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: $1.24

Shares on issue: 179,350,158 (51,482,213 subject to voluntary escrow)

Market cap: $222.4 million

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

Board: Paul Reid (chairman)*****, Dr Highnam, Roger Allen, Prof John Michael Brady, John Diddams, John Pavlidis, Dr Monica Saini.

Financials (December quarter): receipts $NZ1.9 million, cash burn $NZ2.75 million, cash on hand $NZ17.1 million, estimated current quarter outflows $4.4 million.

Major shareholders: Patagorang Pty Ltd (Roger Allen) 11.4%, Dr Highnam 10.1%, Tina Jennings 5.1%, Harbour Asset Management 5.0%, Prof Brady 4.4%, Private Portfolio Managers 3.6%, Craigs Private Clients 3.5%, Marcus Sarner 3.3%.

***** To enable the company to have an independent chair, Mr Reid replaced Mr Allen as chairman as of March 1.

For the Wellington-based diagnostics play, the mantra of 'breast is best' takes on a different meaning from the nursing mother's self-evident dictum.

Volpara's platform technology is all about improving the detection and diagnosis of breast cancer, which can do with plenty of improvement, despite the ubiquity of the disease.

Unlike so many of its life sciences counterparts, Volpara has stuck to its original purpose. But it has also expanded its remit from measuring breast density to introducing software for screening clinics to improve their efficiency and patient experience.

Women with dense breasts - and that's 40 to 50 percent of the female populace - are at much greater risk of contracting breast cancer.

What's more, the dense tissue comes up white on a mammogram - as does a tumor. As a result, 20 to 30 percent of cancers are missed in this cohort.

After 10 years of development, Volpara has entered commercialization stage and is now being judged by the market on its ability to generate recurring revenue.

Volpara founder and CEO Dr Ralph Highnam is a global expert on breast density, which refers to the level of glandular tissue versus fat in the appendages. In fact, he completed an Oxford D Phil (doctorate of philosophy) on the topic, which no doubt provoked many a titter among his fellow scholars.

Volpara was last year's second best performing BDI-40 price wise, surging 198.5 percent despite a sharp retraction in December after a lacklustre quarterly report and slower than expected progress on new contracts.

Volpara's evolution

Initially, Volpara started with Volpara Density, a tool to measure breast density and thus identify at-risk 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.

At a recent major radiology shindig in Chicago Volpara launched Volpara Live!, a tool that assists clinicians in real time. The company claims it's the first such point-of-care tool - and who are we to argue?

Volpara Enterprise enables clinicians to detect a sub-standard image before the patient has left the clinic, avoiding the need for an expensive recall. (It can detect whether different companies' mammography machines are applying optimal - rather than painful or insufficient pressure and whether the x-ray dose is correct.)

Volpara's revenue mix is shifting from up-front capital amounts to a 'software as a service' model that involves a monthly per-patient subscription payment.

In the 2017-'18 year, the number of sites signing up for Volpara Enterprise climbed from 14 to 57.

In October 2018, NZ screening chain Breastscreen Central became the first public body to purchase the enterprise software.

Trials are continuing with Britain's National Health Service.

Other takers for the enterprise software are the Sloan Kettering Cancer Centre in New York, the MD Anderson in Houston, the Stanford University Hospital in California, the University of Virginia Medical Centre, Women's Breast Imaging Perth, the Auckland Breast Centre and Mercy Radiology.

Holland density trial a Dutch treat

One impediment to clinics taking up Volpara's product suite has been the lack of formal proof of the efficacy of density-based screening via a proper randomized trial.

But now Volpara has the smoking gun evidence after the results of a large Dutch screening trial - carried out over eight years - were aired at the European Congress of Radiology in Vienna.

Based on a screening of 40,000 women – with a subset of 400,000 screened women overall deemed to be extremely dense breasted - the trial showed a dramatic drop in "interval cancers" when patients were screened with an x-ray, Volpara Density and then magnetic resonance imaging (MRI).

Interval cancers tend to be detected by symptoms - which usually reflects an advanced stage - a year or two after a screening has returned a negative result and prior to the next scheduled screening, hence 'interval'. That's either because the cancer was hidden by dense tissue, or was extremely fast growing.

Extremely dense-breasted women are defined as having breasts with 15.5 percent or more of the fibrous material. In this cohort, standard mammographies have a sensitivity of 61 percent (in other words, only six in every 10 cancers are detected).

The rate of interval cancers in extremely dense-breasted women is normally 4.4 per thousand, but the trial results in a reduction to around one per thousand.

The trial - aptly named Dense - wasn't a test of Volpara Density as such, but was aimed at determining whether MRIs were a cost-effective way of reducing the number of interval cancers.

In an ideal world every woman with a positive diagnosis should have an MRI, but the trouble is they are five to six times more expensive than a standard mammography. MRIs also require use of a contrast agent and can generate false positives.

The trial resulted in a low false positive rate of seven percent - that is, women who have biopsies that turn out not to be cancer - with plans afoot to reduce that further.

US evidence suggests the false positive recall rate for breast x-rays is around 10 percent. Dr Highnam says the trial has "massive implications" for breast cancer screening globally.

"Screening programs have been waiting for randomized controlled trials to show the benefit of density-based screening," he says. "Finally, now they have a way forward to optimize their screening protocols."

The trial was funded by several charities as well as Bayer AG (which makes MRI contrast agents) and was overseen by renowned Dutch epidemiologist Prof Carla van Gils, of the University Medical Centre Utrecht.

Given the role of Volpara Density in assessing breast density, Dr Highnam said the results were expected to result in “increasing international interest in automated breast density solutions”. Such as … er … Volpara Density.

Investors agreed, pushing Volpara shares eight percent higher on the day.

USA, or bust

Volpara’s quest to dominate the US market is being helped by an expanding number of states issuing breast density screening guidelines.

In February, Georgia became the 38th state to do so, with the guidelines now covering close to 90 percent of US women.

Dr Highnam notes the US Food and Drug Administration recently issued guidelines to improve the quality of mammography and provide more information to patients, especially about breast density.

These guidelines have remained untouched since 1997. So, while breasts conceptually haven’t changed in that time, the imaging technology certainly has.

In September, a new FDA clearance under the 510k pathway expanded the information algorithms can provide to clinicians.

“For instance, Volpara can now refine breast density scoring when there is an area of the breast that is especially dense and provide an overall sensitivity score for the exam,” Dr Highnam says.

Finances and performance

Volpara’s third (December) quarter was a curate’s egg of good and not so good, with over-expectant investors latching on to the latter. The company booked record receipts of $NZ1.9 million ($1.82 million), up 192 percent on the September quarter.

It also lost $NZ2.8 million.

Typical of “cloud” subscription models, revenue is recognized over the life of the contract which means short-term revenues are more constrained. But as subscriptions grow, more annuity income is generated and annual recurring revenues ensue.

Given that, Volpara chalked up annual recurring revenue (ARR) of $NZ755,000, taking the financial year-to-date run rate to $NZ5.6m, up 56 percent.

Management also guided to an 85 percent increase in ARR in the financial year to March 2019. While 85 percent growth sounds bouncy enough, management had set an "aggressive but plausible" target of 150 percent growth.

The company attributes the lag mainly to slower than anticipated uptake by new sites in the US, partly the result of Volpara's need to blood a new sales force.

Volpara subsequently had a record January and Dr Highnam says February has shaped up "okay" as well. At last count. the company had signed 113 customers across 300 sites, and was expecting to sign a further 25 to 30 by the end of March.

The company looks to be sound, cash wise, having raised $20 million from institutions in April last year.

On current expectations, Volpara is expected to remain unprofitable in 2018-'19, (which we'll know soon enough because the Kiwi company reports its full year to March 31), before posting modest earnings in 2019-'20 and immodest ones thereafter.

Meanwhile Volpara shares have traded in a range from 61 cents to $1.55 over the last 12 months.

Dr Boreham's diagnosis:

Given the duration of the trial and the number of patients involved, the Dense trial results promise to be a pivotal point in Volpara's short history.

But for the time being, it's a matter of wearing out the shoe leather to get those US imaging sites on board. After all, the US market accounts for 95 percent of expected revenue.

Volpara has some interesting backers in Australian entrepreneur Roger Allen, founder of Computer Power group and the venture capital firm Allen & Buckeridge. Founding director Mike Brady isn't of Up There Cazaly fame, but a professor of oncological imaging at Oxford University.

Dr Saini is a former medical director of GE Health and a breast screening guru.

Mr Reid and Mr Diddams are serial company directors in Australia and NZ, so there's a nice balance of commercial, medical and entrepreneurial on the board.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. So as to not make a boob of himself, especially on International Women's Day, he does try to stay abreast of things.