



Biotech Daily

Friday April 12, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 11%;
- AVITA DOWN 16%**
- * **DR BOREHAM'S CRUCIBLE: BCAL DIAGNOSTICS**
- * **ARGENICA RAISES \$12m; \$500k CHAIR OPTIONS**
- * **ONCOSIL TREATS 1st UK 'TRIPP-FFX' PANCREATIC CANCER PATIENT**
- * **VOLPARA VOTES 97% FOR \$296m LUNIT SALE**
- * **AMPLIA REQUESTS 'ENTITLEMENT OFFER' TRADING HALT**
- * **FIL (FIDELITY) BELOW 5% OF IMMUTEP**
- * **DAVID SIETSMA INCREASES, DILUTED TO 6% OF PYC**

MARKET REPORT

The Australian stock market was down 0.33 percent on Friday April 12, 2024, with the ASX200 down 25.5 points to 7,788.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 were down, eight traded unchanged and one was untraded.

Universal Biosensors was the best, up two cents or 11.1 percent to 20 cents, with 149,524 shares traded.

Actinogen, Dimerix and Resonance climbed more than six percent; Alcidion, Proteomics and Telix rose more than two percent; Immutep and Nanosonics improved more than one percent; with CSL, Neuren and Volpara up by less than one percent.

Avita led the falls, down 63 cents or 15.8 percent to \$3.35, with 1.8 million shares traded.

Micro-X lost eight percent; Percheron shed seven percent; Syntara was down 5.6 percent; 4D Medical fell 4.1 percent; Imugene, Paradigm and Starpharma were down more than three percent; Emvision and Medical Developments shed more than two percent; Clinuvel, Impedimed, Mesoblast, Nova Eye, Prescient and Resmed were down more than one percent; with Clarity, Cochlear, Genetic Signatures, Polynovo, Pro Medicus and SDI down by less than one percent.

DR BOREHAM'S CRUCIBLE: BCAL DIAGNOSTICS

By TIM BOREHAM

ASX Code: BDX

Share price: 10.5 cents;

Shares on issue: 252,294,714

Market cap: \$26.5 million

CEO: Shane Ryan

Board: Jayne Shaw (executive chair), Ron Phillips, John Hurrell, Jonathan Trollip, David Mark Burrows, Dr David Darling.

Financials (half year to December 2023): revenue nil, net loss \$2.4 million (previously \$2.47 million deficit), cash balance \$5.01 million (up 58%).

Major identifiable shareholders: Jayne Shaw 11.4%, Ronald Anthony and Ann-Marie Phillips 10.65%, Capital Property Corp (Carrington Account) 6.02%, Mera Vale #1 6.06%, Merchant Funds Management 4.4%

While most developers of health diagnosis tools scurry off to the capacious US market, Bcal is happy to use Australia as the springboard for what will be the country's first blood-based breast cancer assay.

"It's a passion of ours to launch the test in the Australian market and then take it global," says Bcal founder Jayne Shaw, a former nurse and entrepreneur who co-founded the Sydney Breast Clinic.

"We want this test available to all women, especially in the regional areas where it is easier to have a blood test than to access a mammogram."

Here, 20,000 breast cancer cases are detected annually, with 3,000 deaths.

As a stepping stone to Therapeutic Goods Administration (TGA) approval, Bcal is developing its test, unoriginally monikered Breastest, as a so-called lab-developed assay.

Such tests can be sold via clinics once approved by the National Association of Testing Authorities (NATA).

"We are currently working in the US with regulatory bodies and focus groups, but the priority is a 'soft' market entry in Australia by the end of 2024," Ms Shaw says.

She adds the company has had "open and frank" discussions with the TGA, which supports the lab-developed test approach.

The story of Bcal

Bcal is an acronym of Breast Cancer Associated Lipids. The company was founded by the Lancashire-born Ms Shaw, who migrated to Australia in 1990. She became the director of nursing and CEO of two NSW hospitals, where she noticed the poor results for breast cancer patients.

In 2000, she co-founded the eyecare clinic consolidation play Vision Group, which listed on the ASX and eventually was acquired by Chinese interests. She then invested in the Sydney Breast Clinic, teaming-up with former New South Wales Liberal Party Health Minister Ron Phillips.

After the Sydney Breast Clinic was sold to Healthscope, the duo acquired the intellectual property pertaining to the blood-based tests.

Bcal listed on the ASX on July 19, 2021, having raised \$10 million at 25 cents apiece, with part of its intellectual property from Louisville University, which was replicating some of the scientific work.

In a management reshuffle announced on March 6 this year, current CEO Dr John Hurrell became a consultant and executive director. The company's chief operating officer since September 2023, Shane Ryan slipped into the CEO chair on April 1 ... no joke.

As a Genesiscare executive, Mr Ryan bought a genomics-based breast cancer test to market in 2021.

About Breastest

The Breastest assay centres on lipids: fats that are a source of energy for cell growth.

"When the lipid metabolism is deregulated, this is the early sign of a cell becoming cancerous," Ms Shaw says.

The blood sample is drawn from the patient and then the extracellular vesicles (EVs) are enriched from the blood plasma that contain lipids. The blood is then matched against a panel of 18 biomarkers "characteristic of the presence of blood cancers".

A facility you can (bio) bank on

Flanked by pollies including Federal Health Minister Mark Butler, last May Bcal opened its own lab in the Sydney suburb of North Ryde. Rather than relying on potentially unreliable third-party biobanks, Bcal has 4,000 samples stored at the facility.

"We have collected 2,500 samples according to clinical protocols," Ms Shaw says. "We haven't just gone to bio-banks and that's why it has taken us 14 years."

Initially, Bcal will roll out the tests to New South Wales and Victorian centres including the Sydney Breast Clinic, Sydney's Westmead and Royal Prince Alfred hospitals and Melbourne's Monash Medical Centre.

Post launch, Bcal plans to seek agreements with local radiology providers to take the test nationally. Costing around \$300 out-of-pocket, the algorithm-based test will be an adjunct to the commonly used mammography, which is a low-dose X-ray scan.

"You have to be realistic, you can't replace the standard-of-care overnight," Ms Shaw says.

Is Breastest the best test?

Mammograms might be the standard-of-care, but they are far from optimal.

In Australia, 2.1 million mammograms took place in 2023, but a further 1.5 million eligible women did not get screened. Thus, 41 percent of women eligible for a mammogram choose not to do so, often because the procedure is uncomfortable or for cultural reasons.

Here, mammograms are not funded for under 40s women, unless they are deemed high risk because of a gene mutation.

The accuracy of mammograms leave much to be desired in terms of both sensitivity (the ability to detect tumors) and specificity (the ability to detect negative samples). On these measures, mammograms are only 54.5 percent and 85.5 percent accurate respectively. Missed tumors aside, poor specificity means many follow-up biopsies are unnecessary.

With Breastest, Bcal claims a 90 percent sensitivity and 85.5 percent specificity.

Magnetic resonance imaging (MRI) scans are the most effective method, with an accuracy of 94.6 percent and 74.2 percent respectively. But they are expensive (\$900-\$1,200 a pop) and hard to access for all but the most vulnerable patients.

Dubbed the 'poor woman's MRI', contrast mammograms involve a contrast dye being injected to highlight the tumors better. This unreimbursed method is not widely available, takes 45 minutes and is dangerous to patients with allergies or compromised kidneys.

But Ms Shaw is heartened that while a lot of women don't want a mammogram, about half of those that undergo one will pay for extra testing out of pocket.

The road to the US

Bcal is angling for US approval - initially as a laboratory test - which makes sense given the US accounts for 60 percent of the breast cancer diagnostics market.

More than 52.3 million mammograms were carried out in the US in 2019 and this year 310,720 cases of breast cancer were expected to be diagnosed.

Bcal has a tie up with the North Carolina-based diagnostics house Precion to validate the protocols and procedures for the studies needed to support regulatory approval.

Ms Shaw is pleased the results of the 656 US samples - drawn from stipulated ethnic groups - replicated the Australian accuracy. Further down the track, Bcal is eyeing the market for post-treatment monitoring of women who have had breast cancer - a poorly-serviced cohort. Bcal also has a licencing arrangement with the University of Louisville covering a similar blood assay for lung cancer.

“But I would rather get one thing right and then diversify, rather than being all things to all people,” Ms Shaw says.

Finances and performance

Despite a \$2.4 million half-year loss, Bcal’s cash balance rose 58 percent to just over \$5 million at the end of December 2023, thanks to a placement and share purchase plan that raised just over \$3 million at 10 cents a share.

As of mid-March 2024 the company had \$3.6 million in the bank.

“The board is always evaluating capital requirements. There are no imminent plans but never say never,” Ms Shaw says.

Other options are licencing agreements, or strategic partnerships.

Bcal shares have gained 35 percent over the last 12 months. Still, they are well below their peak of 25 cents of July 2021, just after listing.

Sizing up the rivals

Blood-based diagnosis is a very active area globally, notwithstanding the reputational damage inflicted by US company Theranos and its jailed fraudster founder Elizabeth Holmes.

Ms Shaw is often asked questions about ASX-listed peer Rhythm Biosciences, which has developed a blood-based bowel testing assay to replace the unsavoury ‘poo’ test.

Rhythm has not cracked TGA approval and the test is being developed as a research-only tool. But another mob - Wisconsin’s Exact Sciences Corp - has developed a US Food and Drug Administration-approved colorectal cancer test.

Bcal is also compared with the ASX listed Inoviq. The result of the merger of Bard1 and Sienna Diagnostics, Inoviq targets blood-based tests for breast and ovarian cancers, but its technology is based on antibodies rather than lipids.

Bcal director, Dr Darling spent 17 years at the ASX-listed Pacific Edge, which took a bladder cancer test from New Zealand to the US but then struck reimbursement problems.

What's it worth?

In the local market, Bcal has assumed Breastest penetration rates of 10 to 30 percent, with 20 percent equating to 400,000 tests and revenue of more than \$100 million.

Initially, Ms Shaw says, the company's laboratory should be able to do 20,000 tests a year across two mass spectrometer machines (which cost about \$500,000 each). This implies revenue of \$7 million.

Naturally, the company is seeking reimbursement and Ms Shaw notes other molecular-based tests for prostate, cervical and colorectal cancers are government funded.

Bcal has the ear of the polities - including Federal Treasurer Jim Chalmers - which goes to show that breasts are always a vote winner.

"We realise there is not an unlimited budget, but can present persuasive data in view of reimbursement," Ms Shaw says.

No pressure, Jim!

Dr Boreham's diagnosis:

Lest we forget, breast cancer is the world's most common cancer for women, with two million new diagnoses a year and 627,000 deaths.

If diagnosed at stage one, the survival rate is 98 percent but this falls to 28 percent at stage four.

But let's talk in real medical language: dollars. Bcal cites the cost of treating stage-one cancer cases at \$44,367, rising to \$418,549 by stage four.

The global testing market is worth about \$US5 billion (\$A7.5 billion) and is forecast to rise to \$US8.7 billion by 2027.

At the risk of stating the obvious, Bcal's fortunes lie not so much with the broader and vast market potential, but in financial discipline and skilful execution of its plans.

On that note, Bcal's board and management are replete with competent, commercial-focused operatives with the right intentions to boot.

Ms Shaw says the board treats every dollar as if it were its own, which is quite true as the directors account for a large wad of the register.

"We have never asked anyone to put a dollar in without backing it ourselves," she says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He doesn't have an unlimited budget, but hopes he presents persuasive data.

ARGENICA THERAPEUTICS

Argenica says it has “commitments” for a \$12.0 million institutional placement at 52.0 cents a share and will issue 500,000 options to chair Dianne Angus.

Argenica said the share price was a 19.4 percent discount to the 15-day volume weighted average market price and an 18.1 percent discount to the last traded price of 63.5 cents.

The company said the placement was “strongly supported by large existing shareholders, new institutional investors, family offices, and sophisticated high-net-worth investors”.

Argenica said the funds would be used to complete its phase II trial of ARG-007 for ischaemic stroke, progress studies in other neurological indications such as traumatic brain injury, Alzheimer’s disease and hypoxic ischemic encephalopathy as well as regulatory activities.

The company said Euroz Hartleys Ltd and Petra Capital Pty Ltd were joint lead managers and joint bookrunners for the placement.

Argenica said it would issue 500,000 options, exercisable at 93.0 cents each by May 31, 2027 to its recently appointed chair Dianne Angus as part of her remuneration package, subject to shareholder approval.

Last year, the company said Dianne Angus would replace Geoff Pocock as non-executive chair, effective from December 1, 2023 (BD: Nov 30, 2023).

Argenica fell 6.5 cents or 10.2 percent to 57 cents.

ONCOSIL MEDICAL

Oncosil says it has treated the first UK patient in the “Tripp-FFX” clinical study of its radiotherapy device in combination with chemotherapy for pancreatic cancer.

Oncosil said the 80-patient study of ‘targeted intra-tumoural placement of phosphorous-32 with Folfirinox (folinic acid, fluorouracil, irinotecan and oxaliplatin), or Tripp-FFX study, would assess safety and efficacy of the Oncosil device when given with standard Folfirinox chemotherapy for the treatment of locally advanced pancreatic cancer.

Last year, the company said it had enrolled the first of 80 patients in its open-label, randomized trial of phosphorous-32 radiation with chemotherapy for pancreatic cancer (BD: May 3, 2023).

Today, Oncosil said the study would assess the safety and efficacy of its device when given with Folfirinox chemotherapy for pancreatic cancer.

The company said the study was being conducted at 16 to 18 sites in Spain, the UK, Australia, Italy and Belgium, with 11 sites still open to recruitment and 29 patients recruited to date.

Oncosil said the UK patient was treated at London’s Hammersmith Hospital, which was also part of its previous ‘Pancosil’ study.

Oncosil chief executive officer Nigel Lange said “the first patient treatment using the Oncosil device for the Tripp-FFX clinical study in the UK represents another significant step in our ongoing efforts to expand our label approval to include one of the backbone chemotherapies in combination with our device as a treatment option for patients with locally advanced pancreatic cancer”.

“It provides further proof that Oncosil Medical is successfully executing on two broad-based components of its overall growth strategy,” Mr Lange said.

“The first of these is to continue our research of the Oncosil device through continued clinical studies,” Mr Lange said.

“The second is to commercialize the device in several key target markets including Western Europe and the UK,” Mr Lange said.

Oncosil was unchanged at 0.6 cents with 18.2 million shares traded.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says its scheme of arrangement meeting has approved the sale to South Korea's Lunit Inc for \$295.7 million, with 96.92 percent of votes cast in favor.

In December, Volpara said that the Seoul, South Korea-based Lunit hoped to acquire the company for \$1.15 a share, valuing it at \$295.7 million, through a scheme implementation agreement (BD: Dec 14, 2023).

Today, the company said that 172,908,889 votes (96.92%) approved the sale, with 5,497,340 opposed.

Volpara said that the votes were 70.13 percent of the total shares on issue.

The company said that if the High Court of New Zealand granted final orders approving the scheme, and subject to conditions, the last day of trading would be May 3, 2024, with implementation and payment expected about May 21, 2024.

Volpara was up 0.25 cents or 0.22 percent to \$1.14.

[AMPLIA THERAPEUTICS](#)

Amplia has requested a trading halt to allow it "to undertake an entitlement offer process". Trading will resume on April 16, 2024, or on an earlier announcement.

Amplia last traded at 8.5 cents.

[IMMUTEP](#)

FIL Limited (Fidelity) says it has ceased its substantial shareholding in Immutep.

The Sydney and Hong Kong-based FIL (Fidelity) said that on March 7, March 8 and April 9, 2024 it sold 2,334,497 shares for prices ranging from 37.56 cents to 40.43 cents a share.

In February, FIL said it held 60,782,556 shares or 5.11 percent of Immutep.

According to its most recent filing, Immutep had 1,188,834,559 shares on issue, meaning that FIL's remaining 58,448,059 shares amounts to about 4.9 percent of the company (BD: Feb 23, 2024).

Immutep was up half a cent or 1.35 percent to 37.5 cents with 1.8 million shares traded.

[PYC THERAPEUTICS](#)

David Sietsma says his substantial shareholding in PYC has increased and been diluted from 283,304,990 shares (7.60%) to 283,400,000 shares (6.07%).

The Melbourne-based Mr Sietsma said with Sietsma Holdings did not disclose the cost of the increase nor the nature of the dilution, nor the date, as required under the Corporations Act 2001.

Yesterday, PYC said its one-for-four retail offer at eight cents a share raised \$13.5 million and that it had "commitments" to place the \$21.2 million shortfall, taking the total with the institutional offer to \$74.6 million (BD: Mar 14, Mar 18, Apr 11, 2024).

PYC fell 0.4 cents or four percent to 9.6 cents with 1.85 million shares traded.