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Freenome aims to take on the big beasts

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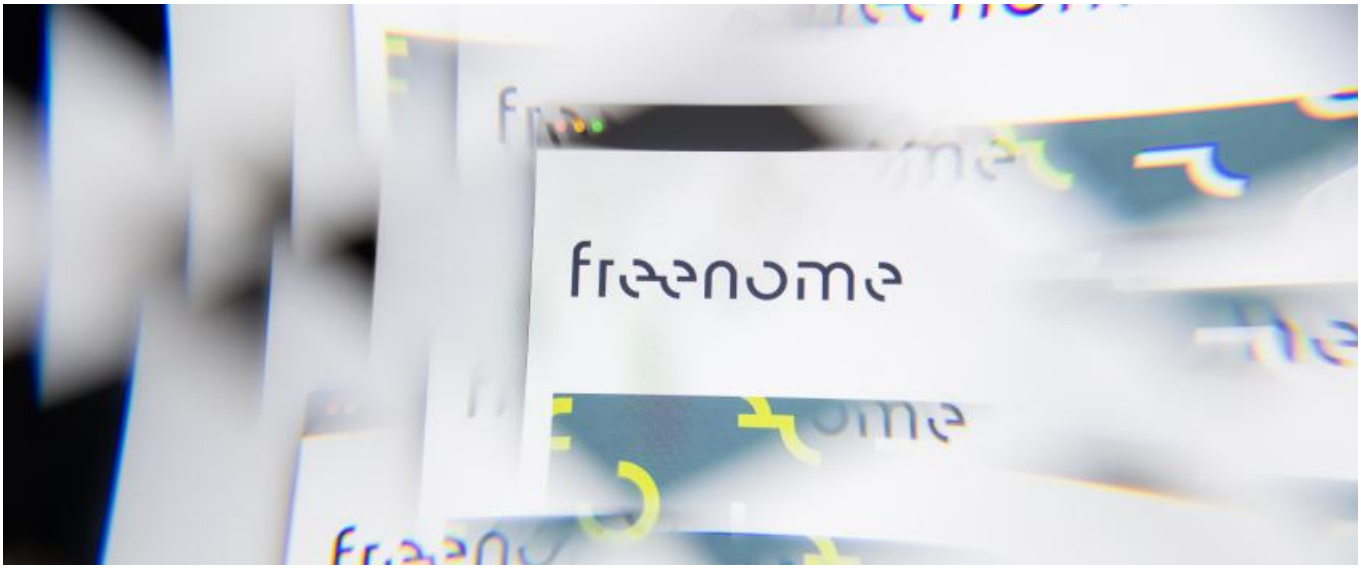

Forthcoming data in colorectal cancer screening could put the company's liquid biopsy on the market – but it looks like Guardant might get there first.

The private liquid biopsy developer Freenome has eschewed the multi-cancer path to focus instead on a very specific setting for its first blood test: screening for colorectal cancer.

But the readout of its vast trial in this setting has been delayed from this year to next, and in the meantime Guardant Health, an established liquid biopsy player, will report data from a very similar study of a rival test. Freenome is banking on its novel approach, looking at RNA and proteins as well as DNA, winning out in the clinic. It might be a harder task to win out in the market.

"Most companies start off building a diagnostic test with the technology first and then try to use the technology to have multiple indications. We flip that on its head," Jimmy Lin, Freenome's chief scientific officer, tells *Evaluate Vantage*.

Freenome is targeting colorectal cancer first because of the overwhelming evidence that if the disease is caught and treated early there is a major improvement in outcomes. Consequently there are also clinical guidelines recommending screening, and a clear path to reimbursement.

The company's unnamed test is in the 25,000-strong study Preempt-CRC, with a plan to file for premarket approval on the results. Preempt-CRC had been expected to report this year, but the company tells *Vantage* that the data will now come in 2023.

Screen test

The current ruler of the non-invasive colorectal cancer screening niche is Exact Sciences, with its stool test Cologuard (*Liquid biopsy developers take aim at colorectal cancer, February 10, 2022*). The argument made by liquid biopsy developers is that blood testing is more acceptable to patients than faecal tests, and would be widely preferred if accuracy was as good.

But the real fly in Freenome's ointment is not Exact but Guardant. That group is aiming to add another cancer blood test to its tumour agnostic Guardant360 assay, approved in 2020. The pivotal Eclipse trial of Guardant's colorectal screen Lunar-2 is to report this summer, so the best case could see this test approved by the end of this year.

Mr Lin is unruffled. "Guardant's technology is solely focused on next-generation sequencing of nucleotides," he says. "Our technology includes nucleotides as well as protein data."

This “multiomics” approach gives a more holistic picture of a patient’s cancer, he says, and also allows detection of adenoma – a pre-cancerous condition that allows the cancer to be headed off before it even develops. “That’s where we’re really going to be shining,” he says.

The proof of this assertion will come with the Preempt-CRC data. But some seem to be convinced already.

Freenome is phenomenally well funded, having raised over $800m in venture cash from no fewer than 34 separate investors, including Google, Novartis and Roche. And earlier this year Roche made a separate investment of $290m, putting Freenome firmly in unicorn territory.

Roche, of course, has its own liquid biopsy, the pan-cancer FoundationOne Liquid CDx. Perhaps it is marking Freenome for a future acquisition, the idea being that it would be able to compete directly against Guardant in not one but two settings.

Mr Lin swerves this question. He hints that, as with Novartis, Roche’s interest might be more to do with the application of Freenome’s tech to aid in either drug discovery or choosing patients for clinical trials. He adds that there is a collaborative aspect to the Roche-Freenome relationship, with the sharing of technology and expertise in both directions.

Multiomics for multi-cancer

And, even within cancer diagnosis, Freenome’s platform could be applicable beyond colorectal. In February the group began enrolling into a trial called Vallania to explore the use of multiomics to detect multiple cancers. The plan is to test the same blood sample using the current colorectal diagnostic and an as-yet to be developed test for other cancers.

Vallania is designed to find out what these tumour types might be; lung and pancreatic cancers are first on the list. Theoretically, it might be possible for Freenome to come up with a pan-cancer test almost by default.

This would involve “taking a real deliberate stepwise approach”, Mr Lin says, adding cancers one by one, or a few at a time. But if Freenome does manage to develop a multi-tumour test it would enter a market with two players already in situ. As with colorectal screening, the technology will need to distinguish itself in terms of performance if Freenome is to make its mark.

Selected liquid biopsies				
Company	**Liquid biopsy**	**Tumour type**	**Intended use**	**Status**
Guardant Health	Guardant360	Pan-cancer	Helps assign targeted therapy	Approved in US Aug 7, 2020, price approx $6,800
	Lunar-2	Colorectal	Screening	Pivotal Eclipse trial to report mid-2022
	Lunar-2	Lung	Screening	Pivotal Shield trial to report 2024
	Reveal	Colorectal	Postsurgical, detects disease recurrence	Launched as LDT Feb 16, 2021
Roche	FoundationOne Liquid CDx	Pan-cancer	Helps assign targeted therapy	Approved in US Aug 27, 2020, price $5,800
Grail (Illumina)	Galleri	Pan-cancer	Screening and identification of tumour origin	Launched as LDT Jun 4, 2021, price $949; approval poss 2023
	Unnamed assay	Pan-cancer	Postsurgical, detects disease recurrence	In development
Exact Sciences	Multicancer early detection (MCED)	Pan-cancer	Screening	FDA breakthrough device status; pivotal trial to start 2022
	Unnamed assay	Colorectal	Postsurgical, detects disease recurrence	Correct-MRD II trial to report 2028
Natera	Signatera	Pan-cancer	Postsurgical, detects disease recurrence	Launched as LDT Aug 21, 2017; Natera will seek individual FDA approvals as CDx
	Signatera	Colorectal, melanoma, lung	Tracks response to immunotherapy	Bespoke trial to report 2025
Freenome	Unnamed assay	Colorectal	Screening	Preempt CRC trial to report 2023
	Unnamed assay	Lung, pancreatic	Screening	Vallania trial to report 2024
Invitae	Stratafide	Pan-cancer	Helps assign targeted therapy	FDA breakthrough device status
	Unnamed assay	Colorectal, bladder, lung	Postsurgical, detects disease recurrence	Maria trial to report 2026

LDT = lab-developed test. Source: Evaluate Medtech & company websites.