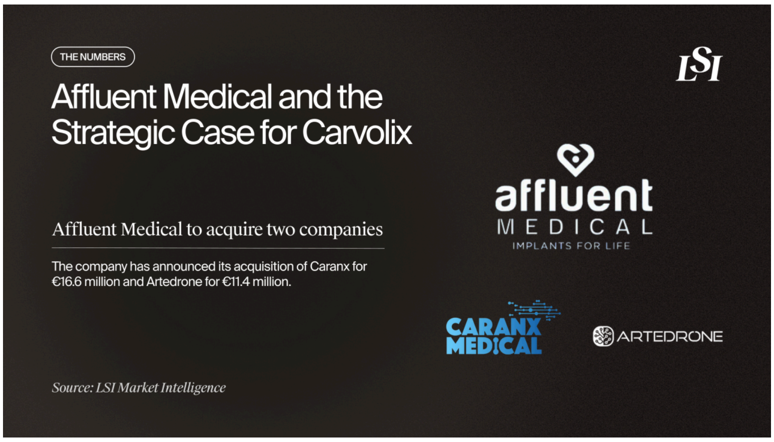

Affluent Medical and the Strategic Case for Carvolix

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It's the last full week of 2025 and we wouldn't blame you if you've been busy hitting the eggnog and missed the news last week of Affluent Medical's acquisition of Artedrone and Caranx Medical.

If that's the case or you just want to learn why this is a big move, we've got you covered.

So what happened?

Affluent Medical, a French clinical-stage medtech company, will acquire and combine the three businesses into a new entity to be called Carvolix. Terms of the acquisition are as follows:

- Caranx is being acquired for €16.6 million. The company brings its FDA-cleared TAVIPILOT Software and its autonomous robot, TAVIPILOT Robot. The robot has been successfully used in the treatment of two patients.
- Artedrone is being acquired for €11.4 million. The company is developing a robotic solution for stroke treatment.

There are additional earn-out considerations for both companies contingent on milestones being achieved.

For Affluent's part, the company brings expertise in minimally invasive biomimetic device development. Their products include: Kalios, an adjustable mitral annuloplasty ring; Epygon, a transcatheter mitral valve replacement (TMVR) implant; and, Artus, an artificial urinary sphincter for treating urinary incontinence.

All three companies sit within the Truffle Capital portfolio, with the deal

There is quite a bit going on here. As we like to do, let's take a look at *the numbers* and share our thoughts on this opportunity.

The Numbers

Over the course of this publication we have talked many times about the opportunities associated with the transcatheter valve market. Transcatheter valve repair and replacement have changed the way patients with structural heart disease are treated.

In 2025, we estimate that nearly 300,000 valve procedures will be performed in the US. Over the five-year forecast period ('24–'29), we project these procedures will grow at a CAGR of 5.0%. This estimate includes both surgical and transcatheter procedures across all valve locations (aortic, mitral, pulmonary, and tricuspid).

Today, the transcatheter approach is used in nearly 75% of all (eligible) valve procedures. For the majority of patients, this means a cardiothoracic surgical robot is unlikely to be utilized. The future is clearly minimally invasive.

When looking at the size of the valve device market, an even more compelling narrative emerges.

Based on global sales, five-year growth rates for select transcatheter devices are as follows:

- Transcatheter Aortic Valves: 9.9%
- Transcatheter Mitral Valves: 23.1%
- Transcatheter Tricuspid Valves: 16.6%
- Transcatheter Pulmonary Valves: 21.4%

These are meaningful growth rates. You might be asking, "So what?"

The answer is this: as we have seen in other surgical robotics markets, whoever controls the approach, meaning the robot, also controls the revenue from consumables and implants.

Put another way, **there is roughly $15B in implant sales alone up for control**.

Certainly, this is interesting food for thought when considering who is backing whom in this space.

The Edwards Lifesciences' Investment

Speaking of following who is backing whom, one of the most interesting elements of this story is the investment from Edwards. To better understand why this intrigued us, let's briefly recap the emerging competitive landscape for structural heart-focused surgical robots.

There is nuance in this landscape. A number of companies are pursuing catheter-based robotic systems, but only a small subset are developing, or signaling intent to develop, platforms for structural heart procedures.

The biggest "fish" in this ocean of opportunity is Capstan Medical. The behemoth, Intuitive.

Moray Medical was developing a microfluidic robotic system for the treatment of leaky heart valves. At the time of publication, the company appears to be defunct. The IP may ultimately be acquired by another entity.

There are plenty of unknowns and possibilities here. One could speculate endlessly about what prompted Edwards to invest in Carvolix. Much of the combined company's offering is synergistic with Edwards and its position as a leader in structural heart disease management.

This could be as straightforward as Edwards cementing commercial rights for TAVIPILOT or Affluent's structural heart devices. However, it could also be the foundation for a future acquisition.

The Carvolix Plan

Building a medtech company carries many challenges. Obtaining capital to sustain R&D and bring a product to market is an ongoing effort that many executives are acutely familiar with.

Fortunately, Carvolix has a plan to mitigate some of the capital acquisition burden. The company has a commercial-ready product - TAVIPILOT. The solution is an AI-driven guidance system for transcatheter aortic valve replacement (TAVR). Carvolix plans to retain direct commercialization rights for the solution in Europe, while pursuing commercial partners in the US, Middle East, and Asia. This initiative will be supported by the aforementioned first tranche of funding the company has received.

These funds have also been allocated to accelerate clinical and marketing progress for Artus, Epygon, and Artedrone's robotic platform for stroke treatment.

Carvolix has stated that it expects to extend its cash runway through a partnership deal for Artus.

Furthermore, the company will remain a public company and will continue to raise capital through equity financing rounds.

It takes a lot to bring a surgical robot to market. Carvolix certainly differentiates itself from its peers through its early access to commercial products.

There was a lot to unpack in this announcement. So much so, that we didn't even get to the stroke component.

There is a lot of work involved in building a medtech company. That effort increases significantly when building a surgical robotics company, and even more so when the robot must operate within the complexities of the cardiovascular system (as seen with recent examples like Swan Endosurgical).

Going forward, the plan for Carvolix appears practical. The combination of investors, management experience, and shared commercial strategy will hopefully allow the company to grow and support the development of a surgical robotics program.

These robots are still years away from broad use in patients, but early enthusiasm from multiple medtech stakeholders is a strong signal that this is an area to watch.

Until next week,

Henry Peck , Gavin Kennedy , Nicholas Talamantes

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Merging 3 synergystic MedTech companies (R&D synergies with AI & robotics platforms, commercial synergies targetting the interventianal cardiologist) is key for Carvolix, ensuring high NPV, attracting talents, decreasing risks and increasing upside for shareholders. A great plan to save patients' lives, adressing major medical needs and markets. W ...more

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Chief Business Officer at LSI | Medtech & Healthtech Engineer, GT...

Dr Philippe Pouletty thank you and Truffle Capital for your added insights, congratulations on the news. We're thrilled to amplify work like this that can benefit providers and patients across the globe.

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