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Illumina sees the light – or thinks it does

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The sequencing group's $8bn deal to recapture Grail leaves shareholders unimpressed.

Illumina's decision to spend billions reacquiring Grail, the liquid biopsy developer it spun out nearly five years ago, is somewhat puzzling. Grail's pan-cancer test, Galleri, is still a year from market, so Grail is expected to be a money pit for some time yet.

What is more, the firms' current arrangement is generally regarded as working pretty well. Illumina owns around 15% of Grail, sells it sequencing instruments and reagents, and takes a royalty on sales. But it also sells sequencers and consumables to some of the other liquid biopsy developers. Once Grail is back on board, Illumina will be competing with its own customers.

On a webcast today Illumina management brushed these concerns aside, saying its modelling suggested that bringing Grail back inside would bring more money in direct revenues than it could hope for from the royalty stream. The liquid biopsy market could top $75bn by 2035, and reacquiring Grail would expand Illumina's addressable market by $60bn, executives claimed.

There is certainly reason to buy before, rather than after, an IPO. Two weeks ago Grail filed for a Nasdaq listing; considering some of the recent post-float share price jumps in the healthcare sector, and the strength of the markets, Illumina might have felt its hand somewhat forced.

Even so, today's move stands in contrast to Illumina's general behaviour. The company does not have a great track record at commercialising actual diagnostics, focussing instead on making and selling the machines on which other companies next-gen sequencing-based tests are run.

Illumina has worked to reduce its stake in Grail over the past couple of years, as the spin-out raised piles of venture cash. It current equity stake amounts to $900,000; to buy the rest of Grail it will pay $4bn in shares and $3.1bn in balance sheet cash plus debt or equity of up to $1bn. The deal is by far the largest acquisition it has ever done.

Playing to the Galleri

However, Illumina is now on the hook for substantial R&D investment and a far from guaranteed outcome.

Grail looks likely to incur over $200m in operating expenses in 2020, and probably even more next year as clinical trial costs rise and pre-commercialisation expenses peak. The Pathfinder trial, which is enrolling 6,200 patients, is intended to evaluate Galleri's ability to aid cancer diagnosis when used in clinical practice. Subjects do not have a cancer diagnosis at enrolment, but the trial does include a cohort at greater risk of developing cancer, such as ex-smokers or those with a genetic predisposition to the disease.

Should this trial succeed at demonstrating a place for Galleri in clinical practice, its launch next year, under a Clia waiver as a lab-developed test, might be welcomed by doctors. But Pathfinder is not the only study Illumina will have to take on, and Galleri not the only assay in development. Grail has three other clinical trials ongoing; in total its current programme has signed up 150,000 subjects.

On top of that, Illumina will have to fork out for the sales force and then look into obtaining regulatory approval, currently pencilled in for 2023.

And there lurks another problem: Guardant and Roche have been selling their tests for some years now, and both obtained their regulatory nods – vital for convincing oncologists that the tests have worth – last month. Illumina will be third to market by a solid three years.

Illumina expects $3.25-3.75 in EPS dilution in first year after the deal closes in the second half of 2021. According to Leerink analysts, this translates to roughly $475-$550m in additional operating expenses in 2022.

Acquiring a customer is not an unprecedented move for Illumina, though the previous time it did so, in January 2013 when it bought the foetal chromosome testing company Verinata, it only spent $350m. And though Illumina is Grail’s sole supplier of sequencing tech, the spin-out is not a major customer, with management saying today that it was not in the top 20 companies to which Illumina sells.

Its other customers in the cancer blood testing space will be far from delighted at having to buy from a competitor. Still, such is the dominance of Illumina here they will have few alternative providers to turn to.

If Illumina’s customers are miffed, so are its investors. Rumours of the deal prompted Illumina to haemorrhage $10bn in market cap last week, and the stock opened 7% lower today. Perhaps shareholders are wondering how their stake might be doing had the PacBio merger come off.

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