



Biotech Daily

Thursday April 14, 2022

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.59 percent on Thursday April 14, 2022, with the ASX200 up 44.4 points to 7,523.4 points. Twenty of the Biotech Daily Top 40 stocks were up, 11 fell and nine traded unchanged.

Opthea was the best, up 6.5 cents or 6.8 percent to \$1.02, with 308,600 shares traded.

Uscom climbed five percent; Micro-X, Neuren, Starpharma and Telix improved more than four percent; Actinogen was up 3.5 percent; Alcidion, Clinuvel, Genetic Signatures, Kazia, Nanosonics, Pro Medicus and Proteomics rose more than two percent; Cynata, Emvision, Immutep, Polynovo and Volpara were up more than one percent; with Avita, Cochlear and CSL up by less than one percent.

Yesterday's 73.8 percent best, Oncosil, led the falls, down 1.4 cents or 19.2 percent to 5.9 cents, with 36.2 million shares traded. Nova Eye lost 10.5 percent; Patrys and Pharmaxis fell four percent or more; Dimerix and Prescient were down more than three percent; Imugene shed 2.3 percent; Next Science, Paradigm and Universal Biosensors were down more than one percent; with Medical Developments and Resmed down by less than one percent.

[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.

OSTEOPORE

Osteopore says it has shipped its first cranial implants to Spain through distribution partner, the Asturias, Spain-based Acuña y Fombona SA.

Last week, Osteopore said it had shipped its first cranial implants to its Colombia distributor Implar SAS, the first sales in Latin America (BD: Apr 7, 2022).

Today, the company said that Acuña y Fombona had more than 50 years of industry experience and was “one of the main distributors of medical and surgical materials in the region”.

Osteopore said the initial shipment would provide Acuña y Fombona S.A with sufficient inventory to engage its network of health professionals, hospitals and health services, as well as support the sales team to initiate clinical use in Spain.

The company said that Spain had about 40,000 cranial procedures a year.

Osteopore executive chair Mark Leong said the first sales in Spain was “yet another fantastic milestone for the company ... [and] a clear example of the immediate commercial opportunity for Osteopore’s innovative regenerative implants”.

Osteopore was up half a cent or 2.6 percent to 20 cents.

CARDIEX

Cardiex says it has filed a 510(k) submission to the US Food and Drug Administration for its Conneqt companion application for dual blood pressure management.

Cardiex said the Conneqt software application was a companion to its Conneqt Pulse device which it said would be the world’s “first home-use dual blood pressure management system” incorporating its Atcor’s Sphygmocor blood pressure management technology, pending FDA approval.

Cardiex chief executive officer Craig Cooper said the filing was “an exciting milestone”.

“Our strategy and vision with Conneqt has always been to bring medical grade diagnostics to the consumer and it’s for that reason that we are seeking FDA clearance for the Conneqt App - unlike other health apps that are not paired to a medical device ecosystem,” Mr Cooper said.

Cardiex was up 2.5 cents or 6.9 percent to 38.5 cents.

EMYRIA

Emyria says it has completed dosing 12 volunteers in its phase I trial comparing the safety and bioavailability of EMD-RX5 cannabidiol capsules to Epidyolex.

Last week, Emyria said that it had dosed the first of 12 volunteers in the phase I trial comparing 150mg EMD-RX5 cannabidiol (CBD) capsules with 100mg/ml Epidyolex CBD (BD: Apr 7, 2022)

In March, Emyria said it had begun recruiting 12 volunteers for a phase I trial comparing its marijuana-based EMD-RX5 to Epidyolex, which it said was the only cannabidiol-only medicine registered with both the Therapeutic Goods Administration and the US Food and Drug Administration (BD: Mar 9, 2022).

Today, the company said it expected a final data report on the trial next month.

Emyria said it was initially targeting the registration of EMD-RX5 as an over-the-counter treatment for symptoms of psychological distress, but that it also intended to pursue other registration programs with the same dose form.

Emyria was up one cent or 3.3 percent to 31 cents.

CANN GROUP

Cann Group says it has begun growing marijuana and manufacturing Satipharm cannabidiol (CBD) capsules in Mildura and manufactured dried flowers in Melbourne. Cann Group said about 4,000 cuttings were propagated in the Southern Melbourne facility and transferred to Mildura, with the harvest expected in June.

The company said its Southern Melbourne facility had released its first batch of good manufacturing practice dried marijuana flower products, "demand ... remains high" and it had increased production of high tetrahydrocannabinol (THC) cultivars to help meet the demand.

Cann Group said that its Mildura factory had begun production of Satipharm cannabidiol capsules in preparation of schedule 3 registration with the Australian Office of Drug Control.

Cann Group chief operating officer Shane Duncan said that with the Mildura facility coming online it was "pleasing to see the company move to producing medicinal cannabis products at scale".

"Work is continuing in Mildura with the installation and commissioning of table automation and processing systems as the first commercial crop goes through vegetative and flowering stages over the coming weeks," Mr Duncan said.

Cann Group was up 5.5 cents or 15.5 percent to 41 cents with 4.0 million shares traded.

TELIX PHARMACEUTICALS

Telix says its annual general meeting will vote to issue 191,742 share appreciation rights to managing-director Dr Christian Behrenbruch and director Tiffany Olson.

Telix said investors would vote to grant Mr Behrenbruch 139,672 share appreciation rights exercisable at \$4.95 within five years, vesting in three tranches, each contingent on performance.

The company said the meeting would vote to elect Ms Olson and grant her 52,070 share appreciation rights exercisable at \$4.95 over four years, and vesting three years from the grant date, with no performance hurdles.

Telix said 2,690,291 employee share appreciation rights had been granted to 128 participating employees.

The company said the meeting would vote on the remuneration report, the re-election of Jann Skinner as director, the equity incentive plan, the issue of placement shares, the issue of share appreciation rights to employees, and amendments to the constitution.

The meeting will be held virtually and at the Events Centre, Collins Square, 727 Collins Street Melbourne on May 18, 2022 at 11am (AEST).

Telix was up 21 cents or 4.7 percent to \$4.67 with 610,888 shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has received \$570,999 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Antisense said the rebate related to research and development expenditure for the year to June 30, 2021.

Antisense was unchanged at 12 cents.

OPTISCAN IMAGING

Peters Investments says it had increased its substantial holding in Optiscan from 78,541,105 shares (12.68%) to 87,000,000 shares (14.051%).

The Cottesloe, Western Australia-based Peters Investments said that on April 13, 2022 and on other unspecified “various dates”, it bought 8,458,895 shares for \$1,231,829, or an average of 14.6 cents a share.

Optiscan fell one cent or 5.7 percent to 16.5 cents.

VAXXAS

Vaxxas says it has appointed Dan Devine as its chief business officer and general counsel.

Vaxxas said that Mr Devine had more than 25 years’ experience in the bio-pharmaceutical industry, including 10 years at Mesoblast.

The company said Mr Devine worked at Pfizer and founded Patrys.

Mr Devine’s LinkedIn page said he held a Bachelor of Science in Economics from the Ithaca, New York-based Cornell University, a Master of Business Administration from New York’s Columbia Law School a Juris Doctor from the State University of New York, Buffalo.

Vaxxas is a private company.