



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Volpara Health Technologies

By TIM BOREHAM

**ASX code:** VHT

**Share price:** 88 cents

**Shares on issue:** 251,935,081

**Market cap:** \$221.7 million

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

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

**Financials\* (December quarter 2021):** customer receipts \$NZ7 million (up 50%), operating outflows \$NZ3.6 million (previously \$NZ3.8 million), cash of \$NZ21.3 million (down 14%) (\*\$NZ1.00 equals 91.8 Australian cents)

**Major identifiable shareholders:** Harbour Asset Management 11.03%, Patagorang Ltd (Roger Allen) 7.3%, Dr Highnam/ /KYC Trustees 6.4%, Prof Sir Michael Brady 2.6%, Marcus Sarner 2.4%.

Fatty and dense.

These descriptors sound like schoolyard taunts, but when it comes to breast cancer prevention their importance is elevated beyond the mean girls' talk.

Evidence has been mounting that dense-breasted women have a much higher chance of developing breast cancer (see below).

The obvious public health 'breast practice' would be for dense-breasted women to be warned of the elevated risk and undergo more regular screening.

In the main, they haven't been. But recent events have heartened Volpara, which has developed software for more accurate appraisal of breast density.

In what Volpara chief Dr Ralph Highnam dubs a "landmark moment," the European Society of Breast Imaging (Eusobi) last month recommended that women should be informed of their breast density score.

The Society says that "in light of the available evidence", women aged 50 to 70 years with extremely dense breasts should be offered magnetic resonance imaging (MRI) screening every two to four years.

"It's certainly not mandatory for [clinics] to do it, but we expect that Europe and Britain will follow suit," Dr Highnam says.

"It's like Dominoes - if one moves, the rest do and that's why we are excited."

In the US, 38 states already have density disclosure rules, but the company is waiting for the Food and Drug Administration to outline a standardized federal approach.

Here, only Western Australia has a mandatory disclosure regime.

So far, Volpara has analyzed more than 56 million mammography images and assessed the breast composition of more than 13.5 million women across 39 countries.

### **More useful than jumping fleas**

Volpara's name derives from 'the quantification of breast composition via volumetric parameters'.

Volpara has its origins with Prof John Michael Brady, who is not the Mike Brady of *Up There Cazaly* fame. Rather, he is an entrepreneur and computer guru who moved from the Massachusetts Institute of Technology to the University of Oxford in 1986 to build a robotics lab.

Prof Brady's interest in breast cancer was piqued when his mother-in-law died from the disorder and he switched to medical imaging.

He got together with his PhD student, Dr Highnam, to devise a protocol for automatically quantifying breast composition from x-rays based on Dr Highnam's thesis on breast density.

Now, this may sound like an obscure doctoral topic, but it's all relative. After all, French veterinary researchers once penned this paper for their doctorate: "a comparison of jump performances of the dog flea, *Ctenocephalides canis*, and the cat flea, *Ctenocephalides felis*." \*\*

Dr Highnam founded Volpara in 2008 and the company has hopped to it since listing on the ASX on April 26, 2016, raising \$10 million at 50 cents apiece.

Volpara now has software for breast cancer risk assessment, volumetric breast density and mammography quality, as well as artificial intelligence and machine learning.

The software is vendor neutral, which means it can be used on any provider's imaging system.

## **Density for dummies**

About half of all women are dense-breasted, which in a scientific sense means they are well endowed with the fibro-glandular tissues. This material contains the glandular lobes and the ducts from which most breast cancers originate.

The amount of this tissue is largely determined by genetic lottery as well as "hormonal stimulation" which means the risk is reduced post-menopause.

Adding to the risk, dense tissue shows up as white on a mammogram. Given the tumors come up as white as well, detecting them is like finding a polar bear in a snowstorm.

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.

While a tumor in a fatty breast has 90 to 100 percent chance of cancer detection at screening, this rate falls to 60 to 65 percent with dense breasts.

## **Expanding the repertoire**

Volpara's flagship product Volpara Density is an algorithmic tool to measure breast density and thus identify at-risk women for more frequent examinations.

The company then devised Volpara Enterprise, an automated tool to help clinics to improve the efficiency and performance of sites with multiple x-ray machines.

The company then followed up with launched Volpara Live! - later renamed to the less expressive Volpara Live - to assist clinicians in real time. For example, clinicians can detect a sub-standard image before the client has headed for the door.

Volpara Scorecard is software that connects to a mammography machine and applies density calculations, which are then sent to the relevant work station.

In February 2021, the company paid \$US22 million for CRA, a US quasi rival that plays strongly in genetic testing and has close ties with the powerful electronic health record (EHR) providers.

In late 2019, Volpara acquired the Seattle-based patient management software house MRS Systems for \$NZ21 million (\$A19 million), funded by a \$NZ55 million capital raising.

From this, Volpara evolved Volpara Patient Hub - a patient management software that contains patient details, patient communications and workflow data. The Hub helps with regulatory, audit and reimbursement compliance.

Meanwhile, Volpara has launched Project Thumb, which enables sites using Volpara Scorecard and Volpara Hub to insert images directly into patient letters.

As well as enhancing client care, this will “provide a more compelling reason for people to buy multiple products”.

The MRS purchase also included a modest lung cancer screening business, Aspen Lung.

So far, 90 percent of Volpara’s revenue have derived from the US, where the company has a 35 percent share of the supplementary screening market.

The Australian and Kiwi markets account for the remaining 10 percent of revenues.

Locally, the company has been selected for Queensland’s public breast screening program and has a strong presence in Adelaide clinics.

### **Dutch density detection delivers**

The European guidelines result from a massive long-running Dutch trial called Dense, which measures the clinical utility of supplemental screening (post magnetic resonance imaging) for women with extremely dense breasts.

The tool used? Volpara Density.

Carried out by the University of Utrecht in the Netherlands, Dense has tracked 60,000 women since kicking-off in 2009.

The first results, in late 2019, 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.

“We want to go another couple of rounds to get the full picture and hopefully pick up signs of reduced mortality, not just reduced number of interval cancers,” Dr Highnam says.

He says Dutch authorities are discussing implementation on the back of the strong results and he also expects action from UK health authorities.

## **Finances and performance**

Emerging from the coronavirus disruptions, Volpara reported third quarter (December) revenues of \$NZ7 million (\$A7.56 million), 50 percent higher than a year previously.

With a March 31 balance date, the company also reiterated revenue expectations of \$NZ25 million for the 2021-'22 year, 25 percent higher than previously.

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.

On that note, annual recurring revenues (from software subscriptions) improved by \$US1.1 million on the September 2021 quarter, to \$US21.5 million.

Average revenue per user (ARPU) was \$US1.47, but within a broad range of \$US1.05 to \$US6.68.

Net cash outflows were \$NZ3.6 million compared with \$NZ3.8 million previously.

"We have plenty of cash in the bank and our aim now is to maintain strong growth while driving down net operating and investing cash flow," Dr Highnam says.

"Reaching [cash flow] break-even is certainly a big part of our thinking and with \$NZ25 million of revenue we are very confident we have very solid foundation."

We would like to say that Volpara shares have duly reflected the company's progress - but we can't.

In line with the overall biotech sell off, Volpara shares have fallen by 40 percent during the last 12 months, but in the last month the price rebounded 27 percent.

The stock peaked at \$2.00 in mid-November 2019 and traded as low as 30 cents in May 2017.

The company is happy with its \$NZ21 million cash kitty, having raised \$A37 million before the pandemic hit.

### **Dr Boreham's diagnosis:**

Given Volpara is a leading provider of risk assessment software, bolstered breast density disclosure rules are 'manna from heaven' for the company.

We stress that Volpara is not without rivals, as it competes with a handful of other breast density products.

But Dr Highnam says Volpara is the only provider to measure breasts in their full three-dimensional glory.

“Volpara, from day one, has always viewed the breast as a 3D object and we believe that all breast density measurement should be done in a true, volumetric way,” Dr Highnam says.

Given the Volpara products can be used alongside any screening product, we guess it’s a case of a better mousetrap.

Meanwhile, investors should expect some movement from the US FDA on the density disclosure rules.

The agency flagged the change some time ago, but things were bogged down by the transition to the Biden Administration.

Last month, President Biden confirmed the objectives of the Cancer Moonshot program, which include halving the incidence of breast cancer over the next decade.

“They identify breast density as being really important, as well as the need for systems to do risk assessment,” Dr Highnam says.

Meanwhile, there’s little the company can do about the share price malaise which has not gone unnoticed by directors - and major shareholders - Highnam, Brady and tech entrepreneur Roger Allen.

“We share the pain,” Dr Highnam says.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a PhD. \*\*But he can report the dog flea jumped both higher and further than the feline equivalent.***