

AT THE HEART OF TECHNOLOGY

**2020 half-year results and
outlook**

September 9, 2020

Safe Harbor



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Speakers



Stéphane Piat

Chief Executive Officer

- Over 20-year experience in the medical device business
- Previously Divisional Vice President Global Market Development at Abbott
- Johnson & Johnson Cordis (2002-2007)



Pascale d'Arbonneau

Chief Financial Officer

- Over 25-year experience in Finance
- Previously VP-Finance at GSK
- Graduate of ESCP Europe

Agenda



- I. Progress made by CARMAT in the first half of 2020
- II. Half-year results
- III. Strategy and outlook



I. Progress made by CARMAT in the first half of 2020

CARMAT program



Available technology

LVAD/BIVAD/TAH* displaying numerous limitations

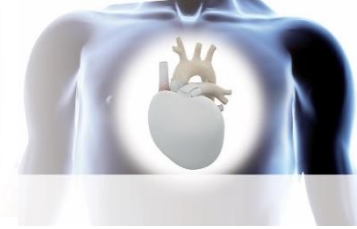
Need for a reliable new-generation solution

Adapts to the patient physiology through an autoregulation system and improved hemocompatibility to provide a better quality of life

Objective of the clinical program

Validate these hypotheses and prepare for commercialization

Impact of the COVID-19 epidemic on CARMAT in the first half



Manufacturing

- Manufacturing impacted by supplier delays

PIVOTAL study

- Access to hospitals made difficult or even impossible

EFICAS study

- Delayed discussions

EFS

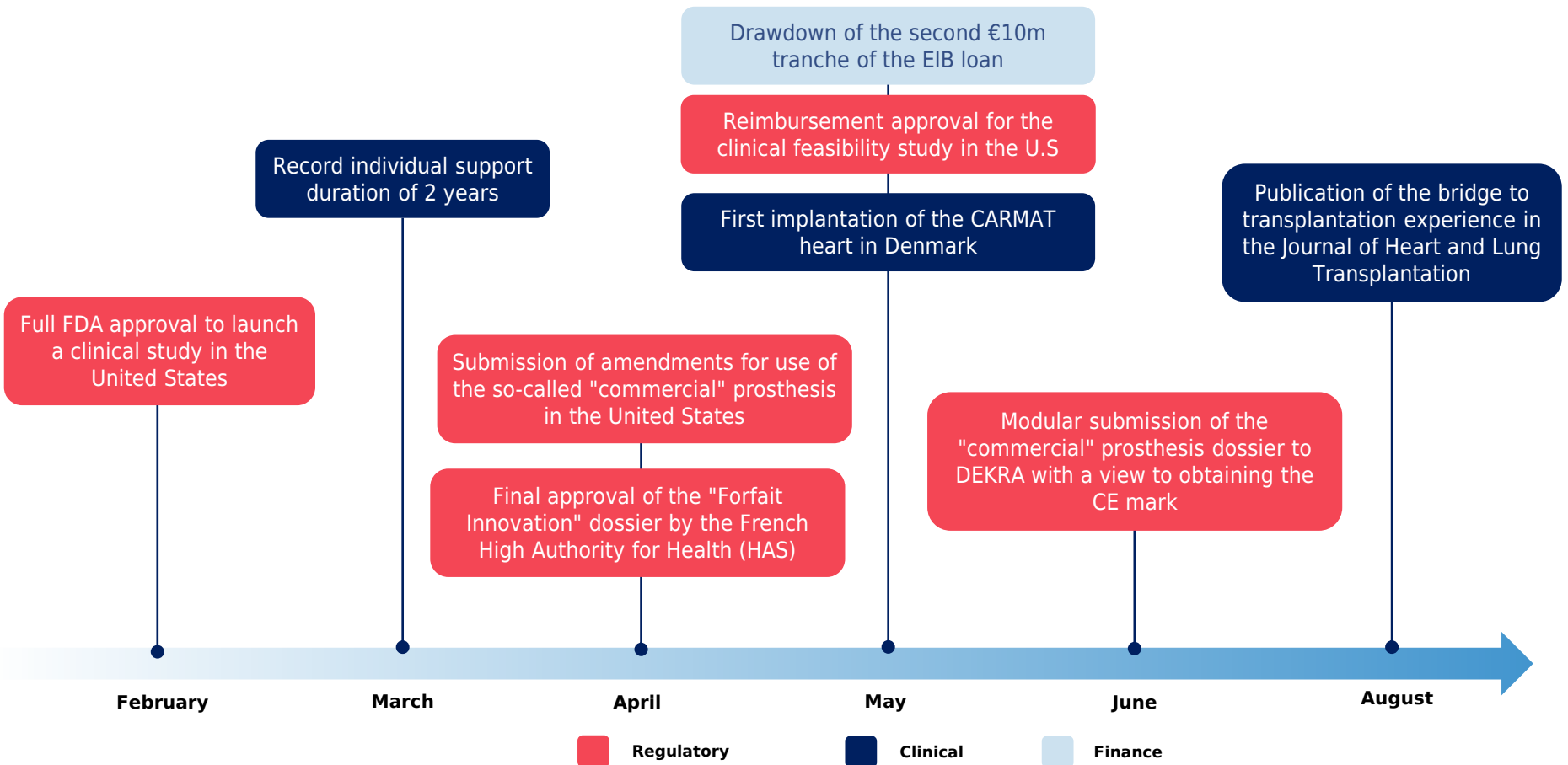
- No impact on discussion times with FDA, CMS and hospitals

Commercialization

- Ongoing discussions with DEKRA

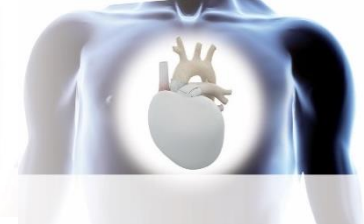
Impact of around 3 months on the PIVOTAL and EFICAS studies

H1 2020: a period of preparation



Major breakthroughs in the CE marking process, materialized by the submission of the technical file for the so-called "commercial" configuration

PIVOTAL study in progress



- Enrollment finalized for the 1st part of the study (10 patients)



- 3 patients from the 2nd part of the study enrolled



- Enrollment target: **20 patients** in total



- Primary endpoint of the study: **6-month** survival

Finalization of recruitment postponed to the Q1 2021 due to COVID-19
Objective of obtaining the CE marking by the end of 2020 is maintained

Summary of clinical experience to date



- **Optimization of the surgical experience**
 - 100% success rate of the procedure
 - Reduction in surgery time thanks to experience
 - Heart transplantation possible after CARMAT implantation
- **Promising functioning**
 - Recovery times comparable to the norm for high-risk patients
 - Proper functioning of the physiological self-regulation of the prosthesis adapting it to the patient's activity
- **Favorable safety profile**
 - No hemolysis, no stroke, no digestive bleeding in the 1st cohort
- **Encouraging clinical results**
 - 73% of the first 11 patients reached the primary endpoint

CARMAT is positioned as a credible solution for patients suffering from biventricular heart failure

Details of clinical experience to date



73%

- Survival at 6 months in the first 11 patients, i.e. 8 patients

100%

- Heart transplant success in 5 patients eligible for transplantation
 - Survival rate of 80% at 12 months after transplant

**~8
years**

- **95 months of cumulative support within the framework of the PIVOTAL study**
 - Including a record 25 months in individual support

**Encouraging results both as a bridge-to-transplant and
a destination therapy**

Production of a new carried configuration



New batteries



New cables



New connections



These changes have been made in order to strengthen the safety profile of the system as well as the quality of life of patients



II. Half-year results

Simplified P&L



| In €m | 2020 (6 months) | 2019 (6 months) |
|-------------------------|--------------------|--------------------|
| Net sales | - | - |
| Operating income | 0.3 | 0.7 |
| Operating expenses | (20.9) | (24.4) |
| Operating Result | (20.6) | (23.7) |
| Financial Result | (1.0) | (0.8) |
| Non-recurring items | - | - |
| Research tax credit | 0.8 | 0.5 |
| Net Result | (20.8) | (24.0) |

- **Prosthesis not yet marketed - no sales in 2020**
- **Operating expenses under control :**
 1. Enhancing the reliability of production processes, securing supplies and increasing output at the Bois-d'Arcy plant
 2. Finalization of the commercial configuration of the prosthesis
 3. Preparing for commercialization in Europe
 4. Continuation of clinical activities (PIVOTAL study in progress, preparation of the EFS study in the United States)
 5. Slight slowdown in spending due to the COVID-19
- **Slight increase in financial interest - impact of the EIB loan**

Simplified Balance Sheet



| In €m | 30.06.20 | 31.12.19 |
|----------------------------------|-------------|-------------|
| Fixed Assets | 5.6 | 5.6 |
| Trade receivables | 6.3 | 3.6 |
| Cash and cash equivalents | 45.3 | 55.5 |
| Total ASSETS | 57.2 | 64.7 |
| Shareholders' equity | 3.6 | 24.5 |
| Other shareholders' equity | 14.5 | 14.5 |
| Provision for risks & charges | 0.6 | 0.7 |
| Liabilities: | 38.4 | 25.0 |
| - Financial debt | 27.5 | 16.4 |
| - Trade liabilities | 10.9 | 8.6 |
| Total LIABILITIES | 57.2 | 64.7 |

- **€45m in cash as of June 30, 2020**

Strong cash position



| Change in cash | In €m |
|---------------------|--------|
| Cash as of 31.12.19 | 55.5 |
| Financing cash flow | 10.0 |
| Operating cash flow | (19.8) |
| Investing cash flow | (0.4) |
| Cash as of 30.06.20 | 45.3 |



- **EIB loan second tranche drawdown in May 2020: +€10m**
- **Last tranche of €10m that can be used at any time (drawing conditions met)**

CARMAT's visibility enables it to carry out its project through to CE marking and commercial launch



III. Strategy and outlook

Upcoming developments



1. Continuous improvement of manufacturing processes in Bois-d'Arcy and securing supplies
2. Finalization of the PIVOTAL study
3. Launch of the EFICAS study in France as part of the “*Forfait Innovation*”
4. Launch of implants in the U.S. Early Feasibility Study
5. Obtaining the CE Marking and preparing the company for commercialization

All strategic projects are progressing well



1

Continuous improvement of manufacturing processes in Bois-d'Arcy

- Increased reliability of prostheses following the implementation of new manufacturing processes
- Control of the processes allowing a better fluidity of the production and its ramp-up
- Focus on suppliers to ensure production continuity

Processes are set to support clinical and commercial demand



2 Finalisation of the PIVOTAL study

- 13 patients enrolled to date
- Extremely encouraging data
- Estimated time to complete the enrollment: 2 quarters (Q1 2021)

CARMAT plans to activate 4 centres in France to alleviate the organizational difficulties linked to COVID-19



3 Launch of the EFICAS study in France (*Forfait Innovation*)

Aims of the study:

- Helping the adoption of the CARMAT heart
- Supporting the "Value proposition" of the CARMAT heart
- Getting a reimbursement in France

Status:

- Favorable opinion from HAS received in February 2020 to enroll 52 patients
- Budget negotiations in the final phase
- Objective: to treat the first patients by the 2nd quarter of 2021

A large French study to collect medico-economic data for the reimbursement of the prosthesis

Early Feasibility Study (EFS) in the USA



4 Launch of implants in the United States

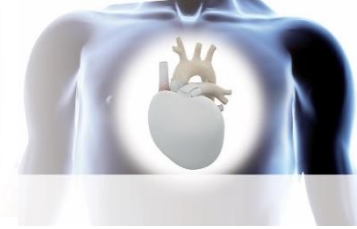
Status:

- Reimbursement from CMS (Centers for Medicare & Medicaid Services) obtained
- Obtaining authorizations from the Ethics Committees (4/7)
- Signature of study contracts with the designated centers (3/7)
- Signature of purchase orders (2/7)

Last step:

- FDA approval for the use of the so-called "commercial configuration"

Objective: to treat a first patient in Q4 2020



5 Preparing the company for commercialization

CE marking



- Few outstanding questions on the technical dossier
- Robust clinical file with 13 patients
- Objective of obtaining the CE Marking by the end of 2020 maintained

Marketing



- Mapping work carried out in Germany
- Preparation of the "promotional" strategy in progress

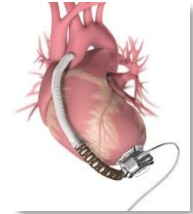
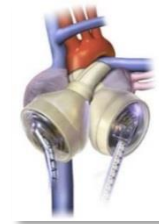
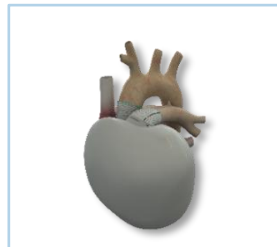
Objective: to be operational for a launch in 2021

CARMAT, a unique and eagerly awaited solution



4 essential requirements to provide physiological support without complications*:

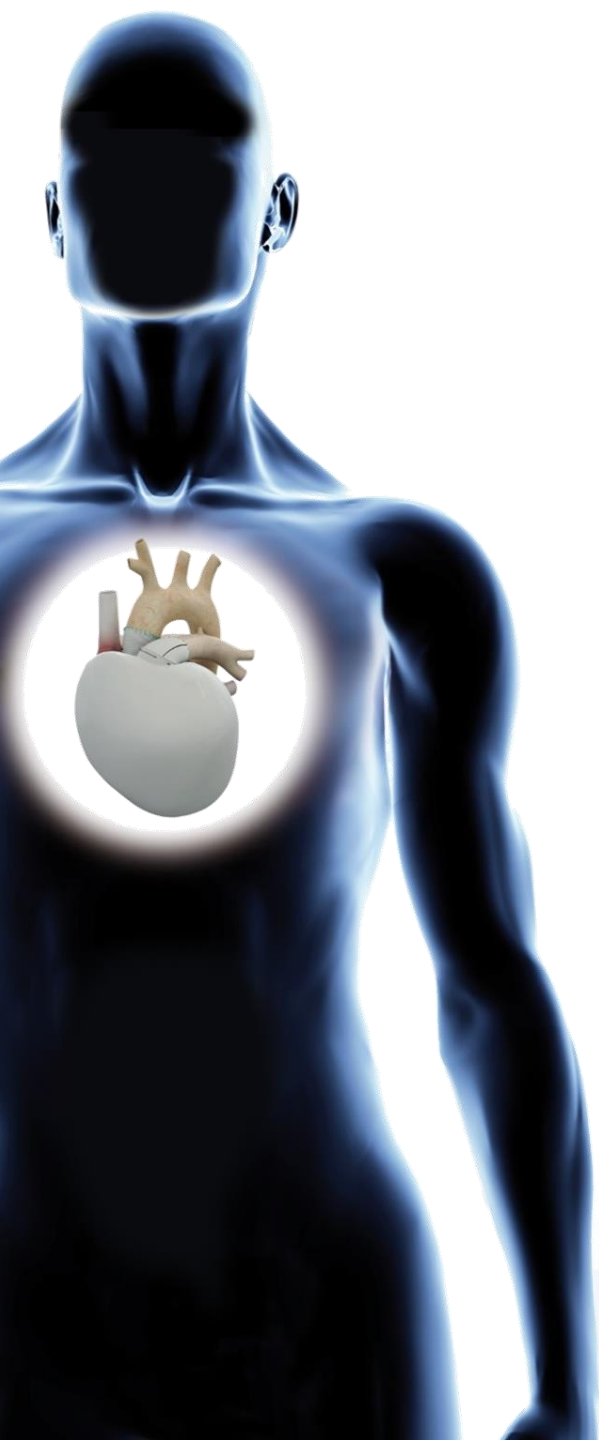
- Biventricular support
- Pulsatility
- Self-regulation
- High biocompatibility



| | CARMAT TAH | Syncardia TAH | BVAD | LVAD + pRVAD | LVAD |
|------------------------------|---------------|------------------|------|-----------------|------|
| Biventricular support | ✓ | ✓ | ✓ | ✓ | ✗ |
| Pulsatility | ✓ | ✓ | ✗ | ✗ | ✗ |
| Self-regulation | ✓ | ✗ | ✗ | ✗ | ✗ |
| High biocompatibility | ✓ | ✗ | ✗ | ✗ | ✗ |

- **The only system to offer real physiological support**

* Rogers JC et al. *N Engl J Med* 2017; Money L et al. *ASAIO J* 2020; Lai JV et al. *ASAIO J* 2020
Mehra M. *Eur Heart J* 2017; Murase S et al. *J Heart Lung Transpl* 2020



Thank you for your attention!