The cancer blood testing company Laboratory for Advanced Medicine is ready to compete on price, which might be necessary in a market already thronged with products.

One of the potential flaws of liquid biopsy tests that rely on the detection of tumour DNA in a patient’s blood is that the tumour has to grow to a sufficient size to shed appreciable quantities of genetic material, making detection at an early, relatively treatable stage of disease that much harder.

Laboratory for Advanced Medicine, or LAM, reckons it has found a better way. Its IvyGene tests work by detecting methylation levels of DNA, a gene expression marker that correlates with cancer and can be picked up at an earlier stage.

“Methylation may be telling the immune system not to kill the tumour,” says Richard Brand, LAM’s chief financial officer. “That’s just a hypothesis – we don’t know that for sure. But we do know that methylation is prevalent at elevated levels, even when the tumour’s beginning.”

There are certainly precedents for this technique, notably Exact Sciences’ highly successful Cologuard colorectal cancer test (Promotion deal is huge boost for Exact – but Pfizer must deliver, August 23, 2018). But this assesses DNA methylation in stool samples, not blood.

LAM’s cancer tests have posted promising data on accuracy. At the AACR meeting last month the company’s liver cancer panel showed an overall sensitivity of 95% and specificity of 97.5%. Its breast cancer test had overall sensitivity of 89% and specificity of 96%, and its colorectal cancer test 93% sensitivity and 100% specificity.

For comparison, Exact claims sensitivity of 92% and specificity of 87% for its colorectal cancer test.

Liver

LAM’s liver cancer test has recently gone on sale in the US under Clia certification. It is the company’s second marketed product, its first being the IvyGene Core Test, a basic form of a pan-cancer liquid biopsy.

“Our first product on the market is a pan-cancer test which has clinical utility but is not good enough to detect
the tissue of origin,” Mr Brand says. It is therefore only useful for patients who are already suspected to have a specific type of cancer.

“We have sales for that service,” Mr Brand says. “But where we’re focusing going forward is cancer-specific tests, and over time we will have 10 or 12 of these; and we will bundle those into a really rock-solid pan-cancer test, which would say that the patient has cancer and be able to detect the tissue of origin.”

That’s the company’s goal. In the meantime it is pursuing these single-cancer tests. The IvyGene Liver Test ought to be particularly useful for US patients who have cirrhosis, many of whom go on to develop liver cancer. Current guidelines call for cirrhosis patients to be evaluated by ultrasound every six months, but accuracy for ultrasound as a means of detecting hepatic cancer is under 77%. Mr Brand says the more accurate IvyGene Liver Test is appealing to doctors.

The test is also on sale in China, where LAM is focusing on patients who have hepatitis – a similar strategy to that of the company’s fellow liver cancer test maker Oncimmune (Deals and data in the offing for Oncimmune, April 25, 2019).

**Going on the LAM**

Last year LAM had sales of $1.5m, Mr Brand says, all of which came from the IvyGene Core Test, then its only product. The group was not spending heavily on sales and marketing at the time, he adds – but now LAM has raised some additional capital and will, for the first time, have a budget for active commercialisation.

“The good news is we know that people will buy the service and pay out of pocket even without any sort of marketing,” Mr Brand says. The tests cost $400, he says, and LAM is in discussions with payers to seek reimbursement. A study to demonstrate the tests’ economic benefit to payers is expected to report in the next nine months.

LAM is also keenly aware that Cia certification might soon no longer be enough to keep the tests on the market in the US, and has trials under way that could allow full FDA approval as well as potentially boosting sales.

But cancer blood testing is a red-hot area of device development right now, and LAM will have to cope with an ever-increasing number of potential competitors.

“We’re preparing for the eventuality that price may be important, in the minds of the governments, the payers and the regulators,” Mr Brand says. The group has a five-year plan to reduce the cost of its tests dramatically so it can be responsive to either competitive pressures or payers’ demands.

The lure of the liquid biopsy is strong, and LAM is close to concluding its first funding round involving institutional investors; so far it has raised a little over $70m, all from mega-high-net-worth family offices. This could help usher its breast and colorectal tests onto the market. Then it will be over to the group’s sales and marketing efforts.