PRESS RELEASE

Carvolix Appoints Anne Lange as Chair of its Board of Directors Confirming the Acceleration of its Ambitions and Reports 2026 Half-Year Results

- Appointment of Anne Lange as Chair of the Board of Directors of Carvolix, alongside a strengthened governance structure (directors, non-voting board observer and international Scientific Advisory Board);
- Commercial expansion for the TAVIPILOT® platform, with the CE marking dossier filed for TAVIPILOT® Software and the FDA dossier filed for TAVIPILOT Robot;
- Positive three-year clinical results for Kalios®: primary endpoint on mitral regurgitation met in 100% of patients, with no device-related adverse events;
- Strengthened financial resources: a €10 million tranche secured on June 24, 2026, bringing H1 equity financing to €20 million, and a €30 million structured bond financing with Claret Capital Partners on August 6, 2026.

Aix-en-Provence, France, September 30, 2026 – 5:45 pm CEST – Carvolix (ISIN: FR0013333077 – Ticker: CVX), a French commercial and clinical-stage medical technology company specializing in the international development, industrialization and commercialization of breakthrough AI-driven mini-robots and biomimetic implants, announces the appointment of Anne Lange as Chair of its Board of Directors and today reports its 2026 half-year results (for the period ended June 30, 2026).

"Our first-half performance reflects continued execution of our roadmap, with a clear focus on the commercialization of TAVIPILOT®, advancing Kalios® towards the US market, and securing the resources needed to deliver on our commitments" **said Sébastien Ladet, Chief Executive Officer of Carvolix.**

GOVERNANCE UPDATE: ANNE LANGE APPOINTED CHAIR OF THE BOARD OF DIRECTORS

On September 30, 2026, the Board of Directors of Carvolix appointed Anne Lange as Chair of the Board of Directors. Anne Lange joined the Carvolix Board in April 2026.

A graduate of the École nationale d'administration (ENA), Anne Lange held senior management positions within the French government and then at Cisco in the United States, before founding Mentis, a software company for smart cities. An entrepreneur, technology investor and board member of major companies, she currently sits on the boards of Pernod Ricard, Orange and Peugeot Invest.

In appointing Anne Lange as its Chair, Carvolix has chosen a leader accustomed to challenging innovation strategies in order to accelerate growth, who will open up new networks internationally and in AI while ensuring rigorous governance.

Anne Lange succeeds Liane Teplitsky, who had chaired the Board of Directors since January 2026. Having been appointed to new executive responsibilities within another group, Liane Teplitsky wished to hand over the chairmanship of the Board while remaining a director of Carvolix, whose development she will continue to support.

"I would like to thank Liane Teplitzky, the Board of Directors, the founders and the shareholders for their confidence. With Carvolix and its management team, we have the opportunity to build a global MedTech leader, developing and commercializing medical devices that can save the lives of hundreds of thousands of patients. Carvolix will bring the benefits of advanced technologies designed in France to increasingly significant markets worldwide. Carvolix has the potential to make a major difference for patients" ***commented Anne Lange, Chair of the Board of Carvolix.***

This appointment follows on from the strengthening of Carvolix's Board initiated in April 2026, with:

- the appointment of Rute Fernandes as non-voting board observer (censeur), bringing additional strategic, operational and international expertise;
- the arrival of Paul LaViolette, CEO of Pulse Biosciences, and Dr. Mirvat Alasnag, M.D., on the international scientific Advisory Board, strengthening the Group's scientific, clinical and strategic leadership;

- the appointment of Michel Therin as Vice-Chair of the Board.

TAVIPILOT®: COMMERCIAL ROLLOUT IN THE US, REGULATORY PROGRESS IN EUROPE

Since the March 19, 2026 press release on the 2025 annual accounts, the TAVIPILOT® AI-driven robotic platform has passed several key milestones.

Clinical data presented at New York Valves 2026 —SAITO program demonstrated, in 30 patients:

- a 100% procedural success rate, with no device-related safety events;
- valve positioning within less than one millimeter of the target in 100% of cases;
- a reduction of up to 50% in procedure time, together with reductions in fluoroscopy time and contrast volume, compared with reference studies (PARTNER 3, SMART BEV), while the treated population presented a risk profile approximately 3 times higher (STS-PROM score of 5.70 versus 1.9);
- for TAVIPILOT® Robot, confirmed success in the First-in-Human study in 10 patients, with no robot-related safety events, and the start of the second clinical study (SAIRO), with 7 patients successfully treated to date.

Several significant regulatory milestones: the CE marking dossier for TAVIPILOT® Software was filed, with certification expected before the end of the year and a commercial launch in Europe targeted for early 2027. The FDA dossier for TAVIPILO®T Robot was filed, with clearance expected in early 2027 for a commercial launch of the complete platform.

Commercial rollout of TAVIPILOT® Software in the United States: as part of the controlled launch with the first reference centers, the company shared feedback from Rush University Medical Center (Chicago), together with an initial series of 10 procedures successfully performed over the summer.

KALIOS® MITRAL RING: POSITIVE 3-YEAR CLINICAL RESULTS

On June 15, 2026, Carvolix announced positive 3-year clinical results for Kalios®, from the European Optimise II pivotal study.

- 100% of the patients assessed (15 patients having reached 3-year follow-up, out of 20 patients at 2 years, across five European centers) met the primary endpoint: mitral regurgitation of grade ≤ 2+;
- no device-related adverse events were reported over 3 years;
- mitral leaflet coaptation length improved, from 3.9 mm at baseline to 6.4 mm at 3 years.

These results reinforce the positioning of Kalios®, the only percutaneously adjustable mitral annuloplasty ring, in a surgical mitral valve repair market estimated at US$1.5 billion across the United States and Europe, growing at 3.5% per year, and which could avoid a repeat procedure for 30% to 40% of patients within a 5-year horizon.

Carvolix plans to file with the FDA, ahead of a US commercial launch targeted for 2027.

STRENGTHENED FINANCIAL RESOURCES

New €10 million tranche (June 24, 2026) Carvolix secured a €10 million tranche, bringing total financing raised in the first half of 2026 to €20 million. The transaction resulted in the issue of 2,976,190 new shares at a price of €3.36 per share, subscribed in equal parts by Edwards Lifesciences and funds managed by Truffle Capital (€5 million each).

€30 million structured bond financing (August 6, 2026) Carvolix concluded a €30 million structured bond financing with Claret Capital Partners, comprising €20 million of convertible bonds and €10 million amortizing bonds (maximum dilution limited to 8.6% of existing share capital).

Following the drawdown of tranche A, Carvolix's resources are secured through February 2027, and through October 2027 in the event of full drawdown.

INCLUSION IN 3 NEW INDICES AND EXPANDED COVERAGE

Inclusion in the Euronext indices (March 23, 2026) Carvolix was included in the CAC® Small, CAC® Mid & Small and CAC® All-Tradable indices, strengthening the visibility of the share, its liquidity and its exposure to index funds.

ODDO BHF initiated coverage of Carvolix (July 29, 2026) with a target price of €10.50, in a report entitled "A multi-specialty interventional platform." Carvolix is now covered by five research firms: Allinvest Securities, Kepler Cheuvreux, Portzamparc (BNP Paribas Group), TP ICAP and ODDO BHF.

LAUNCH OF THE FRENCH–SAUDI SAF-MD PROGRAM

On August 24, 2026, on the occasion of the visit to France of Crown Prince Mohammed bin Salman, Truffle Capital, Carvolix SA and Carvolix Saudi LLC (newly incorporated) announced the launch of the French–Saudi SAF-MD medical exchange and cooperation program.

- An initial three-year program, renewable by mutual agreement, covering training exchanges of 6 months to 2 years between French and Saudi practitioners in the fields of interventional cardiology and neurovascular procedures;
- Co-chaired by Professor Stéphan Haulon (France) and Dr. Mirvat Alasnag (Saudi Arabia), the program will enable the integration of artificial intelligence and robotics into medical procedures, in line with the health objectives of Saudi Vision 2030;
- Carvolix Saudi LLC is also studying the creation of a MedTech manufacturing site in Saudi Arabia, intended to serve several regions.

Events in the Middle East could affect or delay the achievement of Carvolix's objectives in Saudi Arabia.

OUTLOOK

In the coming months, Carvolix intends to continue executing its strategy combining medical robotics and biomimetic implants. Its main priorities include:

- continuing the commercial rollout of TAVIPILOT® Software in the United States;
- obtaining CE marking for TAVIPILOT® Software and preparing its commercial launch in Europe (early 2027);
- filing a US marketing application for Kalios® in 2027 and resuming the European clinical study;
- continuing the pivotal phase of the clinical study of the Artus urinary sphincter;
- advancing the Mitrapilot and Artedrone programs;
- developing the French–Saudi SAF-MD cooperation program and the activities of Carvolix Saudi LLC.

Having strengthened its governance and its financial resources, Carvolix intends to become a global leader in the interventional treatment of heart disease and stroke, and to democratize access to complex cardiovascular and neurovascular procedures.

FIRST-HALF 2026 FINANCIAL RESULTS

The Board of Directors, meeting on September 30, 2026, approved the consolidated half-year results as of June 30, 2026, prepared in accordance with IFRS. These accounts have been subject to a limited review by the statutory auditors. The complete consolidated half-year financial statements are available on the Company's website: www.carvolix.eu

In €K, at June 30 (Consolidated financial information – IFRS)	06/30/2026	06/30/2025
	6 months	6 months
Other operating income	1,267	577
Purchases consumed	(2,778)	(1,719)
External charges	(4,038)	(2,706)
Personnel expenses	(6,326)	(4,090)
Taxes and duties	(154)	(39)
Net additions to provisions	-	-
Other current operating income and expenses	(133)	59
Depreciation and amortization	(2,282)	(1,173)
CURRENT OPERATING INCOME (LOSS)	**(14,444)**	**(9,091)**
OPERATING INCOME (LOSS) after share of net income of equity-accounted companies	**(14,444)**	**(9,091)**
Financial income (expense)	366	(311)
Income tax	195	30
NET INCOME (LOSS)	**(13,883)**	**(9,372)**

Cash flows from operating activities	(13,043)	(6,791)
Cash flows from investing activities	(4,258)	5,213
Cash flows from financing activities	16,167	5,689
Increase (decrease) in cash	(1,134)	4,113
Cash and cash equivalents	613	5,336
Money-market funds (SICAV) presented in other current financial assets	6,405	15

OPERATING EXPENSES REFLECTING THE ENLARGED CONSOLIDATION SCOPE AND TAVIPILOT® SPENDING

Current operating loss stood at €14.4 million in the first half of 2026, compared with €9.1 million a year earlier. This change mainly reflects two factors: the consolidation of Artedrone and Caranx Medical since the end of January 2026, and the acceleration on TAVIPILOT®, with the completion of clinical trials and the preparation of the robot's submission dossier to the FDA.

Other operating income: €1.3 million, compared with €0.6 million. It consists exclusively of the research tax credit, whose increase results from the consolidation of Caranx Medical and Artedrone.

Purchases consumed: €2.8 million, compared with €1.7 million (+€1.1 million). The increase comes mainly from external studies (+€0.9 million), notably in connection with the consolidation of the two companies.

External charges: €4.0 million, compared with €2.7 million (+€1.3 million). They increased mainly as a result of consulting, engineering and recruitment fees (+€0.6 million) engaged to prepare the FDA dossier for TAVIPILOT®. Rental charges and shared-office costs also increased (services outside the scope of IFRS 16).

Personnel expenses: €6.3 million, compared with €4.1 million (+€2.2 million). The consolidation of Caranx and Artedrone contributed €1.4 million, with the average headcount rising from 76 to 102 employees. The remaining €0.8 million corresponds to the increase in the IFRS 2 charge related to BSPCE founder share warrants (€1.1 million, compared with €0.3 million), which has no cash impact.

Depreciation and amortization: €2.3 million, compared with €1.2 million (+€1.1 million). It mainly comprises the amortization of technologies recognized as assets under the purchase price allocation (€1.9 million, compared with €0.9 million), up as a result of the acquisition of Caranx Medical and Artedrone. This charge has no cash impact.

FINANCIAL INCOME AND EXPENSES

Financial income came to +€0.4 million, compared with an expense of €0.3 million in the first half of 2025. This improvement is essentially due to the change in the fair value of derivative liabilities (IFRS 9), at +€1.2 million compared with +€0.4 million, a non-cash item. It offsets the financial expenses for the half-year:

- accrued interest on the Mivana and PIAVE Artus repayable advances: €624K (€641K in H1 2025);
- amortized cost of the bond loan subscribed by certain shareholders in June 2025: €44K (€10K);
- financial interest on lease liabilities (IFRS 16): €41K (€17K);
- interest on the €2.5 million shareholder current-account advance granted by a Truffle Capital fund (received in April 2026 and repaid in June 2026): €27K;
- unwinding of the discount on repayable advances (IAS 20): €25K (€9K).

After an income tax credit of €0.2 million, the net result is a loss of €13.9 million, compared with a loss of €9.4 million in the first half of 2025.

CASH FLOWS AND LIQUIDITY POSITION

Cash consumption from operating activities reached €13.0 million, compared with €6.8 million in the first half of 2025. It reflects the progress of the Group's development programs and clinical studies, as well as the broadening of its scope of consolidation.

Investing cash flows amounted to −€4.3 million. They correspond mainly to the net investment of €6.4 million in money-market funds (SICAV), partly offset by the cash of the companies acquired at the end of January 2026.

In the first half of 2025, they were positive at €5.2 million, due to net disposals of money-market funds (+€5.4 million).

Financing cash flows amounted to +€16.2 million. They mainly comprise:

- capital increases, net of fees: +€19.6 million;
- the subscription of BSA warrants and the exercise of BSPCE founder share warrants: +€0.1 million;
- the repayment of the commercial paper subscribed with BNP Paribas: −€2.5 million;
- repayments of innovation loans (−€0.4 million), of the state-guaranteed loan (PGE) (−€0.3 million) and of lease liabilities (−€0.2 million).

The €2.5 million shareholder current-account advance from Truffle Capital, received and repaid during the half-year, has no net effect. In the first half of 2025, financing cash flows (+€5.7 million) came mainly from the issue of the bond loan (+€5.4 million), the pre-financing of the research tax credit (+€0.6 million) and Italian financing dedicated to digitalization and production efficiency (+€0.3 million, granted by BNL and the financial agency of the Piedmont Region).

As of June 30, 2026, the Group's cash and liquid investments amounted to €7.0 million (€0.6 million cash and €6.4 million money-market funds). They stood at €1.8 million as of December 31, 2025, and €5.4 million as of June 30, 2025.

2026 HALF-YEAR FINANCIAL REPORT

The 2026 half-year financial report was filed with the Autorité des Marchés Financiers on September 30, 2026 and is available to the public. It is also available on the Company's website, in the "Investors" section.

About Carvolix

Carvolix is a French medical technology company at the commercial and clinical stages, founded by Truffle Capital (also founder of the leading European biotechnology company), with the ambition of becoming a global leader in the treatment of structural heart diseases and strokes, the leading causes of mortality and disability worldwide. Carvolix develops novel AI- and imaging-powered mini-robots that make complex procedures accessible to interventional cardiologists, as well as biomimetic heart valves.

For more information: www.carvolix.eu

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Forward-looking statements

This press release contains forward-looking statements relating to the clinical development, regulatory pathway, commercial plans and market estimates of Carvolix. These statements are based on current expectations and assumptions and involve known and unknown risks and uncertainties — including, without limitation, those relating to the results of clinical studies, sample sizes, follow-up data, regulatory approvals and market conditions — which could cause actual results to differ materially from those announced. The clinical results described relate to a limited number of patients and remain subject to longer-term follow-up and to publication

following peer review. Forward-looking statements speak only as of the date of this press release, and Carvolix undertakes no obligation to update them, except as required by law.

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