03 may therefore be converted into 55 ordinary shares.

AGAP 2018:

| AGAP 2018 (free preference shares subject to performance conditions) | Tranche 1 | Tranche 2 | Tranche 3 |
|---|---|---|---|
| Number of preference shares awarded | 580 | 11,500 | 740 |
| Number of preference shares lapsed | 0 | 200 | 0 |
| Number of preference shares vested | 580 | 10,350 | 740 |
| - of which number of preference shares already converted into ordinary shares | 0 | 0 | 0 |
| - of which number of preference shares yet to be converted into ordinary shares | 580 | 10,350 | 740 |
| - of which number of preference shares not convertible into ordinary shares | 0 | 0 | 0 |
| Number of preference shares not yet vested | 0 | 950 | 0 |
| Maximum number of ordinary shares that may be created as at December 31, 2020* | 58,000 | 169,500 | 74,000 |
| Maximum net** number of shares that may be created as at December 31, 2020 | 57,420 | 159,150 | 73,260 |

| AGAP 2018<br><br>Preference share tranches | Performance criteria | Maximum conversion ratio applicable for each performance criteria |
|---|---|---|
| Tranche 1 | Successful completion of "prosthesis" test benches for CE marking | 100 |
| Tranche 2 | Recruitment of 10 patients for the pivotal study for CE marking | 10 |
| | Recruitment of the 20th patient for the pivotal study to obtain the CE marking or finalization of the pivotal study for submission of the dossier to Dekra | 5 |
| | Obtaining authorization to conduct an Early Feasibility Study in the United States by December 31, 2018 | 5 |
| | Maximum number of ordinary shares that may be created, regardless of the number of performance criteria achieved for Tranche 2 | 20 |
| Tranche 3 | Filing of the clinical module of the bioprosthesis' CE marking | 15 |
| | Bioprosthesis CE marking | 20 |
| | Obtaining additional financing for the Company for an aggregate amount, between the allocation date and the convertibility date, of €38.5 million | 25 |
| | Implementation of a production process meeting certain criteria | 15 |
| | Effective commercialization of bioprostheses at 15 European implantation centers | 10 |
| | Successful implantation of the bioprosthesis evaluated on 10 patients in the United States | 10 |
| | Successful implantation of the bioprosthesis evaluated on 100 patients in total worldwide | 10 |
| | Increase in the ordinary share price according to specific criteria | 10 |
| | Maximum number of ordinary shares that may be created, regardless of the number of performance criteria achieved for Tranche 3 | 100 |

AGAP 2019:

| AGAP 2019 (free preference shares subject to performance conditions) | Tranche 1 | Tranche 2 | Tranche 3 |
|---|---|---|---|
| Number of preference shares awarded | 8,000 | 8,000 | 3,600 |
| Number of preference shares lapsed | 120 | 120 | 60 |
| Number of preference shares vested | 7,260 | 7,260 | 3,305 |
| - of which number of preference shares already converted into ordinary shares | 0 | 0 | 0 |
| - of which number of preference shares yet to be converted into ordinary shares | 7,260 | 7,260 | 3,305 |
| - of which number of preference shares not convertible into ordinary shares | 0 | 0 | 0 |
| Number of preference shares not yet vested | 620 | 620 | 235 |
| Maximum number of ordinary shares that may be created as at December 31, 2020* | 78,800 | 78,800 | 35,400 |
| Maximum net** number of shares that may be created as at December 31, 2020 | 71,540 | 71,540 | 32,095 |

* Based on the applicable conversion ratios and performance conditions described in the table below.
** Maximum number of ordinary shares that may be created, net of the number of preference shares canceled upon their conversion

| AGAP 2019 Preference share tranches | Performance criteria | Maximum conversion ratio applicable for each performance criteria |
|---|---|---|
| Tranche 1 | Success of the first patient treated in the United States under the US pivotal study following the positive conclusion of the Early Feasibility Study | 10 |
| Tranche 2 | Obtaining CE marking with sufficient inventory to support the commercial launch | 10 |
| Tranche 3 | Billing and implantation of 5 prostheses within 4 months of CE marking | 10 |

AGAP 2020:

| AGAP 2020 (free preference shares subject to performance conditions) | Tranche 1 | Tranche 2 |
|---|---|---|
| Number of preference shares awarded | 2,240 | 900 |
| Number of preference shares lapsed | 0 | 0 |
| Number of preference shares vested | 0 | 0 |
| - of which number of preference shares already converted into ordinary shares | 0 | 0 |
| - of which number of preference shares yet to be converted into ordinary shares | 0 | 0 |
| - of which number of preference shares not convertible into ordinary shares | 0 | 0 |
| Number of preference shares not yet vested | 2,240 | 900 |
| Maximum number of ordinary shares that may be created as at December 31, 2020* | 224,000 | 90,000 |
| Maximum net** number of shares that may be created as at December 31, 2020 | 224,000 | 90,000 |

* Based on the applicable conversion ratios and performance conditions described in the table below.
** Maximum number of ordinary shares that may be created, net of the number of preference shares canceled upon their conversion

| AGAP 2020 Preference share tranches | Performance criteria | Maximum conversion ratio applicable for each performance criteria |
|---|---|---|
| Tranche 1 | Actual annual production of 150 devices that have passed the quality assurance standards | 50 |
| | Annual sale of 100 devices (excluding clinical trials or "Forfait Innovation" program) | 50 |
| | Maximum number of ordinary shares that may be created, regardless of the number of performance criteria achieved for Tranche 1 | 100 |
| Tranche 2 | Obtaining PMA in the United States | 100 |

## 5.2.6 AUTHORIZED BUT UNISSUED SHARE CAPITAL

Shareholders' Meeting of March 30, 2020

Table of delegations of authority applicable following the Shareholders' Meeting of March 30, 2020:

| Resolution | Purpose of the resolution | Maximum nominal amount in euros | Terms and conditions for determining the issue price | Period of authorization and expiration |
|---|---|---|---|---|
| 11th resolution | Delegation of authority allowing the Board of Directors to increase capital immediately or in the future by issuing ordinary shares or any other securities giving access to the capital or giving right to the allocation of debt securities, with pre-emptive subscription rights | Nominal value of increases in capital: €200,000(1)<br>Nominal value of bonds and other debt securities giving access to the share capital: €120,000,000(1) | N/A | May 30, 2022 (26 months) |
| 12th resolution | Delegation of authority allowing the Board of Directors to decide on the issue of shares and/or transferable securities giving immediate or future access to the share capital or giving right to the allocation of debt securities, with removal of the pre-emptive subscription right by way of a public offer (Article L.225-136) | Nominal value of increases in capital: €200,000(1)<br>Nominal value of bonds and other debt securities giving access to the share 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%) | May 30, 2022 (26 months) |
| 13th resolution | Delegation of authority allowing the Board of Directors to decide on the issue of shares and/or transferable securities giving immediate or future access to the share capital or giving right to the allocation of debt securities, with removal of the pre-emptive subscription rights, by offering to qualified investors or to a limited circle of investors within the meaning of paragraph II of Article L.411-2 of the French Monetary and Financial Code (Article L.225-136 3°) | Nominal value of increases in capital: €200,000(1)<br>Nominal value of bonds and other debt securities giving access to the share 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%) | May 30, 2022 (26 months) |
| 14th resolution | Subject to the listing of the Company's shares on a regulated market, the authorization allowing the Board of Directors, in the event of the issue of shares or of any security giving access to capital with removal of the pre-emptive subscription right, to set the issue price at a maximum of 10% of the share capital and within the limits determined by Shareholders' Meeting | Limited to 10% of the Company's share capital (as existing on the date of the transaction) per 12-month period | At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price, less any discount (maximum 30%) | May 30, 2022 (26 months) |
| 15th resolution | Delegation of authority allowing the Board of Directors to increase the amount of each of the issues with or without pre-emptive subscription right which would be decided under resolutions 11 to 13 | Limited to 15% of the initial issue | Price identical to that of the initial issue | May 30, 2022 (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 the 11th to 18th resolutions is set at €200,000. The maximum nominal amount of debt securities which can be issued under the above delegations is set at €120,000,000.

| Resolution | Purpose of the resolution | Maximum nominal amount in euros | Terms and conditions for determining the issue price | Period of authorization and expiration |
|---|---|---|---|---|
| 16th resolution | Delegation of authority allowing the Board of Directors to increase capital immediately or in the future by issuing ordinary shares or any other securities giving access to the capital, with removal of the pre-emptive subscription right to a category of beneficiaries (Life Sciences and Technology investors) | Nominal value of increases in capital: €200,000(1)<br>Nominal value of bonds and other debt securities giving access to the share 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%) | September 30, 2021 (18 months) |
| 17th resolution | Delegation of authority allowing the Board of Directors to increase capital immediately or in the future by issuing ordinary shares or any other securities giving access to the capital, with removal of the pre-emptive subscription right to a category of beneficiaries (Strategic partners) | Nominal value of increases in capital: €200,000(1)<br>Nominal value of bonds and other debt securities giving access to the share 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%) | September 30, 2021 (18 months) |
| 18th resolution | Delegation of authority allowing the Board of Directors to decide on the issue of shares and/or securities giving immediate or future access to the capital or providing a right to a debt instrument, with removal of the pre-emptive subscription right of shareholders for the benefit of a category of beneficiaries (equity line financing plan) | Nominal value of increases in capital: €200,000(1)<br>Nominal value of bonds and other debt securities giving access to the share 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%) | September 30, 2021 (18 months) |
| 20th 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: €200,000(2) | N/A | May 30, 2022 (26 months) |

(2) Separate limit to the limit for the 11th to 18th resolutions above.

Ordinary share subscription warrants:

| Resolution | Purpose of the resolution | Maximum nominal amount in euros | Method of determining the BSA issue price | Method of determining the BSA exercise price | Period of authorization and expiration |
|---|---|---|---|---|---|
| 21st resolution | Delegation of authority allowing the Board of Directors to issue warrants dedicated to Board members (not employees or managers), persons bound by a service contract or members of Committees set up by the Board of Directors | €4,000 (corresponding to 100,000 shares)(1) | To be set by the Board of Directors<br>Issue price could be free | At least equal to the average of the prices weighted by the volumes of the last 20 trading sessions preceding the fixing of the issue price of the warrants | September 30, 2021 (18 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 the 21th and 22th resolutions is set at €4,000.

Ordinary share subscription or purchase warrants:

| Resolution | Purpose of the resolution | Maximum nominal amount in euros | Terms and conditions for determining the issue price | Period of authorization and expiration |
|---|---|---|---|---|
| 22nd resolution | Authorization granted to the Board of Directors to award options for the subscription or purchasing of shares | €4,000 (corresponding to 100,000 shares)(1) | (2) | May 30, 2023 (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 the 21st and 22nd resolutions is set at €4,000.

(2) The purchase or subscription price per share will be set by the Board on the day the option is granted, based on the following:
- for as long as the shares are admitted for trading on the Euronext Growth market, the purchase or subscription price shall be determined in accordance with the provisions of Article L.225-177 of the French Commercial Code and must be at least equal to the sales price of one share at the close of the Euronext Growth market on the day prior to the decision of the Board of Directors to allocate the options, and for purchases, the price must be no less than 80% of the average price paid by the Company for all of the shares previously purchased;
- in the event that the Company's shares are admitted for trading on a regulated market, the Board may determine the purchase or subscription price per share with reference to the sales price of one share at the close of that regulated market on the day prior to the decision of the Board to allocate the options. However, the purchase or subscription price per share may under no circumstances be less than ninety-five percent (95%) of the average sales price of one share at the close of the said market during the twenty trading days prior to the decision of the Board of Directors to allocate the options rounded down to the nearest euro, or, for stock options, to 80% of the average sales price of the Company's treasury shares, rounded down to the nearest euro.

Free allocation of preference shares:

| Resolution | Purpose of the resolution | Maximum nominal amount in euros | Acquisition period for the preference shares | Lock-up period applicable to the preference shares | Exercise period of the conversion option into ordinary shares | Period of authorization and expiration |
|---|---|---|---|---|---|---|
| 25th resolution | Delegation of authority allowing the Board of Directors to allocate free preference shares convertible into ordinary shares "AGAP 2020-01" dedicated to employees and/or corporate officers | €10,000 (corresponding to 250,000 ordinary shares) | 1 year | 2 years or less | 5 years and 3 months from the end of the lock-up period | May 30, 2023 (38 months) |
| 26th resolution | Delegation of authority allowing the Board of Directors to allocate free preference shares convertible into ordinary shares "AGAP 2020-02" dedicated to employees and/or corporate officers | €3,600 (corresponding to 90,000 ordinary shares) | 1 year | 4 years or less | 3 years and 3 months from the end of the lock-up period | May 30, 2023 (38 months) |

Performance criteria to be met in order to convert AGAP 2020-01 and AGAP 2020-02 preference shares into ordinary shares

- For AGAP 2020-01:

- actual annual production of 150 devices that have passed the quality assurance criteria;

- annual sale of 100 devices (excluding clinical trials or "Forfait Innovation" program).

- For AGAP 2020-02:

- obtaining PMA in the United States.

During 2020, the Board of Directors made use of the delegations of authority approved at the Shareholders' Meeting of March 30, 2020 and awarded the following free preference shares on December 18, 2020:

- 2,240 AGAP 2020-01,
- 900 AGAP 2020-02.

## 5.2.7 INFORMATION ABOUT THE COMPANY'S SHARE CAPITAL SUBJECT TO AN OPTION OR A CONDITIONAL OR UNCONDITIONAL AGREEMENT MAKING THEM SUBJECT TO AN OPTION

None.

## 5.2.8 TABLE OF CHANGES IN THE COMPANY'S SHARE CAPITAL

The Company was registered with the Versailles Trade and Companies Registry on June 30, 2008 with an initial share capital of €40,000.

The table below shows a summary of the changes in share capital over the last 3 years:

| Date of the operation | Transaction | Capital increase (in euros) | Share premium or contribution (in euros) | Number of shares issued or canceled | Nominal value of shares (in euros) | Cumulative number of shares | Share capital following the transaction (in euros) |
|---|---|---|---|---|---|---|---|
| February 12, 2018 | Increase in capital by cash contribution through the exercise of Kepler BSA warrants | 1,840.00 | 957,800.00 | 46,000 | 0.04 | 9,062,544 | 362,501.76 |
| April 16, 2018 | Increase in capital by cash contribution through the exercise of Kepler BSA warrants | 3,640.00 | 1,837,500.00 | 91,000 | 0.04 | 9,153,544 | 366,141.76 |
| December 3, 2018 | Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants | 3,445.00 | 1,785,240.00 | 86,125 | 0.04 | 9,239,669 | 369,586.76 |
| February 11, 2019 | Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrant/ AGAP vesting | 3,522.40 | 1,625,360.00 | 82,250 OS<br>5,810 PS | 0.04 | 9,321,919 OS<br>5,810 PS | 373,109.16 |
| April 1, 2019 | Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants | 630.00 | 329,370.00 | 15,750 OS | 0.04 | 9,337,669 OS<br>5,810 PS | 373,739.16 |

OS: Ordinary Shares PS: Preference Shares

Note that Kepler Cheuvreux does not intend to retain the shares subscribed under the share issue agreements made in January 2015 and in September 2018, and will subsequently sell them to investors or on the open market.

| Date of the operation | Transaction | Capital increase (in euros) | Share premium or contribution (in euros) | Number of shares created or canceled | Nominal value of shares (in euros) | Cumulative number of shares | Share capital following the transaction (in euros) |
|---|---|---|---|---|---|---|---|
| June 24, 2019 | Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrant/ AGAP vesting | 3,366.20 | 972,401.00 | 73,225 OS<br>10,930 PS | 0.04 | 9,410,894 OS<br>16,740 PS | 377,105.36 |
| September 18, 2019 | Increase in capital by cash contribution | 126,315.80 | 59,873,689.20 | 3,157,895 OS | 0.04 | 12,568,789 OS<br>16,740 PS | 503,421.16 |
| September 23, 2019 | Increase in capital by cash contribution through the exercise of both Kepler BSA warrants and BCE warrants | 950.00 | 329,050.00 | 23,750 OS | 0.04 | 12,592,539 OS<br>16,740 PS | 504,371.16 |
| December 2, 2019 | AGAP vesting | 14.80 | - | 370 PS | 0.04 | 12,592,539 OS<br>17,110 PS | 504,385.96 |
| April 1, 2020 | AGAP vesting | 14.80 | - | 370 PS | 0.04 | 12,592,539 OS<br>17,480 PS | 504,400.76 |
| June 22, 2020 | AGAP vesting | 424.00 | - | 10,600 PS | 0.04 | 12,592,539 OS<br>28,080 PS | 504,824.76 |
| September 7, 2020 | Conversion of AGAP | 3,081.20 | - | 78,900 OS<br>(1,870) PS | 0.04 | 12,671,439 OS<br>26,210 PS | 507,905.96 |
| December 2, 2020 | AGAP vesting and capital increase via the exercise of Kepler share warrants | 1,629.00 | 735,660.00 | 33,500 OS<br>7,225 PS | 0.04 | 12,704,939 OS<br>33,435 PS | 509,534.96 |
| December 31, 2020* | Capital increase for cash via the exercise of Kepler share warrants and conversion of AGAP | 10,964.40 | 5,170,620.00 | 275,850 OS<br>(1,740) PS | 0.04 | 12,980,789 OS<br>31,695 PS | 520,499.36 |

OS: Ordinary Shares PS: Preference shares*: transactions carried out between December 3 and 31, 2020 but not legally placed on record until 2021

Note that Kepler Cheuvreux does not intend to retain the shares subscribed under the share issue agreements made in January 2015 and in September 2018, and will subsequently sell them to investors or on the open market.

# 5.3 MAJOR SHAREHOLDERS

## 5.3.1 DISTRIBUTION OF SHARE CAPITAL AND VOTING RIGHTS

To the best of the Company's knowledge, there is no other shareholder owning more than 5% of the share capital or voting rights.

### CURRENT DISTRIBUTION OF SHARE CAPITAL AND VOTING RIGHTS

The table below shows the distribution of the share capital and voting rights (see section 5.3.2 "Voting rights" of this document, which indicates the conditions under which double voting rights may be obtained) of the Company at December 31, 2020.

| Shareholders (December 31, 2020) | Number of shares | Number of voting rights | % of capital | % of voting rights |
|---|---|---|---|---|
| Matra Défense (Airbus Group) | 1,670,640 | 2,652,040 | 12.8% | 17.8% |
| Lohas (Pierre Bastid) | 1,331,479 | 1,331,479 | 10.2% | 8.9% |
| Corely Belgium (Gaspard family) | 790,000 | 790,000 | 6.1% | 5.3% |
| Bratya (Gaspard family) | 267,000 | 267,000 | 2.1% | 1.8% |
| Santé Holding SRL (Dr. Antonino Ligresti) | 925,091 | 925,091 | 7.1% | 6.2% |
| Professor Alain Carpentier | 548,583 | 1,097,166 | 4.2% | 7.4% |
| Alain Carpentier Foundation Research Association | 115,000 | 230,000 | 0.9% | 1.5% |
| Cornovum | 458,715 | 458,715 | 3.5% | 3.1% |
| BAD 21 | 315,790 | 315,790 | 2.4% | 2.1% |
| Thérabel Group | 308,640 | 308,640 | 2.4% | 2.1% |
| Funds managed by Truffle Capital | 196,041 | 196,041 | 1.5% | 1.3% |
| Air Liquide | 76,982 | 76,982 | 0.6% | 0.5% |
| Treasury stock | 4,773 | - | 0.0% | - |
| Free float | 6,003,750 | 6,239,972 | 46.1% | 41.9% |
| Total | 13,012,484 | 14,888,916 | 100.0% | 100.0% |

Funds managed by Truffle Capital

Founded in 2001 in Paris, Truffle Capital is an acknowledged European player in the area of capital investment, investing in and developing innovative SMEs and building technological leaders in the areas of Life Sciences, Information Technology and Energy.

Airbus Group

Airbus Group (formerly EADS), born out of a merger in July 2000 between DaimlerChrysler Aerospace AG, Aérospatiale-Matra and Construcciones Aeronáuticas SA, is a world leader in the aeronautic, space and defense and associated services sectors. Airbus Group holds shares in Carmat through its wholly-owned subsidiary, Matra Défense.

Professor Carpentier

Professor emeritus at the Pierre and Marie Curie University (University of Paris VI) and Professor at the Mount Sinai School of Medicine in New York, he is the founder and director of the Biosurgical Research Laboratory at the Scientific Research Association of the Alain Carpentier Foundation.

Winner of the 1998 Grand Prix from the Foundation for Medical Research, and Vice-President of the French Academy of Sciences, he also received the prestigious Albert Lasker Award for Clinical Medical Research in 2007 in recognition of his two main contributions to the field - the invention of valve bioprostheses (Carpentier-Edwards valves) and the development of techniques for plastic and reconstructive surgery of heart valves, which benefit several hundred thousand patients worldwide each year.

Scientific Research Association of the Alain Carpentier Foundation (ARSFAC)

Set up in December 2007 by Professor Alain Carpentier, the purpose of the Scientific Research Association of the Alain Carpentier Foundation is to finance medical research projects, in particular in the surgical, cardiovascular and neurological areas.

Lohas

This entity is a family office of Pierre Bastid, having acquired the existing shares originally subscribed by ZAKA (another family office of Pierre Bastid) as part of the Company's private placement carried out in 2016, from Babalia (another family office of Pierre Bastid) in July 2018.

Santé Holdings SRL

This entity is the family office of Dr. Antonino Ligresti, who was notably Chairman of Générale de Santé.

CorNovum

This entity is an investment vehicle equally owned by the French State and by BPI France.

Thérabel Group

The Thérabel Group is a pharmaceutical group operating both in the fields of prescription drugs and over-the counter (OTC) drugs.

Corely Belgium and Bratya

These two entities are investment holding companies of the Gaspard family, owner of the Lyreco group.

Bad 21

This entity is the investment holding company of Pierre-Edouard Stérin, founder of Smartbox.

### CHANGE IN THE DISTRIBUTION OF SHARE CAPITAL AND VOTING RIGHTS

The table below shows the distribution of share capital and voting rights in the Company as at December 31, 2019, December 31, 2018 and as at December 31, 2017, insofar as known to the Company.

As a reminder, in December 2017, the Company carried out a capital increase operation through a public offering that benefited from the support of historic shareholders, in particular the family offices of Pierre Bastid (Babalia) and Dr. Ligresti (Santé Holdings SRL).

The Company also announced on September 19, 2019 the success of a private placement of €60 million to investors specializing in the life sciences and medical technologies sectors, and to strategic partners. In particular, some historic shareholders (Matra Defense of the Airbus Group, Lohas, Santé Holdings SRL and Thérabel Group) participated in this financing round, but also new family shareholders and entrepreneurs including Corely Belgium SPRL and Bratya SPRL (Gaspar family investment holdings, owner of the Lyreco Group), and Bad 21 SPRL (investment holding company of Pierre-Edouard Stérin, founder of Smartbox).

These operations explain the changes observed in the composition of Carmat's ownership structure over the past years.

The Company is not aware of any of its shareholders crossing any of the statutory thresholds in the year ended December 31, 2020.

| Shareholders | As at December 31, 2019 | | As at December 31, 2018 | | As at December 31, 2017 | |
|---|---|---|---|---|---|---|
| | % of capital | % of voting rights | % of capital | % of voting rights | % of capital | % of voting rights |
| Matra Défense (Airbus Group) | 13.2% | 18.4% | 14.4% | 20.9% | 14.8% | 20.7% |
| Lohas (Pierre Bastid) | 11.5% | 10.0% | 13.9% | 11.6% | 14.3% | 11.5% |
| Corely Belgium (Gaspard family) | 6.3% | 5.5% | - | - | - | - |
| Bratya (Gaspard family) | 2.0% | 1.7% | - | - | - | - |
| Santé Holding SRL (Dr. Antonino Ligresti) | 7.3% | 6.4% | 7.4% | 6.2% | 7.6% | 6.1% |
| Professor Alain Carpentier | 4.4% | 7.6% | 5.9% | 9.9% | 6.1% | 9.8% |
| Alain Carpentier Foundation Research Association | 0.9% | 1.6% | 1.2% | 2.1% | 1.3% | 2.1% |
| Bad 21 | 5.2% | 4.5% | - | - | - | - |
| Cornovum | 3.6% | 3.2% | 5.0% | 4.1% | 5.1% | 4.1% |
| Funds managed by Truffle Capital | 2.8% | 3.3% | 3.8% | 4.2% | 8.5% | 11.5% |
| Thérabel Group | 2.5% | 2.1% | 1.4% | 1.1% | - | - |
| Air Liquide | 0.6% | 0.5% | 0.8% | 0.7% | 0.9% | 0.7% |
| Treasury stock | 0.0% | - | 0.0% | - | 0.0% | - |
| Free float | 39.6% | 35.0% | 46.1% | 39.1% | 41.4% | 33.6% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

## 5.3.2 VOTING RIGHTS

The voting right attached to shares is proportional to the percentage of share capital that they represent. Each share entitles at least one vote.

However, in accordance with Article 14 of the Articles of Association and the provisions of the French Commercial Code, all fully paid up shares which have been registered to the same shareholder for at least two years benefit from double voting rights compared with those given to other shares with respect to the percentage of share capital that they represent.

For more information on double voting rights, see Article 14 of the Articles of Association, reproduced in section 5.4.3 of this document.

## 5.3.3 STATEMENT CONCERNING THE CONTROL OF THE COMPANY

As at the date of this Universal Registration Document, to the best of the Company's knowledge, no single 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 CONTROL

As at the date of this Universal Registration Document, and to the best of the Company's knowledge, there are no agreements that may bring about a change in control of the Company.

# 5.4 MEMORANDUM AND ARTICLES OF ASSOCIATION

## 5.4.1 CORPORATE PURPOSE (ARTICLE 2 OF THE ARTICLES OF ASSOCIATION)

The purpose of the Company is, either directly or indirectly, both in France and abroad:

- the research and development of medical devices and equipment, specifically in the cardiovascular field, and in all scientific fields directly or indirectly related thereto;
- the production and marketing of (i) medical devices and equipment in the cardiovascular field and (ii) all associated technologies;
- the acquisition or creation of technology products and licenses related to the cardiovascular field;
- the investment in French or foreign companies, which have activities that are similar to, or which complement those mentioned above;
- and, more generally, all operations of any kind – economic, legal, financial, civil or commercial, industrial, securities or real estate – that may be directly or indirectly connected with the above-mentioned purpose or likely to contribute to the development thereof.

## 5.4.2 PROVISIONS OF THE ARTICLES OF ASSOCIATION, CHARTER OR BYLAWS OF THE COMPANY CONCERNING THE MEMBERS OF THE BOARD OF DIRECTORS AND EXECUTIVE MANAGEMENT (ARTICLES 15 TO 21 OF THE ARTICLES OF ASSOCIATION)

### ARTICLE 15 – BOARD OF DIRECTORS

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 Shareholders' Meeting. However, in the event of a merger or demerger, appointments may be made by an Extraordinary Shareholders' Meeting. Directors are appointed for a term of six (6) years, expiring at the end of the Ordinary Shareholders' Meeting held during the year in which their term of office expires to approve the financial statements for the previous year.

Any outgoing director may be re-appointed subject to fulfilling the conditions of this Article.

Directors may be removed from office and replaced at any time by the Ordinary Shareholders' Meeting.

Natural persons aged over eighty-five (85) years may not

be directors; when a director reaches this age during their term of office they are deemed to have officially resigned at the next Shareholders' Meeting. Any appointment made in breach of the above provisions is null and void, with the exception of those which may be made on a temporary basis.

Any director who is a natural person must, at the time of their appointment and throughout their term of office, meet the legal requirements in terms of the total number of directorships that a single person may hold in French joint-stock corporations (sociétés anonymes) based in Metropolitan France, unless otherwise provided for by law.

A Company employee may only be appointed as a director if their contract of employment relates to an actual position within the Company. The number of directors who have a contract of employment with the Company may not exceed one third of the directors in office.

II. Director in the form of a legal entity

Directors may be natural persons or legal entities. In the latter case, at the time of appointment, the legal entity is required to designate a permanent representative who will be subject to the same conditions and obligations and with the same civil and criminal liabilities as if they were a director in their own right, without prejudice to the joint and several liability of the legal entity that they represent. The permanent representative of a director in the form of a legal entity is subject to the age conditions that relate to directors who are natural persons.

The term of office of the permanent representative designated by the legal entity appointed as director is the same as the term of office of the latter.

If the legal entity removes its permanent representative from office, it is required to notify the Company, without delay, by registered letter, of this removal and of the identity of its new representative. The same applies in the case of death or resignation of the permanent representative.

The designation of the permanent representative and the termination of their term of office are subject to the same publication formalities as if they were a director in their own right.

III. Vacancies, deaths, resignations

In the event of a vacancy due to death or resignation of one or more directors, the Board of Directors may proceed with interim appointments between two Shareholders' Meetings.

When the number of directors falls below the legal minimum, the remaining directors must immediately call an Ordinary Shareholders' Meeting in order to make up the numbers on the Board.

Interim appointments made by the Board are subject to ratification by the next Ordinary Shareholders' Meeting. In the absence of ratification, decisions made and actions taken previously by the Board will remain valid.

### ARTICLE 17 – ORGANIZATION AND DELIBERATIONS OF THE BOARD

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 Chairman's compensation.

The Chairman of the Board of Directors organizes and directs the work of the latter, and reports thereon to the Shareholders' Meeting. He ensures that the Company bodies are operating properly, and in particular that the directors are capable of performing their duties.

In order to perform his duties, the Chairman of the Board of Directors must be less than eighty-five (85) years of age. If the Chairman of the Board of Directors reaches this age during his term of office, he will be deemed to have officially resigned and the appointment of a new Chairman will take place subject to the conditions provided for in this article.

The Chairman is appointed for a term that may not exceed that of his term of office as a director. The Chairman is eligible for re-appointment.

The Board of Directors may revoke the appointment at any time.

In the event of the Chairman being temporarily unavailable, or of his death, the Board of Directors may delegate the duties of Chairman to a director.

In the event of the Chairman being temporarily unavailable, this delegation is made for a limited, renewable period. In the event of death, it remains valid until the election of a new Chairman.

II. Board meetings

The Board of Directors meets as often as the interests of the Company require, at the invitation of the Chairman and at least every two (2) months.

When it has not met for more than two (2) months, a minimum of one third of the members of the Board of Directors may ask the Chairman to call a meeting with a specific agenda.

The Chief Executive Officer may also ask the Chairman to call a meeting of the Board of Directors with a specific agenda.

The Chairman is bound to act on requests made to him by virtue of the above two paragraphs.

Notices may be given by any means, including verbally.

The Board meets at the registered office or at any other location (in France or abroad) indicated in the notice, under the chairmanship of the Chairman or, if he is unavailable, the member designated by the Board to chair it.

The Chairman of the Board of Directors chairs the meetings. In the event of the Chairman being unavailable, the Board appoints a chairman for each meeting from among the members present.

At each meeting, the Board may appoint a secretary, who does not necessarily have to be a member.

A register is kept which is signed by the directors attending the Board meeting.

The directors and any person called upon to attend the meetings of the Board of Directors are bound by secrecy in respect of information of a confidential nature indicated as such by the Chairman.

The Board of Directors may also make the following decisions, which fall within its remit, by consulting the directors in writing:

- provisional appointment of directors as provided for in Article L. 225-24 of the French Commercial Code;
- grant of guarantees and other collateral as provided for in the final paragraph of Article L.225-35 of the French Commercial Code;
- amendment of the Articles of Association to bring them into line with new legislative or regulatory provisions by decision made pursuant to a delegation of authority given by the Extraordinary Shareholders' Meeting in accordance with the second paragraph of Article L.225-36 of the French Commercial Code;
- calling of Shareholders' Meetings; and
- transfer of the head office to another location in the same department.

When a decision is made by written consultation, the proposed resolutions and a voting form are sent by the Chairman to each director by email (return receipt requested).

The directors then have three (3) business days in which to return the dated and signed voting form to the Chairman by email (return receipt requested), indicating their vote for each resolution by checking the appropriate boxes.

If no or several boxes have been checked for one of the resolutions, the vote will be null and void and will not be taken into account for the purpose of calculating the majority.

Any director who does not reply within the requisite time period will be deemed to be absent and his/her vote will not be taken into account for the purpose of calculating the majority.

During the three-day reply period, directors may ask the person who prepared the written consultation for any further information or explanations.

No later than five (5) business days after receiving the last voting form, the Chairman draws up and dates the minutes of the proceedings, to which the voting forms are appended, and the minutes are signed by the Chairman and one director who took part in the written consultation.

III. Quorum, majority

Deliberations of the Board will only be valid if at least half of the directors are present or deemed present under the arrangements laid down in the internal rules where videoconference and other means of telecommunication are used.

Unless otherwise stipulated by these Articles of Association and subject to the arrangements laid down in the internal rules, where videoconferencing or other means of telecommunication are used, decisions are taken by a majority of votes of the members present or represented or deemed present.

Directors are deemed present for the purposes of calculating a quorum or majority where they take part via videoconference or telecommunication under the conditions defined by the internal rules of the Board of Directors. However, physical presence or representation will be necessary for all deliberations of the Board relating to approval of the annual financial statements and the consolidated financial statements, and also for drawing up the management report and the consolidated management report, as well as for decisions concerning the removal of the Chairman of the Board of Directors, the Chief Executive Officer and the Deputy Chief Executive Officer.

Furthermore, half of the directors in office may oppose a meeting of the Board being held via videoconference or telecommunication. Such opposition must be notified in the forms and by the deadline required by the internal rules and/or in those that may be laid down in the legal or regulatory provisions.

IV. Representation

Any director may give another director written authority to represent him/her at a meeting of the Board.

Each director may hold only one proxy for the same meeting given by application of the above paragraph.

These provisions are applicable to the permanent representative of a director who is a legal entity.

V. Minutes of meetings

The meetings of the Board of Directors are recorded in minutes drawn up in a special register, numbered and initialed, and kept at the registered office in accordance with the regulatory provisions.

VI. Observers

Throughout the lifetime of the Company, the Ordinary Shareholders' Meeting may proceed with the appointment of observers (censeurs) who may or may not be shareholders.

The number of observers may not exceed three (3).

Observers are appointed for a term of one (1) year. Their terms of office expire at the end of the Ordinary Shareholders' Meeting held during the year in which their term of office expires to approve the financial statements for the previous year.

Any outgoing observer may be re-elected subject to meeting the conditions of this article.

Observers may be removed and replaced at any time by the Ordinary Shareholders' Meeting without any compensation being due to them. The duties of the observers also cease upon the death or incapacity of an observer who is a natural person, or in the event of winding up or receivership in the case of an observer who is a legal entity.

Observers may be natural persons or legal entities. In the latter case, at the time of appointment, the legal entity is required to designate a permanent representative who will be subject to the same conditions and obligations and with the same civil and criminal liabilities as if they were an observer in their own right, without prejudice to the joint and several liability of the legal entity that they represent.

The duty of the observers is to ensure the strict application of the Articles of Association and to present their observations at the meetings of the Board of Directors.

The observers perform a general and permanent role of advice and monitoring within the Company. In the context of their duties they may make observations to the Board of Directors and request access to information at the registered office of the Company.

Observers must be invited to each meeting of the Board of Directors in the same way as directors.

Observers have only consultative powers on an individual or joint basis and have no voting rights on the Board.

Failure to invite an observer or to send documents to an observer or observers prior to the meeting of the Board of Directors may in no case constitute grounds for nullity of the decisions taken by the Board of Directors.

### ARTICLE 18 – POWERS OF THE BOARD OF DIRECTORS

The Board of Directors sets the business strategy of the Company and ensures that this is implemented.

Save for the powers expressly reserved to the Shareholders' Meetings and within the scope of the corporate purpose, the Board of Directors considers any matter relating to the proper operation of the Company and through its deliberations, deals with matters affecting it.

In its relations with third parties, the Company assumes an obligation, even for actions of the Board of Directors that do not fall within the scope of the corporate purpose, unless it can prove that the third party was aware that the action exceeded that scope, or, under the circumstances, must have been aware. The simple publication of the Articles of Association will not however 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/her duties and may obtain from Executive Management all documents he/she considers useful.

The Board of Directors may decide to set up working groups to look into any matters referred to them by the Board or its Chairman.

### ARTICLE 19 – EXECUTIVE MANAGEMENT – DELEGATION OF POWERS

I. Organizational principles

In accordance with the legal provisions, Executive Management of the Company is led, on behalf of the Company, either by the Chairman of the Board of Directors or by another natural person appointed by the Board of Directors and bearing the title of Chief Executive Officer.

The choice between the two methods of Executive Management is made by the Board of Directors, which must inform the shareholders and third parties subject to the regulatory requirements.

The decision of the Board concerning the choice of Executive Management method is taken by a majority vote of the directors present or represented, subject to the specific provisions of Article 17-III where directors attend

the meeting by videoconference or other means of telecommunication.

A change in the Executive Management method does not result in a change to the Articles of Association.

Where Executive Management of the Company is led by the Chairman of the Board of Directors, the following provisions relating to the Chief Executive Officer are applicable to him.

II. Executive Management

Chief Executive Officer

Depending on the choice made by the Board of Directors in accordance with the provisions of the above paragraph, Executive Management of the Company is led by the Chairman of the Board of Directors, or by a natural person, who may or may not be a director, appointed by the Board of Directors and bears the title of Chief Executive Officer.

Where the Board of Directors chooses to separate the functions of Chairman and Chief Executive Officer, it will proceed to appoint the Chief Executive Officer, define his term of office, determine his compensation and, as necessary, the limits to his powers.

A person over the age of eighty-five (85) years may not be appointed as Chief Executive Officer. If a Chief Executive Officer in office reaches this age he is deemed to have officially resigned.

The Chief Executive Officer may be removed from office at any time by the Board of Directors. Where the Chief Executive Officer does not perform the role of Chairman of the Board of Directors, his removal may be subject to payment of compensation if this takes place without good cause.

The Chief Executive Officer is invested with the highest powers to act in all circumstances on behalf of the Company. He exercises these powers within the scope of the corporate purpose, save for those which the law expressly reserves to Shareholders' and Board of Directors' meetings.

He represents the Company in its relations with third parties. The Company assumes an obligation, even for actions of the Chief Executive Officer that do not fall within the scope of the corporate purpose, unless it can prove that the third party was aware that the action exceeded that scope, or, under the circumstances, must have been aware. The simple publication of the Articles of Association will not however suffice as proof.

In respect of the shareholders and without this restriction being binding upon third parties, the Chief Executive Officer may not take any decision on behalf of the Company in the following areas without the prior authorization of the Board of Directors:

- securing loans or advances in order to acquire shares or securities of any subsidiary company except where such subsidiary is wholly-owned;
- granting guarantees on behalf of a subsidiary or to guarantee bank accounts;
- all investments in excess of €250,000;
- all commitments in excess of €100,000 and not provided for in the annual budget;
- hiring, laying off and amending the contracts of employment of employees at management level;
- a change in the normal business of the Company and in its development strategy;
- disposing, transferring, licensing or pledging any industrial or intellectual property or any substantial asset;
- approving the budget and the strategic plan.

The Chief Executive Officer may not, without a prior decision of the Board of Directors by a qualified majority of three quarters of the directors making up the Board as at the date that the decision is taken:

- take any decision to proceed with the transfer of any substantial asset or any intellectual/industrial property belonging to the Company;
- take any decision to acquire a holding in a listed or unlisted company.

Deputy Chief Executive Officers

At the proposal of the Chief Executive Officer, whether this function is assumed by the Chairman of the Board of Directors or by another person, the Board of Directors may appoint one or more natural persons, known as Deputy Chief Executives Officers, who may or may not be chosen from among the directors and shareholders, who are charged with assisting the Chief Executive Officer. The number of Deputy Chief Executive Officers may not exceed five. If the Deputy Chief Executive Officer is a director, his/her term of office may not exceed that of his/her term of office as a director.

A person over the age of eighty-five (85) years may not be appointed as Deputy Chief Executive Officer. If a Deputy Chief Executive Officer in office reaches this age, he/she is deemed to have officially resigned.

Deputy Chief Executive Officers may be removed at any time by the Board of Directors at the proposal of the Chief Executive Officer. Removal without just cause may give rise to damages.

By agreement with the Chief Executive Officer, the Board of Directors decides on the scope and the duration of the powers granted to the Deputy Chief Executive Officers. The Deputy Chief Executive Officers have the same powers in respect of third parties as the Chief Executive

Officer.

Where the Chief Executive Officer ceases or is prevented from performing his duties, the Deputy Chief Executive Officers will retain their functions and powers until the new Chief Executive Officer is appointed, unless otherwise decided by the Board.

The Board of Directors decides on the compensation of the Deputy Chief Executive Officers.

III. Delegation of powers

The Board of Directors may entrust to its corporate officers, who may or may not be directors, the permanent or temporary duties it decides upon, delegate powers to them and set the compensation it considers appropriate.

### ARTICLE 20 – DIRECTORS' COMPENSATION

The Shareholders' Meeting may allocate to the directors, to compensate them for their work, by way of directors' fees, a fixed annual sum defined by the meeting, without being bound by previous decisions. The amount is posted to operating expenses.

The Board of Directors freely distributes among its members the total amounts allocated to the directors as directors' fees; it may in particular allocate a higher share to directors who are members of working groups than to other directors.

The Board of Directors may award exceptional compensation for the duties or mandates entrusted to directors.

The Board of Directors may authorize the reimbursement of travel and subsistence costs and expenses incurred by the directors in the interests of the Company.

### ARTICLE 21 – AGREEMENTS BETWEEN THE COMPANY AND A DIRECTOR, THE CHIEF EXECUTIVE OFFICER OR A DEPUTY CHIEF EXECUTIVE OFFICER

I. Agreements submitted for authorization.

Except for those relating to day to day operations and entered into under normal conditions, any agreement that is made, directly or through a nominee, between the Company and one of its directors, Chief Executive Officers or Deputy Chief Executive Officers, or a shareholder holding more than 10% of the voting rights in the Company, or in the case of a shareholding company, the Company controlling it pursuant to Article L.233-3 of the French Commercial Code, must be referred to the Board of Directors for prior authorization.

The same applies to agreements in which one of the persons referred to in the above paragraph has an indirect interest.

Agreements entered into by Carmat and another company are also subject to prior authorization if they are with a company where the Chief Executive Officer, one of the Deputy Chief Executive Officers or one of the directors of Carmat, is the owner, partner with unlimited liability, manager, director, member of the supervisory committee or, generally speaking, an executive of the other company.

Such agreements must be authorized and approved in accordance with the statutory provisions.

II. Prohibited agreements

It is prohibited, on pain of nullity of the contract, for directors other than those who are legal entities, to contract for loans of whatever kind with the Company, to have an overdraft granted by it, on a current or other account, or to have it act as guarantor or stand surety for undertakings by them to third parties.
The same prohibition applies to the Chief Executive Officer, Deputy Chief Executive Officers and permanent representatives of directors in the form of legal entities. It also applies to the spouses, ascendants and descendants of the persons mentioned in this article and to any nominee.

III. Current agreements

Agreements relating to current and ordinary transactions and agreements concluded between two companies, one of which holds, directly or indirectly, the whole capital of the other, if any, less the minimum number of shares required to satisfy the requirements of Article 1832 of the French Civil Code or Articles L.225-1 and L.226-1 of the French Commercial Code are not subject to the legal authorization and approval procedure. However, these agreements, unless as a result of their subject matter or their financial implications they are not significant for any of the parties, must be reported to the Chairman of the Board of Directors by the interested party. A list and subject matter of such agreements are provided by the Chairman to the members of the Board of Directors and to the auditors at the latest on the day of the meeting of the Board to approve the financial statements for the year ended.

Shareholders may also be sent the list and subject matter of these agreements.

## 5.4.3 RIGHTS, PRIVILEGES AND RESTRICTIONS ATTACHED TO SHARES (ARTICLES 9 TO 14 OF THE ARTICLES OF ASSOCIATION)

### ARTICLE 9 – DEPRECIATION OF THE SHARE CAPITAL

The share capital may be depreciated in accordance with the provisions of Articles L.225-198 *et seq*. of the French Commercial Code.

### ARTICLE 10 – SETTLEMENT OF SHARES

At the time of a capital increase, cash shares are settled, upon subscription, for at least a quarter of their face value and, as appropriate, the full share premium.

Settlement of the balance must take place on one or more occasions at the call of the Board of Directors and within five years of the date when the transaction becomes definitive in the case of an increase in share capital.

Calls for funds are announced to the subscribers and shareholders at least two weeks prior to the date set for payment by individual registered letter with acknowledgment of receipt.

A shareholder who does not make the required payments for shares on the due dates will be liable to pay the Company, automatically and without prior warning, delay interest calculated on a daily basis from the due date at the legal rate for commercial court matters plus three points.

In order to obtain payment of these sums, the Company is entitled to take 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

Ordinary shares are in registered or bearer form depending on the shareholder's choice. They can take the bearer form only after they are fully paid up. Fully paid-up preference shares are registered.

The Company is authorized to identify holders of bearer shares by simple request, for the body in charge of clearing securities, of the name or company name, nationality, year of birth or establishment, shareholders' addresses or number of shares held by each of them.

### ARTICLE 12 – TRANSFER OF SHARES – RIGHTS AND OBLIGATIONS ASSOCIATED WITH SHARES – THRESHOLD CROSSING

12.1. Transfer of shares

The ordinary shares may be freely traded once issued in accordance with the procedures set out by law.

They remain tradable following the winding up of the Company and until liquidation is complete. Preference shares are transferable in accordance with paragraph 12.2.

Ordinary shares and the preference shares give rise to a book entry and are transferred by a movement between accounts under the conditions and according to the procedures set out in the law and the rules in force.

The provisions of this Article are generally applicable to all securities issued by the Company.

12.2. Rights and obligations attached to shares

The share capital of the Company is composed of Ordinary Shares and Preference Shares.

Shareholders are only liable for the Company's debts up to the amount of their contributions.

I. Rights attached to ordinary shares

Without prejudice to the rights attached to the preferred shares, each ordinary share entitles the holder to a share in the profits and in the share capital in proportion to the portion of share capital it represents. It gives the right to participate, under the conditions set by the law and the present Articles of Association, in Shareholders' Meetings and to vote on resolutions.

The ownership of an ordinary share automatically entails unreserved compliance with the Articles of Association and decisions of the Shareholders' Meeting of the Company.

The rights and obligations attached to the ordinary shares remain the same regardless of the holder.

Whenever it is necessary to own more than one share to exercise a right, in case of exchange, consolidation, allocation of shares, capital increase or reduction, merger or any other operation, owners of individual securities or less than the required number can exercise these rights only if they make it their personal business to group and possibly purchase or sell the necessary number of securities.

II. Rights attached to preference shares

Preference shares and the rights of their holders are governed by the applicable provisions of the French Commercial Code, in particular Articles L.228-11 *et seq*.

The maximum number of preference shares that can be issued is:

- 7,600 for 2017 preference shares;
- 13,980 for 2018 preference shares;
- 20,000 for 2019 preference shares; and
- 3,400 for 2020 preference shares.

Preference shares are classified into eleven distinct classes according to the performance criteria attached to them:

- "AGAP 2017-01" for a maximum of 320;
- "AGAP 2017-02" for a maximum of 2,000;
- "AGAP 2017-03" for a maximum of 5,280;
- "AGAP 2018-01" for a maximum of 580;
- "AGAP 2018-02" for a maximum of 11,500;
- "AGAP 2018-03" for a maximum of 1,900;
- "AGAP 2019-01" for a maximum of 8,000;
- "AGAP 2019-02" for a maximum of 8,000;
- "AGAP 2019-03" for a maximum of 4,000;
- "AGAP 2020-01" for a maximum of 2,500; and
- "AGAP 2020-02" for a maximum of 900.

From the time of their vesting and until they become convertible, the preference shares have the right to vote at the Ordinary and Extraordinary Meetings of ordinary shareholders, with one voting right per preference share. From the date on which they become convertible, the number of voting rights that each preference share entitles becomes equal to the number of ordinary shares to which the conversion of each preference share gives entitlement.

From the time of their vesting, preference shares shall have the right to vote at a special meeting of the holders of each class of preference shares. The holders of each class of preference shares shall attend a special meeting for any proposed amendment to the rights attached to such class of preference shares. In addition, in accordance with the provisions of Article L.228-17 of the French Commercial Code, any proposed merger or demerger of the Company whereby preference shares could not be exchanged for shares with specific equivalent rights will be subject to the approval of the special meeting concerned.

The quorum for special meetings will only be met if the shareholders present or represented possess at least one third of the preference shares with the right to vote on the first call and one fifth on the second call. In the event of a change or depreciation of the share capital, the rights of the holders of preference shares are adjusted in such a way as to preserve their rights pursuant to Article L.228-99 of the French Commercial Code. Other rights attached to preference shares are set out in the following paragraph.

From the time of their vesting and until they become convertible, the preference shares benefit from a dividend and give right to the reserves. The amount of the dividend (and, where applicable, the reserves) that each preference share entitles is equal to the amount due in respect of one ordinary share multiplied by the number of ordinary shares to which the conversion of each preference share gives right. For this purpose, the preference shares shall bear dividends from the first day of the financial year preceding the year in which they vest. From the date on which they become convertible, the amount of the dividend (and, where applicable, the reserves) that each preference share entitles becomes equal to the amount due in respect of one ordinary share multiplied by the number of ordinary shares to which the conversion of each preference share gives right.

From the time of their vesting, in the event of the liquidation of the Company, preference shares enjoy the same right to the liquidation bonus as ordinary shares, i.e., a right proportional to the share that their par value represents in the share capital.

From the time of their vesting, preference shares are entitled to pre-emptive subscription rights for any capital increase or any transaction with rights to the ordinary shares.

In the case of capital depreciation or reduction, changes in the distribution of profits, the allocation of free shares, capitalization of reserves, profits or share premiums, distribution of reserves or any issue of equity securities or securities giving right to the allocation of capital securities with a subscription right reserved for shareholders before the preference shares are convertible under the conditions set out in paragraph III below, the maximum number of ordinary shares that the preference shares may entitle by conversion shall be adjusted to take account of such transaction in accordance with the provisions of Article L.228-99 paragraph 2, 3° and paragraph 5 of the French Commercial Code.

For the purposes of this adjustment, the Board of Directors will calculate, at the time of setting the final number of ordinary shares that each preference share entitles, the conversion ratio applicable according to the degree to which the performance criteria are met, such as provided for in paragraph III below, and adjust this ratio for all transactions previously completed, in accordance with the above provisions.

Each beneficiary will be informed of the practical details of this adjustment and of its consequences on the allocation of ordinary shares on conversion of the preference shares he/she has been allocated.

After the preference shares have become convertible and the Board of Directors has calculated the conversion ratio as provided for in paragraph III below (as adjusted in accordance with this article, if necessary), no adjustment shall be made to this conversion ratio, as the holders of preference shares may convert them freely thereafter.

The preference shares will be fully paid up when they are issued by capitalizing the Company's reserves, premiums or profits.

III. Conversion of preference shares into ordinary shares

The issue of preference shares may only be decided in the context of a free allocation of shares to employees and corporate officers of the Company in accordance with the provisions of Articles L.225-197-1 *et seq*. of the French Commercial Code.

The preference shares will vest (the "Vesting") to the beneficiaries at the end of a vesting period of one (1) year from their allocation by the Board of Directors (the "Award").

However, if the beneficiary has a disability classified under the second or third category provided for in Article L.341-4 of the French Social Security Code (or their equivalent in applicable foreign law), the preference shares will vest before the end of the remaining vesting period. In the event of the beneficiary's death, in accordance with the provisions of Article L.225-197-3 of the French Commercial Code, the beneficiary's heirs or successors may, if they wish, apply for the vesting of the preference shares within six months of the date of death. In the event of retirement, the beneficiaries will retain their right to the Vesting of preference shares even though they are no longer bound by a contract of employment.

Holders of preference shares may request conversion of their preference shares into new or existing ordinary shares (the Company's choice) of the Company as follows:

1. The preference shares become convertible into new or existing ordinary shares (at the Company's choice) after a lock-up period (the "Lock-up Period") of:

(i) two years beginning on the Vesting Date for AGAP 2017-01, 2017-02, 2017-03, 2018-01, 2018-02, 2018-03, 2019-01, 2019-02, 2019-03 and 2020-01;

(ii) four years beginning on the Vesting Date for AGAP 2020-02.

The terms and conditions of conversion are set out in paragraphs 2 to 13 below (including in the case of a public cash or stock offer that might lead to early convertibility of the AGAP 2020-01 and 2020-02, to the extent that the Lock-up Period may not be less than one year).

From the date they become convertible (the "Convertibility Date"), preference shares may be converted during a conversion period (the "Conversion Period") of:

(i) five (5) years and three (3) months for AGAP 2017-01, 2017-02, 2017-03, 2018-01, 2018-02, 2018-03, 2019-01, 2019-02, 2019-03 and 2020-01;

(ii) three (3) years and three (3) months for AGAP 2020-02,

except in the case of a public cash or stock offer that might lead to early convertibility of the AGAP 2020-01 and 2020-02, although the date initially proposed for the end of the Conversion Period may not be changed.

2. In accordance with the provisions of Article L.225-197-1 I, paragraph 7 of the French Commercial Code, preference shares will be freely transferable during the Lock-up Period if the beneficiary becomes disabled under the second or third category provided for in Article L.341-4 of the French Social Security Code (or their equivalent in applicable foreign law), regardless of whether the disability occurs before or after the Vesting Date.

In the event of the beneficiary's death, whether the beneficiary dies during the vesting period or the Lock-up Period, his/her heirs will no longer be required to comply with this non-transferability commitment, so the preference shares for which they requested vesting shall become freely transferable.

3. 2017 preference shares are classified into three distinct classes according to the performance criteria attached to them: "AGAP 2017-01", "AGAP 2017-02" and "AGAP 2017-03". The number of ordinary shares to which the conversion of a 2017 preference share will give entitlement will depend on whether one or more (or all) of the 2017 Performance Criteria have been met on the Convertibility Date (the "2017 Performance Criteria").

For the "AGAP 2017-01" 2017 preference shares, the 2017 Performance Criterion will be the definition of the Company's industrial development plan, which will give the right to convert each preference share into 100 ordinary shares.

For the "AGAP 2017-02" 2017 preference shares, the 2017 Performance Criterion will be the successful implantation of the bioprosthesis evaluated on a total of ten patients worldwide, which will give the right to convert each preference share into 20 ordinary shares.

For the "AGAP 2017-03" 2017 preference shares, the 2017 Performance Criteria will be as follows:

- i. the filing of the clinical module of the bioprosthesis' CE marking, which will give the right to convert each preference share into 15 ordinary shares;
- ii. bioprosthesis' CE marking, which will give the right to convert each preference share into 20 ordinary shares;

- iii. obtaining additional financing for the Company for a cumulative amount of €100 million between the Award Date and the Convertibility Date which will give the right to convert each preference share into 25 ordinary shares. Such financing may take the form of, in particular, capital increases, debt instruments, conditional advances, operating subsidies or revenues received from collaborative or licensing agreements;
- iv. the establishment of a production process that (i) meets the applicable regulatory and quality standards, and (ii) enables the production of a sufficient number of bioprosthesis' within a sufficient time frame to carry out the necessary clinical trials and to respond to commercial orders in the contractual deadlines, without any major interruption of production or quality problems leading to a recall of sold products, which will give the right to convert each preference share into 15 ordinary shares;
- v. the effective commercialization of the bioprosthesis at 15 European implantation centers, which will give the right to convert each preference share into ten ordinary shares;
- vi. the successful implantation of the bioprosthesis evaluated on ten patients in the United States, which will give the right to convert each preference share into ten ordinary shares;
- vii. the successful implantation of the bioprosthesis evaluated on 100 patients worldwide, which will give the right to convert each preference share into ten ordinary shares;
- viii. the change in the price of the ordinary share according to the following criteria, which will give the right to convert each preference share into a maximum of ten ordinary shares.

(a) If the Final Price is strictly lower than the Initial Price, the number of ordinary shares that each preference share will be converted into will be equal to zero;

(b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value below the Ceiling Price, the number of ordinary shares that each preference share will be converted into will be equal to:

[(Final Price / Initial Price) - 1] x 10

(c) If the Final Price is equal to or greater than the Ceiling Price, the number of ordinary shares that each preference share will be converted into will be equal to ten.

The "Final Price" is the highest average of the trading session closing prices of ordinary shares taken over a period of sixty consecutive days, calculated at any time during the three (3) years preceding the Convertibility Date.

The "Ceiling Price is equal to the Initial Price multiplied by three, and a maximum of €114.

The "Initial Price" is equal to the closing price of the ordinary share on the date of the Award, with a minimum of €30 and a maximum of €38 per ordinary share.

The conversion ratio thus determined for each class of 2017 preference shares will be adjusted to take into account the shares to be issued to preserve the rights of holders of securities giving access to the share capital of the Company and holders of 2017 preference shares in accordance with the applicable legal and regulatory provisions and paragraph II above.

4. 2018 preference shares are classified into three distinct classes according to the performance criteria attached to them: "AGAP 2018-01", "AGAP 2018-02" and "AGAP 2018-03". The number of ordinary shares to which the conversion of a 2018 preference share will give entitlement will depend on whether one or more (or all) of the 2018 Performance Criteria have been met on the Convertibility Date (the "2018 Performance Critera"), with the 2017 Performance Criteria (together known as the "Performance Criteria").

For the "AGAP 2018-01" 2018 preference shares, the 2018 Performance Criterion will be the successful completion of the "prosthesis" test benches used to obtain the CE marking, which will give the right to convert each AGAP 2018-01 into 100 ordinary shares.

For the "AGAP 2018-02" 2018 preference shares, the 2018 Performance Criterion, which will give the right to convert each AGAP 2018-02 into 20 ordinary shares will be as follows:

- i. the recruitment of ten patients for the pivotal study to obtain the CE marking, which will give the right to convert each AGAP 2018-2 into ten ordinary shares;
- ii. the recruitment of the 20$^{th}$ patient for the pivotal study to obtain CE marking or the finalization of the pivotal study for submission of the dossier to Dekra, which will give the right to convert each AGAP 2018-2 into five ordinary shares;
- iii. obtaining authorization to complete the Early Feasibility Study in the United States by December 31, 2018, which will entitle the holder to convert each AGAP 2018-2 into five ordinary shares.

For the "AGAP 2018-03" 2018 preference shares, the 2018 Performance Criteria will be as follows:

- i. the filing of the clinical module of the CE marking of the bioprosthesis, which will give the right to convert each AGAP 2018-03 share into 15 ordinary shares;
- ii. the CE marking of the bioprosthesis, which will give the right to convert each AGAP 2018-03 share into 20 ordinary shares;
- iii. obtaining additional financing for the Company for a cumulative amount of €38.5 million between the Award Date and the Convertibility Date which will give the right to convert each AGAP 2018-03 into 25 ordinary

shares. Such financing may take the form of, in particular, capital increases, debt instruments, conditional advances, operating subsidies or revenues received from collaborative or licensing agreements;

- iv. the establishment of a production process that (i) meets the applicable regulatory and quality standards, and (ii) enables the production of a sufficient number of bioprosthesis within a sufficient time frame to carry out the necessary clinical trials and to meet commercial orders within the contractual deadlines, without any major interruption of production or quality problems leading to a recall of sold products, which will give the right to convert each AGAP 2018-03 into 15 ordinary shares;
- v. the effective commercialization of the bioprosthesis at 15 European implantation centers, which will give the right to convert each AGAP 2018-03 into ten ordinary shares;
- vi. the successful implantation of the bioprosthesis evaluated on 10 patients in the United States, which will give the right to convert each AGAP 2018-03 into ten ordinary shares;
- vii. the successful implantation of the bioprosthesis evaluated on 100 patients worldwide, which will give the right to convert each AGAP 2018-03 into ten ordinary shares;
- viii. the change in the price of the common share according to the following criteria, which will give the right to convert each AGAP 2018-03 into a maximum of ten ordinary shares.

(a) If the Final Price is strictly lower than the Initial Price, the number of ordinary shares in which each AGAP 2018-03 will be converted will be equal to zero;

(b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value below the Ceiling Price, the number of ordinary shares that each AGAP 2018-03 will be converted into will be equal to:

[(Final Price / Initial Price) - 1] x 10

c) If the Final Price is equal to or greater than the Ceiling Price, the number of ordinary shares that each AGAP 2018-03 will be converted into will be equal to ten.

The "Final Price" is the highest average of the trading session closing prices of ordinary shares taken over a period of sixty consecutive days, calculated at any time during the three (3) years preceding the Convertibility Date.

The "Ceiling Price" is equal to the Initial Price multiplied by three, and a maximum of €114.

The "Initial Price" is equal to the closing price of the ordinary share on the date of the Award, with a minimum of €30 and a maximum of €38 per ordinary share.

The conversion ratio thus determined for each class of 2018 preference shares will be adjusted to take into account the shares to be issued to preserve the rights of holders of securities giving access to the share capital of the Company and holders of 2018 preference shares in accordance with the applicable legal and regulatory provisions and paragraph II above.

5. 2019 preference shares are classified into three distinct classes according to the performance criteria attached to them: "AGAP 2019-01" for a maximum number of 8,000, "AGAP 2019-02" for a maximum number of 8,000 and "AGAP 2019-03" for a maximum number of 4,000. The conversion of a 2019 preference share will give the right to ten ordinary shares if the performance criteria corresponding to the class in question have been achieved as at the Convertibility Date (together, the "Performance Criteria").

For the "AGAP 2019-01" 2019 preference shares, the Performance Criterion will be the success of the procedure on the first patient treated as part of the pivotal study in the United States following the positive conclusion of the Early Feasibility Study (EFS), which will give the right to convert each preference share into ten ordinary shares.

For the "AGAP 2019-02" 2019 preference shares, the 2019 Performance Criterion will be the obtaining of CE marking with sufficient inventory to support the commercial launch of the Carmat prosthesis, which will give the right to convert each preference share into ten ordinary shares.

For the "AGAP 2019-03" 2019 preference shares, the Performance Criterion will be the invoicing and implantation of five prostheses within four months of the CE marking (excluding implantations as part of the innovation package in France), which will give the right to convert each preference share into ten ordinary shares.

The conversion ratio thus determined for each class of 2019 preference shares will be adjusted to take into account the shares to be issued to preserve the rights of holders of securities giving access to the share capital of the Company and holders of 2019 preference shares in accordance with the applicable legal and regulatory provisions and paragraph II above.

6. 2020 preference shares are classified into two distinct classes according to the timetable (as indicated above) and the performance conditions attached to them: "AGAP 2020-01" for a maximum number of 2,500 and "AGAP 2020-02" for a maximum number of 900. The conversion of a 2020 preference share will give the right to 100 ordinary shares if the performance criteria corresponding to the class in question have been achieved as at the Convertibility Date (together, the "Performance Criteria").

For the "AGAP 2020-01" 2020 preference shares, the Performance Criterion, which will give the right to convert each AGAP 2020-01 into 100 ordinary shares will be as follows:

- i. actual annual production of 150 devices and systems that have passed the quality assurance standards, which will entitle the holder to convert each AGAP 2020-01 into 50 ordinary shares;
- ii. annual sale of 100 devices (excluding clinical trials or "Forfait Innovation" program). which will entitle the holder to convert each AGAP 2020-01 into 50 ordinary shares.

For the "AGAP 2020-02" preference shares awarded in 2020, the Performance Criterion will be obtaining PMA in the United States, which will entitle the holder to convert each AGAP 2020-02 into 100 ordinary shares.

The conversion ratio thus determined for each class of 2020 preference shares will be adjusted to take into account the shares to be issued to preserve the rights of holders of securities giving access to the share capital of the Company and holders of 2020 preference shares in accordance with the applicable legal and regulatory provisions and paragraph k above.

7. The achievement of each Performance Criterion shall be determined at a Board of Directors' meeting held as soon as possible after completion of the Performance Criterion, which shall independently determine the number of ordinary shares entitled by each preference share at that date. As soon as possible after the Convertibility Date, the Board of Directors will meet to independently determine the final number of ordinary shares entitled by each preference share. The conversion ratio of AGAP 2017-03 and of AGAP 2018-03 may under no circumstances exceed 100, regardless of the number of Performance Criteria achieved.

However, in the event of a takeover bid or exchange on the ordinary shares:

a) For the 2017, 2018 and 2019 preference shares:

- (i) taking place as of the Award Date,
- (ii) whose definitive results are announced no later than the day before the Convertibility Date, and
- (iii) being made at a price per share between the Initial Price and a ceiling equal to three times the Initial Price,

the Board of Directors will determine the number of ordinary shares entitled by the preference shares on the date of announcement of the final results of the offer exclusively under the following conditions:

- For each beneficiary, a number "p" equal to the ratio (i) of the aggregate number of ordinary shares entitling all preference shares (all classes) which have been allocated to the beneficiary according to the achievement of the Performance Criteria at the date of the announcement of the final results of the bid, and (ii) the aggregate number of ordinary shares entitling all preference shares (all classes) if all Performance Criteria are achieved.

- If "p" is less than or equal to 0.35, the "N" number of ordinary shares entitling each of the preference shares (whichever class) allocated to the beneficiary will be calculated using the following formula:

$$N = [0.35 + 0.65*(R-1)/2]*n$$

N being capped at 100 for AGAP 2017-01, 20 for AGAP 2017-02, 100 for AGAP 2017-03, 100 for AGAP 2018-01, 20 for AGAP 2018-02, 100 for AGAP 2018-03 and 10 for AGAP 2019-01, 2019-02 and 2019-03.

n being equal to 100 for AGAP 2017-01, 20 for AGAP 2017-02, 100 for AGAP 2017-03, 100 for AGAP 2018-01, 20 for AGAP 2018-02, 100 for AGAP 2018-03 and 10 for AGAP 2019-01, 2019-02 and 2019-03.

With

R = (Acquisition Price) / (Initial Price)

The "Acquisition Price" is equal to the closing price of the ordinary share on the last day of the offering period, with a maximum of €114 per ordinary share.

The "Initial Price" is equal to the closing price of the ordinary share on the day of the allocation of preference shares, with a minimum of €30 for 2017 preference shares and 2018 preference shares and €22 for 2019 preference shares and a maximum of €38 per ordinary share for all preference shares.

- If "p" is greater than 0.35, N will be calculated according to the following formula:

$$N = [p + (1-p)*(R-1)/2]*n$$

knowing that, in any case, N can not be less than n*0.35, i.e., 35 for AGAP 2014-01, 7 for AGAP 2017-02, 35 for AGAP 2017-03, 35 for AGAP 2018-01, 7 for AGAP 2018- 02, 35 for AGAP 2018-03 and 10 for AGAP 2019-01, 2019- 02 and 2019-03.

The preference shares concerned will vest to the beneficiaries on the Vesting Date, irrespective of whether or not an attendance condition is provided for in the terms of the Preference Share Plan and of the Performance Criteria above. In any case, preference shares will only become convertible on the Convertibility Date.

b) For 2020 preference shares:

- (i) taking place as of the Award Date, and

- (ii) whose definitive results are announced no later than the day before the Convertibility Date,

the preference shares will vest for the holders on the Vesting Date whether or not any continuing presence condition provided for in the preference share award plan has been met, and will become convertible into 100 ordinary shares, whether or not the Performance Criteria have been met, no sooner than one year after the Vesting Date or, if later, immediately after the announcement of the final results of the offer.

8. If on the Convertibility Date none of the Performance Criteria has been achieved or if no takeover bid has been made under the conditions described above, the Company may (not an obligation) redeem the preference shares at any time at their par value.

Similarly, preference shares which may be converted but which have not been converted at the end of the Exercise Period, may (without this being an obligation for the Company) be bought at any time by the Company at their par value.

9. At the end of the Exercise Period, the Company may, in accordance with the applicable legal and regulatory provisions, cancel preference shares not yet converted, including those which it has bought back. The share capital will then be correlatively reduced and creditors will have a right of opposition under the conditions provided for in Article L.225-205 of the French Commercial Code.

10. The new ordinary shares resulting from the conversion of the preference shares shall be assimilated to the ordinary shares in circulation and shall bear dividend from the first day of the financial year preceding the year in which the preference shares are converted and will confer on their holders, upon delivery, all rights attached to the ordinary shares. They will be the subject of a request for admission to trading on the Euronext Growth market on the same trading line as the ordinary shares.

11. The Board of Directors will recognize the conversion of the preference shares into ordinary shares for which the conversion is in accordance with the conditions set out above, take note of the number of ordinary shares resulting from the conversions of preference shares and amendments to the Articles of Association, in particular as regards the allocation of shares by class. This option may be delegated to the Chief Executive Officer under the conditions laid down by law.

12. Shareholders will be informed of the conversions made through the reports of the Board of Directors and the Statutory Auditors provided for in Article R.228-18 of the French Commercial Code. These additional reports will be made available to the shareholders at the registered office as from the date each meeting is convened.

13. Capital increases resulting from the creation of preference shares and new ordinary shares will be carried out by special incorporation of all or part of available reserve accounts and, in particular, into the share premium account.

12.3. Threshold crossing

Any natural person or legal entity acting alone or together with others who comes to possess a number of shares representing a percentage of the share capital or the voting rights in excess of the thresholds set by law, will inform the Company within the statutory period, starting from when the holding threshold is crossed, of the total number of shares or voting rights held.

This information is also provided within the same time frames when the holding of share capital or voting rights drops below the thresholds mentioned in this paragraph.

A person required to provide this information will state the number of securities held giving access to the share capital and the voting rights attached to these.

If required by the rules of a securities market other than a regulated market on which the Company's securities are admitted for trading, this person will also inform the French Financial Markets Authority within a time frame and according to the arrangements set by the General Regulations of the latter, with effect from when the threshold to the holding is crossed. If necessary, this information is made public under the conditions laid down by the General Regulations of the French Financial Markets Authority.

Failure to make a due declaration under the above conditions will result in the shares exceeding the fraction that should have been declared by law having their voting right removed for any Shareholders' Meeting held within a period expiring two years after the date that the notification is dealt with.

Similarly, voting rights attached to these shares and which are not duly declared may not be exercised or delegated by the defaulting shareholder.

The commercial court having jurisdiction for the registered office, at the request of the Chairman of the Company, a shareholder or the French Financial Markets Authority, holds sole jurisdiction to pronounce a total or partial suspension, for a period not to exceed five years, of the voting rights of any shareholder who has not made the required declarations.

### ARTICLE 13 – INDIVISIBILITY OF SHARES – BARE OWNERSHIP – USUFRUCT

1 - Shares are indivisible with respect to the Company.

Co-owners of undivided shares are represented at Shareholders' Meetings by one of these or by a single proxy. In the event of disagreement, the proxy is appointed by a court at the application of the most diligent co-owner.

2 - The voting right belongs to the usufructuary at Ordinary Shareholders' Meetings and to the bare owner at Extraordinary Shareholders' Meetings. However, shareholders may agree on any other distribution of the voting right at Shareholders' Meetings. The agreement is notified by registered letter to the Company, which will be required to apply this agreement at any meeting that takes place following expiration of a period of one month after such letter is sent.

The voting right is exercised by the owner where securities are pledged.

### ARTICLE 14 – DOUBLE VOTING RIGHT

The voting right attached to capital or dividend shares is proportional to the percentage of the share capital that they represent. Each share gives entitlement to one vote.

However, a voting right that is double that conferred on other shares, having regard to the percentage of the capital that they represent, is attributed to all shares that are fully paid up, and which can be shown to have been registered to the same shareholder for at least two (2) years. This right is exercised subject to the provisions of Article 12.3 (5) of the Articles of Association.

This double voting right is also conferred from the time they are issued, in the event of an increase in capital through capitalization of reserves, profits or share premiums, upon registered shares in a scrip issue to a shareholder based on previous shares providing such an entitlement.

The transfer of a share as a result of succession, liquidation of community property between spouses or donation by living persons to a spouse or a parent entitled to inherit, does not result in the loss of the right acquired and does not interrupt the periods provided for above.

## 5.4.4 CONDITIONS FOR CHANGING SHAREHOLDERS' RIGHTS

The Articles of Association of the Company do not make any special provision that derogates from general company law.

## 5.4.5 SHAREHOLDERS' MEETINGS (ARTICLES 24 TO 31 OF THE ARTICLES OF ASSOCIATION)

### ARTICLE 24 – QUORUM AND MAJORITY

Shareholders' Meetings deliberate under the conditions set by law.

The Ordinary Shareholders' Meeting takes all decisions other than those reserved to the Extraordinary Shareholders' Meeting by law and by these Articles of Association. The quorum will only be met at the first call if the shareholders present or represented hold at least one fifth of shares with voting rights. At the second call no quorum is required. It acts by a majority of the votes cast by the shareholders present or represented. Votes cast do not include those attached to shares for which the shareholder did not take part in the vote, abstained or cast a blank vote.

The Extraordinary Shareholders' Meeting alone has the power to modify any of the provisions of the Articles of Association. The quorum will only be met if the shareholders present or represented hold at least one quarter of shares with voting rights at the first call and one fifth of the shares at the second call. In the absence of the latter quorum, the meeting on second call may be postponed to a date no later than two months after the date for which it was called. It acts by a two-thirds majority of the votes cast by the shareholders who are present or represented. Votes cast do not include those attached to shares for which the shareholder did not take part in the vote, abstained or cast a blank vote.

Where videoconferencing or other means of telecommunication permitted by law is used under the conditions set out in Article 25 below, shareholders are deemed present for the purposes of calculating a quorum or majority where they take part by such videoconferencing or other means of telecommunications.

## ARTICLE 25 – CALLING OF SHAREHOLDERS' MEETINGS

Shareholders' Meetings are called either by the Board of Directors, or by the Statutory Auditors, or by a proxy appointed by a court under the conditions and arrangements laid down by law.

They take place at the registered office or at any other location specified in the notice of the meeting.

Where shares in the Company are not traded on a regulated market or if all its shares are not registered shares, the Company is required to publish in the Bulletin des Annonces Légales Obligatoires (BALO - French Mandatory Legal Announcements Bulletin), at least thirty-five (35) days before the meeting, a notice of such meeting containing the information required by the current regulations in force.

Shareholders' Meetings are called by publication in a journal authorized to carry legal notices in the department where the registered office is based and also in the French Mandatory Legal Announcements Bulletin (BALO).

However, the publications referred to in the above paragraph may be replaced by a call made, at the cost of the Company, by normal or registered letter sent to each shareholder. Such a call may also be sent by electronic means of telecommunication employed under the regulatory conditions.

If this is decided by the Board at the time the meeting is called, any shareholder may also take part and vote in meetings by videoconference 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, it may not be canceled if all shareholders are present or represented.

## ARTICLE 26 – MEETING AGENDA

The agenda is set by whoever issues the notice of the meeting.

However, one or more shareholders representing at least 5% of the share capital (or an association of shareholders meeting the legal conditions) are empowered to request, under the conditions laid down by law, the inclusion in the agenda of draft resolutions. Such a request must be accompanied by the text of the draft resolutions which may be accompanied by a brief outline of the reasoning.

These draft resolutions, which must be brought to the attention of the shareholders, are included in the agenda and put to a vote of the meeting.

The meeting may not deliberate on a matter that is not included in the agenda.

However, it may under any circumstances remove one or more directors and proceed with their replacement.

The agenda may not be changed if the meeting has to be called a second time.

When the meeting is called upon to deliberate on changes to the economic or legal organization of the Company, in respect of which the works council has been consulted in accordance with Article L.2323-6 of the French Labor Code, the opinion of the council is made known to the meeting.

## ARTICLE 27 – ADMISSION TO MEETINGS

Any shareholder may participate personally, by proxy, or by postal vote in Shareholders' Meetings, of whatever kind.

A legal right of participation in Shareholders' Meetings exists:

- for registered shares, as a result of the entry of these in the books of registered shares kept by the Company at midnight at the start of the second working day prior to the meeting, Paris time;
- for bearer shares, as a result of the entry of these in the books of bearer shares kept by the authorized intermediary, at midnight at the start of the second working day prior to the meeting, Paris time.

The entry or registration of securities in the books of bearer shares kept by the authorized intermediary is acknowledged by a shareholding certificate issued by the latter.

However, the Board of Directors may reduce or remove these time frames, provided that it is in the interests of shareholders.
Shareholders who have not settled their shares by making the payments due are not admitted to meetings.

## ARTICLE 28 – REPRESENTATION OF SHAREHOLDERS AND POSTAL VOTING

I. Representation of shareholders

A shareholder may be represented by another shareholder or by their spouse.

Any shareholder may be empowered by other shareholders to represent them at a meeting, without any restriction other than those resulting from the legal provisions setting the maximum number of votes that the same person may hold in their own name and as a proxy.

II. Postal voting

Once the meeting has been called, a postal voting form and attachments will be sent, at the cost of the Company, to any shareholder who makes a written request for this.

The Company must comply with any request filed or received at the registered office at the latest six days prior to the date of the meeting.

### ARTICLE 29 – OFFICERS FOR THE MEETING

Shareholders' Meetings are chaired by the Chairman of the Board of Directors or, in his absence, by a director delegated for this purpose by the Board. Failing this, the meeting elects a chairman itself.

Where a meeting is called by the Statutory Auditors, a court-appointed proxy or by the liquidators, the meeting is chaired by whichever of these has called it.

The two attendees at such meeting holding the largest number of shares and accepting this function will act as vote tellers.

The officers for the meeting will appoint a secretary, who does not need to be a shareholder.

### ARTICLE 30 – MINUTES OF MEETINGS

The deliberations of Shareholders' Meetings are recorded in minutes drawn up by the meeting officers and signed by them.

These will state the date and place of the meeting, how it was called, the agenda, the composition of the group of meeting officials, the number of shares participating in the voting and the quorum achieved, the documents and reports submitted to the meeting, a summary of the proceedings, the text of the resolutions voted upon and the outcome of these votes.

The minutes are recorded in a special register kept at the registered office under the conditions laid down in the regulations.

If, in the absence of a quorum, a meeting is unable to deliberate properly, minutes to that effect are drawn up by the officers of said meeting.

### ARTICLE 31 – SHAREHOLDERS' RIGHT OF INFORMATION AND CONTROL

Before each meeting, the Board of Directors must provide shareholders with the documents necessary to allow them to speak in full knowledge of the facts and to come to an informed judgment on the functioning of the Company.

Upon receipt of the information referred to above, any shareholder will be entitled to submit written questions, to which the Board of Directors will be required to respond during the meeting.

At any time, any shareholder has an entitlement to receive the documents that the Board of Directors is required, as the case may be, to keep available at the registered office, or to send them, in accordance with the legislative and regulatory provisions in force.

## 5.4.6 PROVISIONS OF THE MEMORANDUM AND ARTICLES OF ASSOCIATION, CHARTER OR BYLAWS OF THE COMPANY THAT MAY DELAY, DEFER OR PREVENT A CHANGE IN ITS CONTROL

With the exception of the double voting rights attached to some shares pursuant to Article 14 of the Articles of Association of the Company (see section 5.3.2 of this document), the Articles of Association do not make any special provision that derogates from general company law.

## 5.4.7 CHANGES TO THE SHARE CAPITAL (ARTICLE 8 OF THE ARTICLES OF ASSOCIATION)

1 - The share capital may be increased by any process and under any arrangements provided for by law.

Only an Extraordinary Shareholders' Meeting is competent to decide on an increase in capital based on a report from the Board of Directors.

Shareholders have a pre-emptive right, in proportion to the number of shares they hold, to subscribe to cash shares issued in order to increase the capital, and may waive this on an individual basis. The Extraordinary Shareholders' Meeting may decide to withdraw this pre-emptive subscription right in accordance with the statutory provisions.

2 - A reduction in capital is authorized or decided upon by the Extraordinary Shareholders' Meeting and may in no case adversely affect the equality of shareholders.

A reduction in capital to below the legal minimum may only be decided subject to the condition precedent of an increase in capital intended to bring this up to at least the

legal minimum, unless the Company converts into another form of company that does not require capital in excess of the share capital after it has been reduced.

Failing this, any interested party may seek a legal order to wind up the Company. This may not be issued if, on the day on which the court rules on the merits of the case, the situation has been regularized.

# 5.5 INFORMATION ON THE LEGAL AFFAIRS OF THE COMPANY DURING THE FINANCIAL YEAR

## 5.5.1 INFORMATION ABOUT COMPANY CORPORATE OFFICERS AND CONTROL

### FREE SHARES, SHARE WARRANTS AND STOCK OPTIONS

The historical allocation of stock options and share warrants to the various corporate officers of the Company, as well as the options and warrants they exercised during the 2020 financial year, are detailed in section 4.5.1.

The historical allocation of free shares (preference shares subject to performance conditions) to the various corporate officers, as well as the free shares that became available during the 2020 financial year, are detailed in section 4.5.1.

As at December 31, 2020, to the knowledge of the Company:

- Stéphane Piat (Chief Executive Officer and director) holds 58,070 shares in the Company (i.e., 0.45% of the share capital).
- The other current executive directors of Carmat do not hold any shares in the Company.

### SHARE TRANSACTIONS BY EXECUTIVES

We indicate below the transactions made by corporate officers of the Company (directors, chief executive officer, deputy chief executive officers) and their relatives on the shares of the Company during the 2020 financial year, as declared by these persons pursuant to the provisions of Article 223-26 of the AMF General Regulations.

| Persons concerned | Transaction | Date of transaction | Number of shares | Value of transaction |
|---|---|---|---|---|
| Lohas (Pierre Bastid) | Disposals | March 17, 2020 | 10,104 | €138k |
| Lohas (Pierre Bastid) | Disposals | March 18, 2020 | 29,510 | €357k |
| Lohas (Pierre Bastid) | Disposals | March 19, 2020 | 36,996 | €447k |
| Lohas (Pierre Bastid) | Disposals | March 20, 2020 | 20,875 | €252k |
| Lohas (Pierre Bastid) | Disposals | March 23, 2020 | 10,869 | €127k |
| Lohas (Pierre Bastid) | Disposals | March 24, 2020 | 9,770 | €115k |
| Truffle Capital (Philippe Pouletty) | Disposals | April 20, 2020 | 600 | €11k |
| Truffle Capital (Philippe Pouletty) | Disposals | April 21, 2020 | 706 | €12k |
| Truffle Capital (Philippe Pouletty) | Disposals | April 22, 2020 | 694 | €12k |
| Truffle Capital (Philippe Pouletty) | Disposals | December 24, 2020 | 78,493 | €2,546k |
| Truffle Capital (Philippe Pouletty) | Disposals | December 28, 2020 | 49,853 | €1,704k |
| Truffle Capital (Philippe Pouletty) | Disposals | December 29, 2020 | 17,066 | €545k |
| Truffle Capital (Philippe Pouletty) | Disposals | December 30, 2020 | 12,571 | €361k |

## 5.5.2 INFORMATION ON THE COMPANY'S SECURITIES

### EMPLOYEE SHAREHOLDING

In accordance with the provisions of Article L.225-102 of the French Commercial Code, we hereby indicate that the Company has not set up any company savings plan for the benefit of employees and that no agreement provides for employee participation in the share capital of the Company.

On the other hand, certain employees of the Company are beneficiaries of stock options, share warrants (BSA and BSPCE) and free shares (preference shares subject to performance conditions), detailed in section 4.5.1

Table 9 in section 4.5.1 specifies the number of stock options granted to the top ten employees who are not corporate officers, and the options exercised by these beneficiaries during the 2020 financial year.

Table 10 ter in section 4.5.1 specifies the number of free shares (subject to performance conditions) awarded to the top ten employees who are not corporate officers, and the free shares that vested to them during the 2020 financial year.

### DEALINGS BY THE COMPANY IN ITS OWN SHARES

Carmat is also obliged to report to you on purchases and sales by the Company of its own shares for the purposes of regulating the price, in accordance with the provisions of Article L.225-209-1 of the French Commercial Code.

During the year ended December 31, 2020, the Company made the following transactions in its own shares under the liquidity agreement entered into for a period of one year with an independent financial services provider, as authorized by the Shareholders' Meetings of March 28, 2019 (9th resolution) and of March 30, 2020 (9th resolution):

- purchase of 157,498 shares at an average price of €19.77;
- sale of 156,895 shares at an average price of €19.81.

As at December 31, 2020, the Company held 4,773 treasury shares, i.e., 0.037% of the share capital. The carrying amount of these shares was €135,075.90.

### SECURITIES GIVING ACCESS TO CAPITAL

At December 31, 2020, securities issued by the Company confer subscription rights to a total of 1,032,285 new shares (7.93% of the existing capital as at December 31, 2020).

For details on the securities giving access to the Company's share capital and currently valid, see section 5.2.5 "Other securities giving access to the share capital".

### PARTICIPATING AND CONTROLLING INTERESTS

In accordance with the provisions of Articles L.233-6 and L.247-1 of the French Commercial Code, we can report that the Company has not acquired any participating or controlling interests during the reporting period.

# 5.6 RELATED-PARTY AGREEMENTS

## 5.6.1 DESCRIPTION OF RELATED-PARTY AGREEMENTS

### ROYALTIES AGREEMENT

Under a royalties agreement signed on June 24, 2008 and amended by an addendum of February 5, 2010 between Carmat, Professor Alain Carpentier and Matra Défense (a subsidiary of Airbus Group) as a result of contributions made when the Company was established, it was agreed that Carmat would pay Professor Alain Carpentier and Matra Défense a total sum equal to 2% of the direct net sales generated by the Total Artificial Heart in the countries covered by at least one of the patents initially contributed by them to the Company after obtaining CE marking and FDA authorization. These payments will be made on a half-yearly basis within thirty days of the end of each sixth-month period, according to a distribution between Professor Alain Carpentier and Matra Défense established in proportion to their holdings in the share capital of the Company on the date it was established.

However, Carmat may repurchase this right to royalties by paying Professor Alain Carpentier and Matra Défense, in proportion to their holdings in the share capital of the Company on the date it was established, a total sum of €30 million less the amount of royalties already paid at the time this right to royalties is repurchased. This sum of €30 million is indexed-linked to the Production prices

index for industry and services to companies – Medico-surgical and orthopedic material for export in the Eurozone PVIC Code 3310921007M with a base level of 100.3 in April 2008 as calculated and published by the French National Institute for Statistics and Economic Studies (INSEE).

### RELATIONS BETWEEN CARMAT AND THE 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 2020, no expenses were recorded under this agreement.

As a reminder, Henri Lachmann, director of Carmat, was Chairman of the Board of Directors of CCML until January 1, 2020.

## 5.6.2 STATUTORY AUDITORS' SPECIAL REPORT ON RELATED-PARTY AGREEMENTS

This is a free translation into English of the Statutory Auditors' special report on related-party agreements and commitments issued in French and is provided solely for the convenience of English speaking readers. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

Carmat SA
36, avenue de l'Europe
78941 Vélizy-Villacoublay cedex
France

To the Shareholders,

In our capacity as Statutory Auditors of Carmat, we hereby report to you on related-party agreements.

It is our responsibility to report to shareholders, based on the information provided to us, on the main terms and conditions of agreements that have been disclosed to us or that we may have identified as part of our engagement, as well as the reasons given as to why they are beneficial for the Company, without commenting on their relevance or substance or identifying any undisclosed agreements or commitments. Under the provisions of Article R.225-31 of the French Commercial Code (Code de commerce), it is the responsibility of the shareholders to determine whether the agreements are appropriate and should be approved.

Where applicable, it is also our responsibility to provide shareholders with the information required by Article R.225-31 of the French Commercial Code in relation to the implementation during the year of agreements already approved by the Shareholders' Meeting.

We performed the procedures that we deemed necessary in accordance with professional standards applicable in France to such engagements. These procedures consisted in verifying that the information given to us is consistent with the underlying documents.

### AGREEMENTS AND COMMITMENTS TO BE SUBMITTED FOR THE APPROVAL OF THE SHAREHOLDERS' MEETING

We were not informed of any agreement authorized and entered into during the year to be submitted for the approval of the Shareholders' Meeting pursuant to the provisions of Article L.225-38 of the French Commercial Code.

### AGREEMENTS ALREADY APPROVED BY THE SHAREHOLDERS' MEETING

Agreements approved in previous years

In accordance with Article R.225-30 of the French Commercial Code, we were informed of the following agreements, approved by the Shareholders' Meeting in previous years, which were not implemented during the year.

RESEARCH COLLABORATION AGREEMENT WITH THE MARIE LANNELONGUE SURGICAL CENTER (CCML, NOW ST-JOSEPH)

A collaboration agreement for the training of clinical teams was concluded with the CCML as of January 1, 2014. Under the terms of this agreement, Carmat undertakes to reimburse the costs incurred by the CCML as described in the appendix to the said agreement.

No expenses were recorded under this agreement for the past financial year.

Mr. Henri Lachmann, director of Carmat, is Chairman of the CCML Board of Directors.

ROYALTIES AGREEMMENT BETWEEN CARMAT (HEREINAFTER "THE 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 Agreement, the Company undertakes to pay to Professor Alain Carpentier and Matra Défense 2% of the net sales proceeds of the Carmat artificial heart manufactured and distributed by Carmat SAS, this amount to be divided between the two beneficiaries in proportion to their respective share in the capital of the Company on the date of its creation. These royalties will be payable every 6 months within thirty days after the end of each six-month period, from the first marketing of the Carmat Artificial Heart and until the expiration of the patents presented in Appendix 1 of the Agreement.

The Company is also authorized to repurchase at any time the right to benefit from these royalties for a sum of €30,000,000 less any royalties already paid under the agreement, with this total sum being shared between the two beneficiaries in proportion to their respective shares in the share capital of the Company on the date it was established. This amount of €30,000,000 is indexed to the Producer Price Index of the Business Services Industry - Euroarea orthopedic and orthopedic equipment.

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

As at December 31, 2020, since Carmat has not yet obtained both the CE marking and the marketing authorization from the FDA, no royalty has been paid under the Agreement.

Signed in Lyon and Paris, February 24, 2021

The Statutory Auditors

| | |
|---|---|
| PricewaterhouseCoopers Audit | Lison Chouraki Audit |
| Gonzague Van Royen | Lison Dahan Chouraki |

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# 6

# ADDITIONAL INFORMATION

# 6.1 PERSON RESPONSIBLE FOR THE UNIVERSAL REGISTRATION DOCUMENT

## 6.1.1 NAME OF THE PERSON RESPONSIBLE FOR THE UNIVERSAL REGISTRATION DOCUMENT

Stéphane Piat, Carmat's Chief Executive Officer, is the person responsible for the Universal Registration Document.

## 6.1.2 DECLARATION BY THE PERSON RESPONSIBLE FOR THE UNIVERSAL REGISTRATION DOCUMENT

"Having taken all reasonable steps to verify the content of this 2020 Universal Registration Document, I declare that the information contained therein is accurate to the best of my knowledge, and that no material information has been omitted.

I further declare that, to the best of my knowledge, the financial statements have been prepared in accordance with the applicable accounting standards and give a true and fair view of the Company's financial position and results, and that the management report, for which a cross-reference table appears in section 6.7.2 of this document, gives a true and fair view of changes to the business, results and financial position of the Company and that it describes the main risks and uncertainties it faces."

Vélizy-Villacoublay, February 24, 2021

Stéphane Piat
Chief Executive Officer, Carmat

# 6.2 STATUTORY AUDITORS

## 6.2.1 STATUTORY AUDITORS

PricewaterhouseCoopers Audit, registered member of the Compagnie régionale des Commissaires aux Comptes de Versailles

Represented by Gonzague Van Royen

63, rue de Villiers – 92200 Neuilly-sur-Seine, France

Start of first term: the incorporation of the Company on June 25, 2008.

Duration of current term: six financial years, following renewal at the Shareholders' Meeting of June 24, 2015.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

Lison Chouraki Audit, registered member of the Compagnie des Commissaires aux Comptes de Paris

Represented by Lison Dahan Chouraki

3, rue Anatole de la Forge – 75017 Paris, France

Start of first term: June 24, 2015.

Duration of current term: six financial years.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

## 6.2.2 ALTERNATE STATUTORY AUDITORS

Jean-Christophe Georghiou, registered member of the Compagnie régionale des Commissaires aux Comptes de Versailles

63, rue de Villiers – 92200 Neuilly-sur-Seine, France

Start of first term: June 24, 2015.

Duration of current term: six financial years.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

Soulika Benzaquen, registered member of the Compagnie des Commissaires aux Comptes de Paris

5, rue de Prony – 75017 Paris, France

Start of first term: October 16, 2008.
Duration of current term: six financial years, following renewal at the Shareholders' Meeting of June 24, 2015.

Expiration of current term: at the close of the Shareholders' Meeting to approve the financial statements for the year ending December 31, 2020.

## 6.2.3 FORMER STATUTORY AUDITORS (RESIGNED, REMOVED OR NOT RE-APPOINTED)

Since appointment, the Statutory Auditors and their alternates have not been removed or resigned.

# 6.3 THIRD-PARTY INFORMATION, STATEMENTS BY EXPERTS AND DECLARATIONS OF ANY INTEREST

None.

# 6.4 AVAILABLE DOCUMENTS AND 2018-2019 HISTORICAL INFORMATION

Copies of this Universal Registration Document are available free of charge from the Company and from the Company's website (www.carmatsa.com) or the website of the French Financial Markets Authority – AMF (www.amf-france.org).

All documents that must be made available to shareholders (such as the Articles of Association, minutes of Shareholders' Meetings, historical financial information and the evaluations and opinions given by experts at the Company's request included or referred to in this Universal Registration Document) may be consulted at the Company's registered office at 36, avenue de l'Europe – 78140 Vélizy-Villacoublay, France.

All regulatory information, as defined in Article 221-1 of the AMF General Regulations, is available on the Company's website.

The Company's financial information for the years ended December 31, 2018 and December 31, 2019 incorporated by reference into this document was previously presented in the 2018 Registration Document and the 2019 Registration Document, which were filed with the AMF on March 12, 2019 under number D.19-0135 and on March 13, 2020 under number D.20-0126, respectively, and was the subject of reports by the Statutory Auditors, which contained no observations.

# 6.5 INFORMATION ON HOLDINGS

At the date of this Universal Registration Document, the Company did not have any holdings in the share capital of other companies.

# 6.6 RECENT EVENTS

Since December 31, 2020, the Company has published the following press releases:

- on January 6, 2021, a press release entitled: Carmat outlines commercial and development plan for its total artificial heart.
- on February 1, 2021, a press release entitled: Carmat appoints Pr. Christian Latrémouille as Director of Surgical Affairs.
- on February 10, 2021, a press release entitled: Carmat reports its financial results for 2020, and confirms its 2021 prospects.
- on February 10, 2021, a press release entitled: Carmat receives FDA approval to use the new version of its artificial heart in the US Early Feasibility Study (EFS)

The full text of these press releases may be viewed on the Company's website, https://www.carmatsa.com/en/documentation/?p_thema=press-release.

Carmat plans to communicate on the completion of significant milestones in its clinical trials. In accordance with good clinical practice and subject to regulatory requirements or special circumstances, Carmat will not communicate on patient implants and the health of said patients individually.

# 6.7 CROSS-REFERENCE TABLES

## 6.7.1 UNIVERSAL REGISTRATION DOCUMENT CROSS-REFERENCE TABLE

The table below provides cross-references with the information required under Annex 1 of Commission Delegated Regulation (EU) 2019/980, presented in order.

SECTION 1
PERSONS RESPONSIBLE, THIRD PARTY INFORMATION, EXPERTS' REPORTS AND COMPETENT AUTHORITY APPROVAL

| | | |
|---|---|---|
| • 1.1. Name of the person responsible | Section 6.1.1 | Page 182 |
| • 1.2. Declaration by the person responsible | Section 6.1.2 | Page 182 |
| • 1.3. Experts' reports | Not applicable | |
| • 1.4. Third-party information | Not applicable | |
| • 1.5. Statement from the competent authority with no prior approval | | Page 2 |

SECTION 2
STATUTORY AUDITORS

| | | |
|---|---|---|
| • 2.1. Current and alternate Statutory Auditors | Sections 6.2.1 and 6.2.2 | Pages 182 and 183 |
| • 2.2. Statutory Auditors who have resigned, been removed or have not been re-appointed | Section 6.2.3 | Page 183 |

SECTION 3
RISK FACTORS

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|---|---|---|
| • 3.1. Risks specific to the issuer and its business sector | Chapter 2 | Page 53 |

SECTION 4
INFORMATION ABOUT THE ISSUER

| | | |
|---|---|---|
| • 4.1. Legal and commercial name of the issuer | Section 5.1.1 | Page 138 |
| • 4.2. Place of registration, registration number and LEI | Section 5.1.2 | Page 138 |
| • 4.3. Date of incorporation and length of life of the issuer | Section 5.1.3 | Page 138 |
| • 4.4. Domicile and legal form of the issuer, applicable legislation, website | Section 5.1.4 | Page 138 and page 15 |

SECTION 5
BUSINESS OVERVIEW

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| • 5.1. Principal activities | Section 1.3 | Page 32 and page 8 |
| • 5.2. Principal markets | Sections 1.1 and 1.2 | Pages 18 and 27 |
| • 5.3. Important events in the development of the issuer | Sections 3.1.1 to 3.1.5 | Page 68 |
| • 5.4. Strategy and objectives | Section 1.5 | Page 42 |
| • 5.5. Extent of dependence on patents or licenses, industrial, commercial or financial contracts or new manufacturing processes | Sections 1.5.4 and 3.1.10 | Pages 44 and 75 |
| • 5.6. Statements regarding the issuer's competitive position | Section 1.2.2 | Page 28 |
| • 5.7. Investments | Section 3.1.2 | Page 71 |

SECTION 6
ORGANIZATIONAL STRUCTURE

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|---|---|---|
| • 6.1. Brief description of the group | Sections 5.1.5 and 5.1.6 | Page 138 |
| • 6.2. List of significant subsidiaries | Not applicable | |

SECTION 7
OPERATING AND FINANCIAL REVIEW

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| • 7.1. Financial condition | Section 3.1.1 | Page 68 |
| • 7.2. Operating results | Section 3.1.1 | Page 68 |

SECTION 8
CAPITAL RESOURCES

| | | |
|---|---|---|
| • 8.1. Information on the issuer's capital resources | Sections 3.2.1 and 3.2.2.4.6 | Pages 78 and 90 |
| • 8.2. Cash flows | Sections 3.1.1 and 3.2.1 | Pages 68 and 78 |
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# 6.8 GLOSSARY

Actuator
A device that controls the movement of a fluid or a solid.

Acute heart failure
Sudden inability of the heart to provide sufficient blood flow and supply oxygen to the organs. The symptoms are severe. It occurs either following a heart attack (see myocardial infarction) that caused lesions to an area of the heart, or following a sudden incapacity of the body to compensate for chronic cardiac insufficiency (see chronic heart failure).

AFSSAPS
French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Aliments et Produits de Santé). This agency evaluates and monitors the safe use of health products, examines their quality in the laboratory and inspects production, distribution and testing sites. It also produces information campaigns to ensure the correct use of health products. It was replaced by the ANSM (see corresponding entry) by French Law no. 2011-2012 of December 29, 2011.

Angiotensin-converting enzyme (ACE) inhibitors
Drugs reducing vascular resistance.

Annuloplasty
Procedure to tighten or reinforce the mitral valve.

ANSM
French National Drug and Health Product Safety Agency (Agence nationale de sécurité du médicament et des produits de santé). This French public institution's objective is to evaluate the health risks of health products for humans. It has authority over the regulation of biomedical research.

Anticoagulant
Drug limiting blood-clotting to avoid the formation of clots by acting on coagulation factors other than platelets (see corresponding entry). Dosages are complex: too much risks hemorrhage, not enough risks thromboembolic events. Use at high dosage is required for all metal or plastic implanted devices that are not hemocompatible and are the source of numerous complications.

Aorta
The aorta is the body's largest artery, supplying oxygenated blood from the left ventricle to all parts of the body.

Atrium
One of the two small upper chambers of the heart that receive blood before passing it into the corresponding ventricle. Each atrium communicates with the corresponding ventricle through an atrioventricular valve, the tricuspid valve on the right and the mitral valve on the left.

Beta blockers
Drugs which reduce the cardiac rhythm and output to decrease blood pressure.

Bioprosthetic (valves) or bioprosthesis
An artificial valve made from animal tissue in order to replace a failing heart valve. By extension, a medical device containing animal tissue.

Bpifrance
French public investment bank (Banque Publique d'Investissement), which now includes the activities of Oseo Innovation (formerly ANVAR), aiming to promote innovation through financial guarantees and partnerships.

Cardiogenic shock
Inability of the myocardial pump function to generate adequate blood flow to the peripheral organs.

CE marking
A declaration by the manufacturer certifying that the product complies with the applicable legal requirements and European directives (meeting a number of conditions including safety, efficacy and traceability).

Chemically treated animal pericardial tissue
A double-walled sack that contains the heart and the roots of the large blood vessels of animal origin (bovine, porcine or equine) treated with a sterilizing fixative, glutaraldehyde. Known to be the least thrombogenic biomaterial and does not bring about transplant rejection.

Chronic heart failure
The incapacity of the heart to provide sufficient blood flow to deal with the oxygen needs of the various organs. The main causes of chronic heart failure are angina and myocardial infarction, high blood pressure, valvular heart disease and myocardial degeneration. In each of these cases, the result is the progressive destruction of the cardiac muscle with loss of its ability to contract.

Cleanroom
Room or suite of rooms where the concentration of particles is controlled in order to minimize the introduction, generation and retention of particles inside, generally with a specific industrial or research aim. Factors such as temperature, humidity and relative pressure are also maintained at a precise level.

Clinical Trial Authorization (CTA)
Authorization issued by the French national agency that evaluates drug safety (Agence Nationale de sécurité du Médicament – ANSM). One of two authorizations required to carry out biomedical research on humans in France, the other being that of the Patient Protection Committee (Comité de Protection des Personnes – CPP) (see corresponding entry).

Coagulation (blood)
Blood clot formation. This is the body's normal reaction to stop blood loss. However, when clots form in the heart, a blood vessel or in an implanted device, they may obstruct blood flow and cause a pulmonary embolism or cerebrovascular accident.

Compliance
In medical terms, the ability of a hollow organ to change volume under the influence of a variation in pressure.

Coronary disease
Decrease in the power of one or more arteries of the heart (coronary arteries), resulting in angina and myocardial infarction (heart attack).

Critical Event Committee (CEC)
Committee made up of members who are completely independent from the sponsor and study investigators, established as part of the ISO 13485 standard and the Good Clinical Practice (GCP) guidelines. The Committee's role is to review all adverse events, serious or otherwise, and to determine their causal link with the device under investigation.

Data Safety and Monitoring Board (DSMB)
Board made up of members who are completely independent from the sponsor and study investigators, established as part of the ISO 13485 standard and the Good Clinical Practice (GCP) guidelines. The Board's role is to review all study data and issue an opinion to the sponsor on whether to continue the inclusion of subjects in the clinical study.

Destination Therapy (DT)
Definitive implantation, as opposed to bridge therapy.

Diastole
The period of relaxation of the muscle tissue of the chambers of the heart that allow them to fill with blood.

Diuretic
Drug that removes excess fluids, to decrease pressure on the heart and prevent pulmonary edema.

Etiology
The study and analysis of the causes of diseases.

Ex vivo
Refers to tests which are performed on cadavers (see in vivo).

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.

Hardware-in-the-Loop (HIL) simulation
Real-time simulation that makes computers believe they are navigating the actual system.

Hemocompatibility
A measure of the compatibility between non-living materials used in medical devices that are in contact with blood and other organs.

Hemolysis
Destruction of red blood cells, releasing hemoglobin into the blood plasma and reducing oxygen-carrying capacity.

High blood pressure
Condition associated with cardiovascular disease characterized by arterial pressure greater than normal levels, causing an increase in the left ventricular volume.

HUD
See Humanitarian Device Exemption (HDE).

Human whole blood
Unprocessed blood containing plasma, red blood cells, white blood cells and platelets.

Humanitarian Device Exemption (HDE)
FDA approval process allowing a device to be marketed without evidence of effectiveness (only data relating to the safety of the device are required). The FDA calls a device approved in this way a Humanitarian Use Device (HUD). This approval limits the number of devices that can be released on the US market to 4,000 per year.

Hyperlipidemia
Condition caused by abnormally high levels of fat in the blood.

Hypertrophy
Excessive growth of an organ or body tissue.

Immunosuppressant
Drugs that limit the body's immune reactions in order to reduce rejection risk following a transplant. The most well known is cyclosporin.

Incidence
The number of new cases of a disease observed during a given period and in a specific population. It differs from the prevalence, which is a status measurement that counts all cases (new or not) at a given time.

Inotrope
Drug increasing the force of heart muscle contractions. Dependence on inotropes marks the terminal phase of heart failure.

In silico
Refers to tests that are performed on computers and/or by digital simulation.

Investigational Device Exemption (IDE)
Approval process allowing a device to be used during a clinical study with the aim of generating the safety and efficacy data required to obtain PMA.

In vitro
Refers to tests that take place outside the organism, in the laboratory or on a test bench. Originally, these tests were carried out in glass tubes.

In vivo
Refers to tests which are performed in living organisms (see also ex vivo).

Ischemia
Decrease of the arterial blood flow to an organ.

ISO standards
Standards created by the International Organization for Standardization (ISO) in order to guarantee reliable and good quality products and services.

Medical Board
Professional, administrative and legal body for the defense and regulation of the medical profession.

Mitral valve
Valve in the heart that separates the left atrium from the left ventricle.

Myocardial infarction
Necrosis (death) of part of the cardiac muscle. In plain language, a heart attack. It occurs when one or more coronary arteries become blocked slowing the flow of blood, and therefore oxygen, to the cells of the myocardium (the muscular tissue of the heart), causing them to suffer (painful sensation) and potentially die.

New York Heart Association (NYHA) Classification
A scale based on symptoms that aims to quantify and monitor the functional impact (on activity) of cardiac insufficiency for an individual.

Orthotopic
Refers to the transplantation of an organ to its normal anatomical location.

Patient Protection Committee (Comité de Protection des Personnes – CPP)
The Patient Protection Committee's role is to ensure that all biomedical research projects on humans carried out in France comply with medical, ethical and legal considerations aimed at ensuring the protection of the persons participating in the research.

Platelet aggregation inhibitor
Drug preventing blood platelets, which are partly responsible for blood coagulation (see corresponding entry), from sticking together and forming the beginning of a clot. The best known is aspirin.

Polyetheretherketone (PEEK)
A high-performance plastic with a unique combination of properties used for its strength in the medical, aeronautical, automobile, electronics, food and industrial sectors.

Polyurethane
A plastic material used in varnishes, paints and synthetic rubbers obtained through polymerization.

Pre-Market Approval (PMA)
FDA approval process before the marketing of a device. It requires exhaustive safety and effectiveness data, notably by means of a clinical study (IDE).

Prevalence
Measurement of the state of health of a population at a given time, which can be expressed as a percentage. For a given pathology, the prevalence is obtained by dividing the number of people affected at a given time by the size of the total population.

Product Lifecycle Management (PLM)
Software used to create and maintain product definition throughout their life cycle, from initial offering to end of useful life. PLM covers the management of product definition, including configuration, development and project management.

Proteinic
Concerning proteins.

Pulmonary artery
Arteries that carry blood from the heart to the lungs.

Pulmonary edema
Pulmonary alveoli fill with blood plasma that has passed through the walls of capillaries (small blood vessels). Acute pulmonary edema (APE) is a medical emergency and typically results in cardiac decompression.

Pulmonary embolism
Situation where a blood clot blocks a pulmonary artery.

Pulsatile
Rhythmic pulsations of the heart beat.

Red blood corpuscles
Red blood cells.

Reduced ejection fraction
Terminal chronic heart failure in patients with an ejection fraction measurement under 40%.

Research Tax Credit (RTC)
Financial aid created to encourage research and development efforts within companies.

Septicemia
Serious generalized infection when bacteria from a local infection enter the bloodstream of an organism.

Stasis
In medical terms, this refers to the abnormal stagnation of blood in an organ.

Stroke
Sudden neurological damage due to blockage of blood flow or hemorrhage in the brain.

Systole
Contraction phase of the chambers of the heart muscle to eject the blood it contains.

Telemetry
Means of monitoring certain biological, particularly cardio-respiratory, or technical factors, remotely.

Thromboembolism
Condition characterized by the formation of blood clots in veins (thrombus) which, upon detaching, may cause

embolisms (sudden blockages of blood vessels).

Thrombogenic, thrombogenicity
Refers to causing a thrombus (blood clot).

Thrombosis
Obscuration, through the formation of a clot (thrombus), of an artery, vain or cardiac chamber (embolism). The blood no longer flows or supplies organs.

Total orthotopic artificial heart
A total artificial heart (TAH) is a device that replaces the natural heart. It is different from a ventricular assistance device, which supports the function of a diseased heart.

Transplantation
Surgical operation consisting in replacing a diseased organ with a healthy one.

US Food and Drug Administration (FDA)
Regulatory agency that authorizes the marketing of drugs and medical devices in the United States.

Vasodilator
Drug which relaxes blood vessels to increase the blood and oxygen flow to the heart without increasing its workload.

Design and production:
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