

Biotech Daily

Friday April 16, 2021

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Volpara Health Technologies

By TIM BOREHAM

ASX code: VHT

Share price: \$1.42

Shares on issue: 251,019,081

Market cap: \$356.4 million

Chief executive officer (and co-founder): Dr Ralph Highnam

Board: Paul Reid (chairman), Dr Highnam, Dr Monica Saini (chief medical officer), Roger Allen, John Diddams, John Pavlidis, Karin Lindgren

Financials* (December quarter 2020): customer receipts \$NZ4.6 million (up 2%), operating outflows \$NZ3 million (previously \$NZ3.5 million), cash of \$NZ60.6 million**

- * One \$NZ1.00 equals \$A0.92
- ** \$NZ35 million after \$US22 million CRA Health purchase

Major shareholders: Harbour Asset Management 9.2%, Roger Allen 7.4%, Dr Highnam 6.5%

With the dastardly effects of the coronavirus first becoming apparent a year ago, the breast cancer imaging play beat the rush and raised \$28 million in a placement, plus \$9 million in an oversubscribed share purchase plan.

Given the uncertainties, it was simply a prudent thing to raise as much funds as possible but eventually so much idle moolah can burn a hole in one's corporate pocket. A few months later, management was much more confident about where things were headed and turned its thoughts to potential acquisitions.

The result is the \$US22 million (\$A33 million) purchase of CRA (Cancer Risk Assessment Co), a US quasi rival that plays strongly in genetic testing and has close ties with the powerful electronic health record (EHR) providers.

Management knows the acquisition playbook well: in late 2019, the company acquired US group MRS Systems for \$NZ21 million (\$A19 million), funded by an \$NZ55 million capital raising.

Volpara founder and CEO Dr Ralph Highnam says it's always preferable to carry out due diligence physically, but the border bans meant the company's Wellington, New Zealand-based management was going nowhere.

"We had worked closely with [CRA] over the last five years and that gave us enough confidence about who we were buying," he says.

In the meantime, Volpara was able to keep calm and carry on because of an unusual advantage: the district's calamitous earthquake in 2017 meant that management and staff were already well-versed in working from home.

'Absolute double whammy'

Volpara's reason for being is the distinction between fatty and dense breasts, which is more than an aesthetic consideration for swimsuit catalogues.

Since the 1970s, clinicians have been aware that dense-breasted women are more at risk of breast cancer - about four to six times more so, in fact.

The problem with traditional imaging is that the dense tissue shows up as white on a mammogram - as do the tumors. Thus, finding the latter is like finding a polar bear in a snowstorm.

Put another way, a tumor in a fatty breast has 90 to 100 percent chance of detection at screening, but this rate falls to 60 to 65 percent with the dense- breasted variety.

"It's an absolute double whammy," Dr Highnam says.

About half of all women are dense breasted, but this cohort falls from around 80 percent for the under 40s to 20 percent for the over 70s.

Who said old age did not have its rewards?

About 10 percent of women are classed as "extremely fatty" in the mammary department, while 10 percent are "extremely dense" and it's nothing to do with their IQ.

Motivated by the number of friends and family members lost to breast cancer, Dr Highnam completed an Oxford University Doctorate of Philosophy on the topic in the early 1990s.

He founded Volpara in 2008 and the company listed on the ASX on April 26, 2016, raising \$10 million at 50 cents apiece.

Volpara started with Volpara Density, a tool to measure breast density and thus identify atrisk women for more frequent examinations.

Volpara then devised Volpara Enterprise: automated tools used by clinics to improve the efficiency and performance of sites with multiple x-ray machines.

The company then launched Volpara Live! - since renamed the less expressive Volpara Live - to assist clinicians in real time. Live enables clinicians to detect a sub-standard image before the patient has left the clinic, avoiding the need for an expensive recall.

Users of Volpara Enterprise include New York's Sloan Kettering Cancer Centre, the Houston Texas MD Anderson, California's Stanford University Hospital, the University of Virginia Medical Centre, Women's Breast Imaging Perth, the Auckland Breast Centre and Auckland Mercy Radiology.

The Seattle-based MRS, as in Mammography Reporting Systems, provides its services to more than 1,600 US breast clinics and hospitals. The MRS purchase also included a modest lung cancer screening business, Aspen Lung.

Based on parts of the acquired MRS, Volpara Patient Hub is patient management software that contains patient details, patient communications and workflow data. This tool helps with regulatory, audit and reimbursement compliance.

Augmenting market share

Currently almost one in three US women who undergo breast cancer screening are subject to Volpara's supplementary screening.

Dr Highnam says the CRA purchase will boost this penetration further, while exposing the company to the booming genetic testing market. Dr Highnam says it's a "great feeling" that Volpara is ensuring that 12.5 million American women get safe and reliable x-ray results.

The aim now is to penetrate the remaining two-thirds of the screening market; and to expand screening to the one-third of US women who don't undergo screening.

He notes that Volpara does have competition, with about eight other products providing density scores. But these provide a crude ranking from A to D, rather than providing exact breast density measures that can be tracked over time. 'A' means extremely fatty and 'D' means extremely dense.

"If you write good software and it provides good value, you can get very large market shares in breast imaging," Dr Highnam says.In mid-March Volpara announced its biggest contract to date, via the CRA Health subsidiary.

Worth \$US400,000 in annual recurring revenue, the deal pertains to providing breast cancer risk scores to a large Indiana based organization that has sites in 20 states and runs expansive electronic health records.

Win for women in windy Wellington

Volpara derives 90 percent of its revenue from the US, but women do exist elsewhere.

In Australia, Volpara has a strong presence in private Adelaide clinics and in Queensland, where the company has been selected for the state's public screening program.

"We still have a long way to go in New South Wales, Victoria and Western Australia despite having some excellent sites," Dr Highnam says.

Volpara also has customers in Auckland and Palmerston. Despite being based in Wellington, Volpara only recently signed its first customer in the windy capital.

"It was a great moment for women in Wellington," Dr Highnam says. "We have long wanted them to get the benefit of what we do here."

Dutch density detection delivers

Volpara's ability to prevent breast cancer has been validated in the latest results from a marathon 10-year study being carried out by the University of Uechtrecht in the Netherlands.

Dubbed DENSE, the study measures the clinical utility of supplemental screening (post magnetic resonance imaging, or MRI) for women with extremely dense breasts – as measured by Volpara Density.

The first results, in late2019, showed a significant reduction in interval cancers - those detected between breast exams - but also a high false positive rate.

Covering 3,000 women, the second round of results showed the false positive rate had reduced.

The randomized, controlled trial also opens the way for hesitant potential customers - notably public screening programs - to adopt Volpara products.

Finances and performance

Despite the coronavirus, Volpara reported third (December) quarter receipts of \$NZ4.6 million, up two percent.

Volpara's revenue has been transitioning from capital purchases to 'software as a service' subscription revenues, which allows for smoother annuity income over contracts that typically run for five years.

The company also recorded an operating loss of just over \$NZ3 million, compared with \$3.5 million in the second (September) quarter.

Dr Highnam says he's not too concerned about Volpara being loss-making, as the company is focusing on customer acquisition that will lead to reliable annuity revenue in the longer term.

Later this month Volpara is due to report its full year results for the year to March 2021. Broker Morgans forecasts a net loss of \$NZ13.4 million, on revenue of \$NZ22.6 million. The firm then expects revenue of \$28.5 million and a \$NZ6.5 million loss in the current (2021-'22) year.

The company brings home the bacon in the year to March 2023, delivering a \$6.5 million profit on revenue of \$NZ44 million.

Volpara cites an average revenue per user (ARPU) of \$US1.22, up five percent. But there's an historical lag here, with the ARPU on deals struck during the quarter ranging from \$US1.43 to \$US5.12.

Management has a target of increasing this ARPU to an average \$US10, through higher take-up of bundled products and rolling out high-margin genetic testing.

Currently, most customers use only one Volpara product.

Broker Morgans reckons that every additional 10 US cents of ARPU should increase the value of Volpara shares by 43 cents - or close to one third.

Volpara shares have wandered between 30 cents (May 2017) and a peak of \$1.99 (November 2019). The stock has recovered from a Covid-era low of 99 cents (March 27, 2020).

Dr Boreham's diagnosis:

In February, Dolly Parton graciously requested leaders of her home town of Nashville not to build a statue of her, given "everything else that is going on".

In renouncing the chance to be remembered for a different kind of bust, the singer and philanthropist was referring to the pandemic and Washington's turmoil.

But there's also a lot going on in breast cancer detection, with the CRA Health purchase aligning Volpara with rapidly evolving risk assessment and prevention techniques.

"There's a whole world of preventative strategies opening up, but the key to getting the right patients on them is to do very accurate risk prevention," Dr Highnam says.

"That's why we bought CRA because they are the best of breed at risk and genetics."

Volpara, meanwhile, has been awaiting a new US Food and Drug Administration requirement that screening clinics must inform all patients of their breast density measures. A number of states have adopted this rule already.

The FDA flagged the rule 18 months ago and it was meant to have been formalized in October, but things were a bit busy in Washington at the time.

If the Biden administration gives the nod - and it didn't run on an anti-breast platform - Volpara can edge closer to gold standard 'breast practice' status in the world's biggest breast imaging market.

Disclosure: Dr Boreham is not a qualified medical practitioner. He does not possess a doctorate of any sort but does like to keep abreast of medical technologies.