Biotech Daily

Friday April 21, 2023

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.43 percent on Friday April 21, 2023, with the ASX200 down 31.8 points to 7,330.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and two were untraded. All three Big Caps were up.

Impedimed was the best on no news, up 2.5 cents or 20.8 percent to 14.5 cents, with 18.3 million shares traded. Uscom climbed 12.5 percent; Amplia was up 10.5 percent; Atomo improved 5.7 percent; Neuren was up 4.2 percent; Telix rose 2.15 percent; Micro-X, Nanosonics, Nova Eye, Opthea, Resmed and Universal Biosensors were up one percent or more; with Cochlear, CSL and Pro Medicus up by less than one percent.

Patrys led the falls, down 0.1 cents or 6.25 percent to 1.5 cents, with 200,425 shares traded. Cyclopharm and Cynata lost five percent or more; Genetic Signatures, Prescient and Proteomics fell more than four percent; Antisense, Dimerix, Imugene and Orthocell were down more than three percent; Kazia, Paradigm and Starpharma shed two percent or more; Avita, Clinuvel, Next Science and Polynovo were down more than one percent; with Emvision down by 0.3 percent.

DR BOREHAM'S CRUCIBLE: VOLPARA HEALTH TECHNOLOGIES

By TIM BOREHAM

ASX code: VHT

Share price: 77.5 cents**; Shares on issue:** 254,089,909**; Market cap:** $196.9 million

Chief executive officer: Teri Thomas

Board: Paul Reid (chair), Ms Thomas, Roger Allen, Ann Custin, John Pavlidis, Karin Lindgren, Mark Bouw

Financials* (December quarter 2022): receipts $NZ11.2 million (up 60%), operating cash flow $NZ1.78 million, net cash flow $NZ1.3 million, cash of $NZ11.95 million

***** $NZ1.00 equals 93.2 Australian cents)

Major identifiable shareholders: Harbour Asset Management 14.9%, Patagorang Ltd (Roger Allen) 7.3%, Dr Ralph Highnam (KYC Trustees) 6.4%, Prof Michael Brady 2.8%, Marcus Sarner 2.35%.

New-ish Volpara chief executive Teri Thomas refers to "boobies" in a way in which her more straitlaced predecessor Dr Ralph Highnam would never have got away.

Ms Thomas's "boobies" are avian in nature - an allusion to the breast imaging outfit's new corporate mascot of the blue-footed booby (an endangered South Pacific species with distinctive blue feet, as the name implies).

"We enjoy having fun - life is too short," Ms Thomas says. "But our purpose is quite serious: saving families from cancer."

The frivolity about the Wellington, New Zealand-based Volpara's new emblem (named Kiko) also can't overshadow Ms Thomas's reformist intent to put the company on a more commercial footing.

In fact, 'elephants' are more likely to be mentioned at the company's Wellington HQ than blue-footed boobies. The metaphorical pachyderms are the larger customers that she wants Volpara to focus on, generating $NZ300,000 or more of annual revenue, each.

"A $300,000 sale is not the same as a $3,000 sale, yet sometimes it can involve the same effort," she says.

Ms Thomas says some Asian contracts to date have averaged a humble $US5,000 and "you can't get rich picking up beer cans".

The tough medicine appears to be effective, with the company reporting maiden net positive cash flow in the (third) December 2023 quarter.

Dense versus fatty

While Volpara provides algorithmic-based products to interpret and handle mammograms and improve practice management, the company's flagship product pertains to measuring the density or otherwise of breasts.

The mammaries are classed on a scale of A (extremely fatty) to D (not D-cup, but extremely dense).

About half of all women are dense-breasted, which in a scientific sense means they are well endowed with fibro-glandular tissues. The dense-versus-fatty assessment can't be done by hand, as they are not firmer to the touch as one might think.

The dense material contains the glandular lobes and the ducts from which most breast cancers originate.

As a result, they are four to six times more prone to cancer than fatty-breasted women.

The double-whammy for the dense breasted women is that tumors are white on the mammogram, while the background is white as well. While a tumor in a fatty breast has a 90 to 100 percent chance of cancer detection at screening, this rate falls to 60 to 65 percent with dense breasts.

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

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

Keeping abreast of the news

Given the increased risks, one would have thought that women should be informed of their breast density score when undergoing a mammogram.

Outside of Western Australia there's no requirement here, or in New Zealand.

But in eagerly awaited news, the US Food and Drug Administration (FDA) has ordered that density scores be provided to patients. While 38 US states already had such a requirement, the measure standardizes the process across the Union.

While the decision takes 18 months to come into effect, Ms Thomas says it is "an enormous validation of Volpara's work" and is likely to spur international interest.

"I fully hope and expect Australia and New Zealand will follow suit and institutionalize the processes to inform and empower women," she says.

Meanwhile, a humungous Dutch trial of 60,000 women showed that supplemental screening of dense-breasted women cut the incidence of interval cancers - those detected between screening - as well as false positives.

Busting out from Oxford roots

Volpara owes its existence to the University of Oxford, where founders Prof John Michael Brady and Dr Highnam met.

Prof Brady is a US entrepreneur and computer guru, who moved to the University of Oxford in 1986 to build a robotics lab. Motivated by the loss of his mother-in-law from breast cancer Prof Brady got together with Dr Highnam, who had completed a Doctor of Philosophy (D Phil) on breast density.

Based on Dr Highnam's theories, the duo devised a protocol for automatically quantifying breast composition from x-rays.

Dr Highnam founded Volpara in 2008 and the company listed on the ASX on April 26, 2016, raising $10 million at 50 cents apiece. He stepped down in April 2022 and is now the company's chief science and innovation officer. Ms Thomas was elevated from chief executive to managing-director in October 2022.

In February 2021, the company paid $US22 million ($A33 million) for Boston's CRA Health LLC, a US quasi-rival that plays strongly in genetic testing and has close ties with the powerful electronic health record (EHR) providers. Volpara recently renamed the CRA Health system as Risk Pathways.

In late 2019, Volpara acquired the Seattle-based patient management software house Mammography Reporting Systems Inc (MRS) for $NZ21 million ($A19 million), funded by a $NZ55 million capital raising, now known as Patient Hub.

Volpara prides itself on being 'vendor neutral', which means its software can be used on any mammography unit.

Balancing profits with purpose

Ms Thomas's resume includes more than 20 years at the US health provider Epic, where CRA Health, coincidentally, had been integrated. By chance, she and her family ended up in New Zealand because of an Epic sabbatical program that sent valued staff on a trip to a country they had not yet visited.

"I thought New Zealand was a good outdoorsy culture in which to bring up kids," she says.

Based around the picturesque Bay of Plenty, Ms Thomas did some Covid nursing and pondered retirement before taking on consulting work for Volpara.

"I didn't think a New Zealand company would fit my background so I was bit surprised to get to know Volpara," she says.

Ms Thomas moved to cauterize Volpara's bleeding bottom line with a circa $NZ11 million cost cutting drive that included retrenching 20 of the company's 180 staff. The two acquisitions were more closely integrated with the Volpara mothership.

Ms Thomas's mantra is "no money, no mission".

"The company's culture was great, but to be strong and sustainable you need to balance purpose with an eye on the money," she says. "Some people might have seen us as not-for-profit. But we are not. We are a public company and it is our fiduciary duty to return shareholder value."

The art of the mammogram

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

"Squishing a breast against a panel is not easy," Ms Thomas says. "Our analytics give feedback on the art of doing the best quality mammogram."

She says some technicians are trained to compress the breasts until the patient says 'ow!'

"Over-compression is painful, but I know some very stoic women and even if you pulled their fingernails off, they wouldn't say 'ow!'"

Another common clinical problem is that women are recalled for another mammogram and fear the worst. But more likely it's because the first scan wasn't of high enough quality. The Volpara Live product can detect a sub-standard image before the client has left, hopefully avoiding the need for a revisit.

"They are often ignorant about why they are being called back," she says. "Reducing pain and reducing such frustration are the key drivers for us."

Anything else?

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

As a risk assessment platform, Volpara potentially has the ability to develop tools for other cancers as well as non-cancer diseases.

Cancers of interest include lung, ovarian, colorectal and pancreatic.

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

"The lung product is profitable, but they are not elephant size deals," she says. "I'm keen to expand beyond breast and potentially beyond cancer as well."

The company is also doing work with Microsoft on an artificial-intelligence-based tool to measure calcium build-up in arteries, which is a big heart attack risk factor for women.

"There's lot of directions we can go."

Finances and performance

Volpara achieved maiden net positive cash flow in the third (December 2022) quarter, of $NZ1.3 million compared with a $NZ3.1 million September 2022 quarter deficit. Net cash flow from operations was $NZ1.78 million.

Almost all of Volpara's revenue derives from subscription income, with contracted annual recurring revenue of $US25.6 million (six percent higher than the second quarter).

Ms Thomas cautions that not every quarter from now on will be cash flow positive, partly because of the timing of receipts. In the US, the company still has to go to its post box, collect the customer cheques and deposit them into the bank.

About 90 percent of Volpara's revenue is from the US and most of the rest from Australia.

The company held just under $NZ12 million of cash at the end of December, which should be enough to fund its activities without the need to raise capital. The company also has an unused $NZ10 million debt facility with Kiwibank. The company reports its March (fourth) quarter results on April 28.

Over the last 12 months, Volpara shares have ranged between 92 cents (late March 2022) and 41 cents (late June 2022). The shares hit a record $1.99 in November 2019.

Dr Boreham's diagnosis:

Ms Thomas says that, as with other providers, Volpara should do well in an economic downturn because "cancer doesn't stop and if anything, people get sick a bit more".

She adds that by eliminating some of the drudge work, Volpara's products should help attract radiologists and technicians.

As more 'elephants' join the Volpara game park the company should become consistently profitable while not forgetting its social charter.

"We are no flash in the pan," she says. "We do three million annual risk assessments and have thousands of facilities and technologists using our software."

Volpara products are used in about 40 percent of US mammograms, but 80 percent of clinics use only one product, so the company really has a 10 percent US market share.

"There's still a lot more we can do in the US," Ms Thomas says, adding she strives to make Volpara "the New Zealand equivalent of Pro Medicus".

Given Pro Medicus is worth $6.8 billion these days, Volpara truly would be in elephant country if it even were one quarter the size of the ASX imaging success story.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's never danced with an elephant but sure has been called a useless booby a few times [but never by me – Ed].

ECHO IQ

Echo IQ says a retrospective 9,189 sample trial shows its Echosolv identified 72 percent more patients with severe aortic stenosis than human diagnosis alone.

Echo IQ said the study at St Vincent's Hospitals in Sydney and Melbourne examined echo-cardiograms and was designed to test the effectiveness of its artificial intelligence-backed software Echosolv to identify patients with, and at risk of dying from, aortic stenosis, or a narrowing of the exit from the left ventricle of the heart.

The company said aortic stenosis was "one of the most common forms of heart valve disease in older people … associated with high risks to life if not identified and treated".

Echo IQ said that women were 66 percent less likely to have been accurately diagnosed than men using human-only assessment and its Echosolv resolved the discrimination.

The company said that Echosolv "clearly distinguishes between patients with varying severity of disease as well as those at high and low risk of dying".

Echo IQ said that where patients had aortic stenosis with significant risk of death, the study showed "a lack of intervention and proactive management when this hadn't been recorded on patient records".

The company said that the study was funded by the Irvine, California-based Edwards Lifesciences and was conducted with the National Echo Database of Australia.

Sydney's St Vincent's Hospital's Prof Michael Feneley said the study "clearly demonstrates not only the effectiveness of novel technologies such as Echosolv in enhancing human diagnosis, but also its potential to reduce bias in decision-making".

"With the general ageing of the population leading to the increasing prevalence of aortic stenosis, it is encouraging to see how artificial intelligence could be used to improve the identification of disease and all the increased opportunities to treat patients in a timely manner this provides," Prof Feneley said.

Echo IQ said that of the 9,189 studies reviewed, 218 individuals had been diagnosed by humans, as per routine clinical care, with guideline-defined severe aortic stenosis.

The company said that when Echosolv reviewed the same population it identified 376 individuals with this level of disease, an increase of 72 percent in disease detection.

Echo IQ said that even when identified as having severe aortic stenosis, "women were 50 percent less likely to receive intervention than men" re-enforcing the need for unbiased identification of disease.

The company said that in addition to the 376 patients identified as having guideline-defined severe aortic stenosis, Echosolv identified an additional 174 patients with aortic stenosis who fell outside diagnostic guidelines but showed significant risk of dying from the disease and 94 percent of the study population to be at low risk.

Echo IQ said the being able to categorize patients could support healthcare facilities to better allocate resources and prioritize patients for additional review and/or treatment.

The company said that clinical trials at St Vincent's Hospitals and Beth Israel Deaconess Medical Center reviewed more than 40,000 echocardiograms and supported the commercial deployment of Echosolv.

Echo IQ executive chair Andrew Grover said trial showed "how valuable Echosolv could be when integrated into clinical practice".

"With rates of under and mis-diagnosis of structural heart disease recognized as being higher than they should be, our solution is ready for deployment to reduce this diagnosis gap almost immediately," Mr Grover said.

"In the US, diagnostic errors affect an estimated 12 million adults each year," Mr Grover said. "We know that one in three medical malpractice cases resulting in death or permanent disability are due to inaccurate or delayed diagnosis," Mr Grover said.

Echo IQ fell half a cent or 2.9 percent to 17 cents with 1.6 million shares traded.

COCHLEAR

Cochlear says the UK Competition and Markets Authority has provisionally found that the proposed acquisition of Oticon Medical may lessen competition in the UK.

Cochlear said the UK Competition and Markets Authority (CMA) said the acquisition of Demant's hearing implant business could potentially lead to recipients who need hearing implants "losing out, with less choice, reduced quality or higher prices".

Last year, the company said it would buy the Smørum, Denmark-based Oticon Medical for DKK850 million ($A186 million) (BD: Apr 28, 2022).

In December, Cochlear said the CMA was reviewing the acquisition due to "competition concerns" about bone conduction product supplies and earlier that month, the Australian Competition and Consumer Commission (ACCC) said it had "significant preliminary competition concerns" with the acquisition (BD: Dec 1, 7, 2022).

Today, Cochlear said it disagreed with the conclusion drawn by the CMA, having invested more than "$2.5 billion in research and development" and investing about "12 percent of sales revenue [into research and development] to improve hearing outcomes and quality of life."

"The commitment to innovation and product quality has always been driven by the highest regard for our customers' welfare and the need to provide more people with better hearing solutions," the company said.

Cochlear chief executive officer Dig Howitt said that the company's interest in acquiring Oticon was "driven by our concern for the 75,000 Oticon Medical implant recipients who may miss out on the lifetime of support needed to maintain and improve their hearing".

"Demant has been clear about its intent to exit the hearing implants business and approached Cochlear to provide the support required by its recipients," Mr Howitt said.

"We believe only Cochlear can provide Oticon Medical recipients with that lifetime care, supported by our financial strength, scale, innovation capability and global reach," MR Howitt said.

The company said that the UK Competition and Markets Authority would invite comment on its provisional findings and potential remedies, and its finding might alter r in response to the comments received, with its final report expected by June 5, 2023.

Cochlear said the acquisition was conditional on approval from the CMA, the ACCC and the European Commission, as well as a review by the French Foreign Direct Investment authority.

The company said it was waiting for feedback from the Australian Competition and Consumer Commission and the European Commission.

Cochlear said the purchase was no longer expected to close before June 30, 2023.

Cochlear was up $1.17 or 0.5 percent to $249.42 with 118,656 traded.

ONCOSIL MEDICAL

Oncosil says Defender Asset Management has committed to subscribing up-to $3 million of any shortfall from the company's $9.9 million rights offer.

In March, Oncosil said an unnamed investor committed to subscribe for up to $2 million of any shortfall in its non-underwritten, one-for-one, non-renounceable entitlement offer, which closes on April 27, 2023 (BD: Mar 17, 2023).

Today, the company said the total binding commitments amounted to $5 million, exceeding the minimum subscription amount for the offer.

According to Defender Asset Management's website, Oncosil former deputy chair Martin Rogers was one of its responsible managers.

Oncosil was unchanged at one cent with 108.6 million shares traded.

INCANNEX HEALTHCARE

Incannex says it will offer a one-for-15 “loyalty options” at 0.1 cent each and exercisable at 25 cents each by April 30, 2026.
Incannex said the record date for the options was May 8, the offer would open on May 10 and close on May 26, 2023.
The company’s most recent filing said that it had 1,587,010,357 shares on offer and Biotech Daily calculates that if all options were acquired, it would raise $105,801 and if all those options were exercised it would raise $26,450,173.
Incannex said that investors would receive on “piggy-back option” for every two “loyalty options” exercised, in turn exercisable at $1.00 each by May 1, 2028
Incannex chief executive officer Joel Latham said the options were being granted to shareholders as “a reward for their continued support”.
“The bonus issue follows an unfortunate period of significant share price volatility, which may have been exacerbated by international liquidity selling unrelated to the fundamentals of our company,” Mr Latham said.
Incannex fell half a cent or 4.2 percent to 11.5 cents with 5.1 million shares traded.

AND HEALTH

AND Health (Australia’s National Digital Health Initiative) says it has partnered with Chicago ARC to distribute Australian digital health products in the US.
AND Health said it would work with Chicago ARC (accelerate, redesign and collaborate) to “accelerate and de-risk” US market entry for Australian digital health startups.
The organization said that Chicago ARC partners had more than 750 healthcare delivery and training facilities in Chicago and the Midwest of the US.
The Chicago ARC website said that it provided investment capital, venture collaboration and had a social impact foundation.

INVEX THERAPEUTICS

Invex says it has French ethics approval for its 240-patient, phase III ‘Evolve’ trial of Presendin for idiopathic intracranial pressure.
Yesterday, Invex said that it had Israeli approval for the randomized, placebo-controlled, double-blind trial along with Australia, the US, the UK, Germany and New Zealand approvals (BD: Nov 21, 2022; Apr 20, 2023).
Today the company said that it intended to open up-to six French clinical sites.
Invex was up four cents or nine percent to 48.5 cents.

PHARMAUST AUSTRALIA

Pharmaust says two dogs in its monepantel B-cell lymphoma trial have had 30 percent or more decrease in tumor size, with eight dogs having “stable disease”.
Pharmaust said one dog had surpassed 280 days with stable disease and “continued excellent quality of life”.
Last year, the company said it had enrolled the first of 10 dogs in a US trial of monepantel as a treatment for canine B cell lymphoma (BD: Sep 7, 2022).
Pharmaust was unchanged at 10 cents.

TELIX PHARMACEUTICALS

Telix says its annual general meeting will vote to issue 120,268 performance rights to managing-director Dr Chris Behrenbruch.
Telix said the performance rights had a notional exercise price of $6.90 each, had a term of five years and would vest in three tranches pending earnings before interest, taxation, depreciation, amortization and restructuring or rent (Ebitdar) performance targets.
Telix said Dr Behrenbruch's base salary was $475,650.
The company said the meeting would vote to re-elect as directors chair Harry Kevin McCann and Dr Mark Nelson, and adopt the remuneration report.
The meeting will be held virtually and at The Events Centre, Collins Square, 727 Collins Street, Melbourne on May 24, 2023 at 11am (AEST).
Telix was up 21 cents or 2.15 percent to $10.00 with 3.3 million shares traded.

DIMERIX

The Nedlands, Western Australia-based Merchant Funds says it has ceased its substantial shareholding in Dimerix.
Merchant Funds said that between October 2021 and April 2023 it bought and sold shares, with the single largest sale 4,625,000 shares for $1,060,240 or 22.9 cents a share in December 2021.
In October 2021, Merchant Funds said it became a substantial shareholder in Dimerix with 17,925,000 shares or 5.59 percent of the company (BD: Oct 6, 2021).
Biotech Daily calculates Merchant Funds holds 14,052,000 shares or 4.38 percent of the company.
Dimerix fell 0.3 cents or three percent to 9.6 cents with 1.25 million shares traded.

MEDADVISOR

Medadvisor says Cotiviti's nominated board director Raeann Grossman has resigned as non-executive director of Medadvisor, effective from today.
Last year, Medadvisor said it had appointed Raeann Grossman director as a representative of shareholder, the South Jordan, Utah-based Cotiviti (BD: Feb 1, 2022).
In 2020, Cotiviti said it acquired 43,999,999 Medadvisor shares for $US11,305,140 ($A16,830,188) in an off-market transfer from the Irving, Texas-based Health Management Services (BD: Aug 24, 2020).
Today, the company said it would appoint a new US-based, Cotiviti-nominated director.
Medadvisor was up half a cent or 2.1 percent to 24 cents.