Evaluate Vantage

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Interview – Heartflow gets $240m to start selling at last

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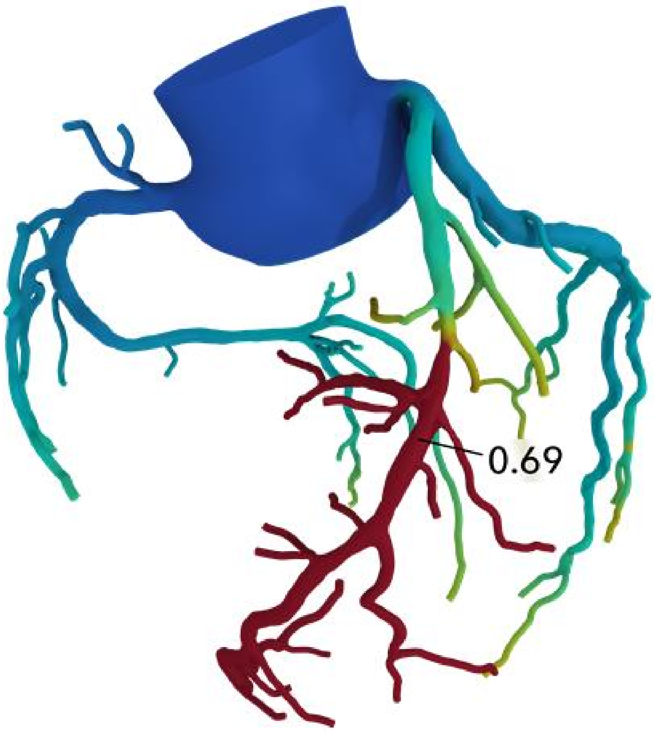
A $240m fundraising closes and medtech's newest unicorn emerges blinking into the light. Heartflow, the maker of software that analyses CT images to aid in the diagnosis of coronary artery disease, is now valued at $1.5bn – and its technology is not yet even on sale.

"We have been in beta," says the group's chief executive, John Stevens. "In healthcare, unless there's a reimbursement pathway, it's impossible to commercialise. We made a very conscious decision to gather data, and when insurance companies and governments say they will pay for it, then Heartflow will begin to commercialise."

That point has now been reached. Heartflow's technology is approved and reimbursed by both Medicare, which set up an entirely new payment code for the product, and insurance companies in the US.

"We are literally this quarter just starting to commercialise in the US," Mr Stevens says.

The technology uses CT images of a patient's coronary vasculature to create a digital 3D model of the arteries and simulate blood flow, identifying blockages. The process takes around two hours, though Mr Stevens believes that the turnaround time could be brought down to less than an hour by 2019.



An image created using Heartflow's FFRct software

Heartflow seems to have proved to payers' satisfaction that the procedure is as good as or better than, and much cheaper than, the current method of assessing blockages, fractional flow reserve. FFR involves inserting pressure-sensing wires into the coronary arteries.

In the UK, for instance, not only is the Heartflow procedure available within the NHS, treatment guidelines produced by the National Institute for Health and Care Excellence (Nice) have been changed to recommend use of the software, which is called FFRct.

“Nice came out in 2017 with an entirely new pathway for virtually all patients with chest pain and suspected CAD,” says Mr Stevens. “They said a CT of the coronaries should be the first test. If that scan is normal you’re pretty much done. But if it’s abnormal, that’s where we come into play.”

The NHS and Medicare reimbursement prices for FFRct are £700 ($971) and $1,450 per patient respectively.

Heartflow’s latest funding will be used to ready the company for its new commercial phase. But it will also be used to fund several large clinical trials, despite FFRct’s widespread regulatory approvals.

“For sceptical cardiologists there’s no such thing as enough data,” says Mr Stevens. The company is conducting a handful of large randomised trials with the aim of overwhelming the naysayers with data backing FFRct’s clinical utility and cost-effectiveness.

It is also constantly working on software updates, and is putting in place a collaboration with Imperial College London that will involve a Heartflow team joining Imperial’s Biomedical Image Analysis group. The team will develop algorithms for extracting models of the coronaries from 4D CT data and improving image acquisition and reconstruction.

No pressure

One way and another the money ought soon to start rolling in, which is doubtless something of a relief for the company’s investors. Last month’s series E round was put up by Baillie Gifford and Wellington Management, along with unnamed existing investors. Over the years Heartflow has drummed up funding from a number of sources: VCs, hedge funds, strategic investors, and, with Baillie Gifford and Wellington, large mutual funds.

“They’ll be large supporters at the time we decide to become public,” says Mr Stevens.

Heartflow's funding

Financing date	Financing round	Investment ($m)	Investor
Feb 2018	Series E	240.0	Baillie Gifford, Wellington Management, Existing shareholders
May 2016	Series D (second close)	64.0	Undisclosed
Feb 2015	Series D	35.9	Undisclosed
Feb 2014	Series C (third close)	29.7	Undisclosed
Feb 2012	Series C (second close)	10.0	Undisclosed
Dec 2011	Series C	65.0	Undisclosed
Feb 2011	Series B (second close)	6.3	Undisclosed
Aug 2010	Series B	14.1	Undisclosed
Apr 2010	Series A	1.6	Undisclosed
Jul 2009	Seed capital	0.2	Undisclosed
-	Undisclosed	-	Emergent Medical Partners, HealthCor Partners, US Venture Partners
-	Undisclosed	-	GE Ventures
	Total	**466.8**	

Source: EvaluateMedTech.

Mr Stevens is cagey on the details of any future listing but says that the next three to six quarters is the most realistic timing: “I’d be surprised if we exited 2019 private, let’s put it that way.”

Heartflow is not the only diagnostic imaging company to be thinking about an IPO. Siemens is to spin off its Healthineers unit on March 16, and Heartflow has an interest in the German company’s success (*Event –*

Siemens and the incredible shrinking IPO, March 5, 2018).

"We have a very intimate collaboration agreement with Siemens, both commercially and on the technology side," says Mr Stevens. He says there is a lot of enthusiasm for the coming spin out, with the independent Healthineers emerging as a more agile company.

Heartflow is also partnered with the other two major imaging companies, GE Healthcare and Philips (*Philips expands from imaging to treatment, October 5, 2017*). These collaborations mean FFRct can be used to analyse images produced on these companies' machines, and vastly increase Heartflow's commercial reach. "There are not many hospitals in the world that those three companies don't touch," Mr Stevens says.

Heartflow certainly cannot be faulted for failing to set itself up for an effective launch. But over the past decade or so it has sold itself to its investors on the promise of enormous success. Anything less than that risks coming as a major disappointment.

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