PRESS RELEASE

ESTIMATED FULL-YEAR 2025 RESULTS:

Carvolix reports estimated financial information for the 2025 fiscal year and confirms its strategic transformation toward medical robotics and innovative cardiovascular implants

- **Strategic focus on interventional cardiology, with the creation of Carvolix** following the acquisition of Caranx Medical and Artedrone, combining biomimetic implants with AI-driven autonomous micro-robots
- **Total financing of up to €30 million, with an initial €10 million tranche secured** from Truffle Capital and Edwards Lifesciences to support the development of the new entity
- **Commercial launch of the TAVIPILOT software** in the United States, an AI-powered guidance system for transcatheter aortic valve implantation (TAVI)

Aix-en-Provence, March 19, 2026 – 5h45 p.m. CEST – Carvolix (formerly Affluent Medical) (ISIN: FR0013333077 – Ticker: CVX), a French medical technology company specializing in the development of medical robotics and innovative implants, reports estimated consolidated financial information for the 2025 fiscal year relating to Affluent Medical, which became Carvolix on January 30, 2026. The consolidated financial statements, currently under audit, will be approved by the Board of Directors no later than April 29, 2026.

The year 2025 was marked by several major strategic milestones for the Company. In particular, the acquisitions of Caranx Medical and Artedrone were announced on December 19, 2025 (Full press release here) and successfully completed on January 30, 2026 (Full press release here), following approval by the Shareholders' Meeting. These acquisitions were supported by a €10 million financing from Edwards Lifesciences and Truffle Capital, at a price of €2.34 per share, representing a 19% premium to the closing share price on 30 January 2026.

On this occasion, Sébastien Ladet, Chief Executive Officer of Carvolix, stated:

*"**The beginning of 2026 marks a major transformation for our Company with the creation of Carvolix**, combining AI-guided autonomous medical mini robots with innovative biomimetic implants. This strategic evolution **significantly expands our product portfolio in a market estimated at €23 billion**.*

*The clinical and regulatory achievements obtained for the **TAVIPILOT** platform, including **FDA clearance** and the **commercial rollout of the software in the United States**, demonstrate the potential of our approach to democratize access to complex cardiovascular procedures.*

*At the same time, we have continued to execute on our roadmap, with progress toward an FDA submission in 2026 for the **Kalios™** mitral ring, advancement of clinical studies with promising results for the **Epygon** biomimetic mitral valve, and completion of the pilot clinical study of the **Artus** urinary sphincter.*

Supported by the continued commitment of our shareholders and secured financing, ***we are approaching the next stages of Carvolix's development with confidence****, with the ambition of becoming a global leader in microrobotics for interventional cardiology to replace heart valves and treat stroke[1]."*

STRENGTHENING OF FINANCIAL RESOURCES

As part of this strategic transformation, the Company has secured an **initial €10 million financing tranche**, subscribed by funds managed by Truffle Capital and by Edwards Lifesciences.

This financing is part of a broader transaction of up to **€30 million**, intended to support the clinical and technological development of the entire product portfolio.

The funds raised will notably be used to finance:

- the commercial launch of the TAVIPILOT software in the United States
- the structural heart programs Kalios™ and Mitrapilot (formerly Epygon)
- the continued clinical development of the Artus urinary sphincter
- the development of the robotic platform dedicated to stroke treatment

This financing is expected to extend the Company's cash runway beyond May 2026.

TAVIPILOT ROBOTIC PLATFORM: CLINICAL AND REGULATORY PROGRESS

Since July 2025, the **TAVIPILOT** robotic platform has achieved several major milestones.

The **TAVIPILOT software**, based on artificial intelligence and designed to guide transcatheter aortic valve implantation (TAVI) procedures, has received clearance from the **U.S. Food and Drug Administration (FDA)**.

The commercial rollout of TAVIPILOT software has commenced in the United States, initially focusing on leading centers under a controlled early-access deployment during the first months. **The recent appointment of a U.S. Director of Business Development** to oversee the initial phase of the commercialization plan.

A clinical study conducted in Australia demonstrated the software's performance across ten TAVI procedures, all successfully completed **with a 100% success rate and no complications**, confirming the system's precision in valve positioning.

In December 2025, the **TAVIPILOT Robot** platform reached a significant milestone with its **first clinical use**, performed at Macquarie University Hospital in Sydney as part of a First-in-Human study. This study is progressing according to plan, with submission to U.S. authorities targeted in H1 2026.

These results represent a key step forward in the robotization of cardiovascular procedures and support the execution of our vision: to democratize access to complex, life-saving procedures through AI-driven mini robots.

KALIOS™ MITRAL RING: ACCELERATED REGULATORY PATHWAY TOWARD THE U.S. MARKET

In January 2025, Kalios™ reached a key regulatory milestone with the FDA, validating an accelerated pathway to the U.S. market through a *De Novo* process, based on existing data from the European OPTIMISE II pivotal study. No additional patients were required, which could enable the Company to significantly shorten its submission and time-to-market timeline.

[1] According to Truffle MedTech 10 Index (18/03/2026), **Carvolix ranks #1 in Europe and #6 worldwide** among publicly listed interventional MedTech companies in the pre-commercial or early commercialization stage. Read the full press release here. Read full press release here.

Combined with the exclusive purchase option granted to Edwards Lifesciences, a global leader in structural heart disease, this milestone underscores the potential of Kalios™ and strengthens its strategic positioning in the North American market.

During the second half of the year, the Company continued adapting its supply chain to meet FDA requirements, including the selection and adjustment of manufacturing processes with suppliers, which required optimizations to achieve the Company's business objectives.

The Company is also working on resuming the European clinical study, with at least 15 clinical centers across Europe selected during strategic meetings held at the EACTS cardiac surgery congress. This study aims to support the CE marking submission.

The Company's priority remains the submission of a U.S. marketing application in 2026, paving the way for potential commercialization, subject to decisions by Edwards Lifesciences.

EPYGON MITRAL VALVE: PROMISING CLINICAL RESULTS

In October 2025, the Company presented preliminary clinical results from two patients implanted with the Epygon biomimetic mitral valve at the **TCT cardiology conference in San Francisco and at London Valves**.

The data presented notably show:

- elimination of mitral regurgitation
- a reduction of more than **50% in left ventricular workload**
- restoration of the natural vortex in the left ventricle, leading to promising clinical improvements

These results confirm the potential of Epygon's unique biomimetic design, aimed at reproducing the physiological blood flow dynamics within the left ventricle.

ARTUS URINARY SPHINCTER: CLINICAL VALIDATION AND PREPARATION OF THE PIVOTAL PHASE

The **Artus** artificial urinary sphincter continued its clinical development in 2025.
Results from the pilot phase of the European clinical study were presented at several international conferences, including the **Urological Association of Asia and the International Continence Society**.

Preliminary data show a **median reduction in urinary leakage** (measured by pad weight) of **74% at 3 months and 80% at 6 months in implanted patients**, confirming the device's potential to significantly improve the quality of life of patients suffering from urinary incontinence.

Following these encouraging results, the Company is continuing the **pivotal phase of the clinical study**, aimed at validating the device's efficacy in several dozen patients.

OUTLOOK

In the coming months, the Company intends to continue executing its strategy aimed at combining biomimetic implants with medical robotics.

Key strategic priorities notably include:

- the commercial launch of the TAVIPILOT software in the United States
- the submission of regulatory filings for the Kalios™ mitral ring, as well as for the TAVIPILOT robot, to the FDA
- continued progress in the pivotal phase of the Artus urinary sphincter
- the development of robotic platforms for interventional cardiology and stroke treatment

With the creation of Carvolix, the Company aims to become a leading global MedTech player, capable of democratizing access to complex cardiovascular procedures through robotics and artificial intelligence.

ESTIMATED CONSOLIDATED FINANCIAL INFORMATION FOR THE 2025 FISCAL YEAR

The Group's main financial indicators, prepared in accordance with IFRS, are presented in the table below.

These figures correspond to estimated consolidated financial information, currently under audit and not yet approved by the Board of Directors.

Given that the acquisitions of Caranx and Artedrone were completed after the fiscal year-end, the estimated consolidated financial information for the 2025 fiscal year relates solely to the scope of Affluent Medical, which became Carvolix on January 30, 2026. It does not include the acquired companies, as no pro forma consolidated financial information as of December 31, 2025 including these entities has been prepared.

The full consolidated financial statements will be included in the Universal Registration Document, which will be made available on the Company's website no later than April 30, 2026: www.carvolix.eu

in K€ (Estimated consolidated financial information, unaudited – IFRS)	12/31/2025 12 months	12/31/2024 12 months
Other income	-	4 118
Other operating income	900	1 232
Cost of goods consumed	(3 129)	(3 262)
External expenses	(4 903)	(6 887)
Payroll expenses	(7 673)	(7 240)
Tax and duties	(75)	(65)
Allocation to provisions	(15)	11
Other current operating income and expenses	16	(150)
Depreciation and amortization	(2 187)	(2 396)
CURRENT OPERATING INCOME (LOSS)	**(17 066)**	**(14 639)**
Impairment of non current assets (Kardiozis)	(6 627)	-
OPERATING INCOME (LOSS)	**(23 693)**	**(14 639)**
Financial result	(1 401)	(242)
Income tax	123	142
NET INCOME (LOSS)	**(24 971)**	**(14 739)**
Operating cash-flow	(11 550)	(11 324)
Investing cash-flow	5 248	(480)
Financing cash-flow	6 825	11 370
Net cash-flow for the period	**524**	**(434)**
Cash and cash equivalent	**1 747**	**1 223**
Other current financial assets	**10**	**5 393**

Other income as of December 31, 2024, includes the portion allocated under IFRS in connection with the global agreement with Edwards Lifesciences relating to the grant of a worldwide non-exclusive license for the Epygon valve.

Other operating income mainly consists of the R&D Tax Credit (Crédit d'Impôt Recherche) for the periods presented, amounting to €0.9 million in 2025 and €1.2 million in 2024.

The change in operating expenses between 2024 and 2025 reflects overall stability. As of December 31, 2025, the Company had an average workforce of 68 employees, compared to 69 as of December 31, 2024. External expenses decreased slightly, primarily due to the completion of the pilot study for the Epygon valve.

Goodwill related to the Kardiozis technology, as well as the tangible and intangible assets associated with this technology, totaling €6.6 million, were fully impaired as of December 31, 2025. This reflects the fact that this technology is no longer part of the strategic priorities of the new Carvolix group.

Depreciation and amortization expenses in 2024 and 2025 notably include charges related to internally developed technologies, as recognized at the time of the Group's creation in 2018.

Financial result as of December 31, 2025, notably includes changes in accrued interest on repayable advances, offset by changes in the fair value of the derivative liability related to Kreos warrants (BSA) and convertible bonds issued in June 2025.

Net consolidated loss as of December 31, 2025, amounted to €25.0 million, compared with a net consolidated loss of €14.7 million as of December 31, 2024.

As of December 31, 2025, cash and cash equivalents, as well as investments in money market funds (presented under other current financial assets under IFRS), amounted to a total of €1,747 thousand, compared with €6,616 thousand as of December 31, 2024.

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About Carvolix

Carvolix is a French medical technologies company, commercial and clinical stage, founded by Truffle Capital, aiming to become a global leader in the treatment of structural heart disease and brain stroke, two of the leading causes of mortality and disability worldwide. Carvolix develops novel AI- and imaging-driven mini-robots that make complex procedures accessible to interventional cardiologists, as well as next-generation biomimetic heart valves.

Discover more at www.carvolix.eu

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