



Biotech Daily

Friday September 17, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: ACTINOGEN UP 11%; IMPEDIMED DOWN 8%**
- * **DR BOREHAM'S CRUCIBLE: BCAL DIAGNOSTICS**
- * **FEDERAL \$4m FOR TRAUMATIC BRAIN INJURY; 'ROADMAP'**
- * **CRESO: CANNADOL ON-LINE SALES, \$80k ANIBIDIOL FOR POLVET**
- * **EPSILON REQUESTS 'VALENS 1st MATERIAL ORDER' TRADING HALT**
- * **ELLERSTON TAKES 7.3% OF ATOMO**
- * **AUSTRALIAN ETHICAL REDUCES TO 14% OF COGSTATE**
- * **REGAL FUNDS TAKES 5.8% OF IMRICOR**
- * **OSTEOPORE TO RELEASE 39m ASX ESCROW SHARES, 9.7m OPTIONS**
- * **HEXIMA TO RELEASE 3.6m ASX ESCROW SHARES**
- * **MICRO-X APPOINTS CHARLIE HICKS MOBILE DR HEAD**
- * **FEDERAL MRFF: 4 NEW ADVISORY BOARD MEMBERS**

MARKET REPORT

The Australian stock market fell 0.76 percent on Friday September 17, 2021, with the ASX200 down 56.5 points to 7,403.7 points. Eighteen of the Biotech Daily Top 40 stocks were up, 17 fell and five traded unchanged. All three Big Caps were up.

Actinogen was the best, up one cent or 11.1 percent to 10 cents, with 5.8 million shares traded. Imugene climbed 9.4 percent; Prescient improved eight percent; Alterity rose 6.7 percent; Compumedics was up five percent; Telix rose 4.9 percent; Cynata, Nova Eye and Pharmaxis were up more than three percent; Amplia, Next Science, Oncosil, Orthocell, Polynovo and Volpara rose more than two percent; Clinuvel, Pro Medicus and Starpharma were up more than one percent; with Cochlear, CSL and Resmed up by less than one percent.

Impedimed led the falls, down one cent or 8.3 percent to 11 cents, with 2.1 million shares traded. Avita, Cyclopharm and Osprey lost more than seven percent; Opthea and Paradigm were down more than five percent; Medical Developments fell 4.4 percent; Immutep, Mesoblast, Universal Biosensors and Uscom were down more than three percent; Optiscan and Proteomics shed more than two percent; Nanosonics and Neuren were down one percent or more; with Genetic Signatures and Kazia down by less than one percent.

[DR BOREHAM'S CRUCIBLE: BCAL DIAGNOSTICS](#)

By TIM BOREHAM

ASX Code: BDX

Share price: 19.5 cents; **Shares on issue:** 206,875,633; **Market cap:** \$40.3 million

Executive chair: Jayne Shaw

Board: Ms Shaw, Ron Phillips, Dr Merylyn Sleight, Jonathan Trollip, Mark Burrows

Financials (year to June 30, 2021): revenue nil, net loss \$1.52 million (previously \$696,000 deficit), cash balance \$13m

Major identifiable shareholders: Jayne Shaw 13.88%, Ron Phillips 13.35%, Trust Company Australia 8.77%, Regal Funds Management 5.8%

As with other types of medical imaging, breast cancer diagnosis has taken great leaps forward with the use of techniques such as 3-D screening and ultrasound.

Yet mammograms - the standard of care - have a miserable reliability rate of between 60 percent and 85 percent.

In this context, BCal Diagnostics hopes to reduce the incidence of both false positives and false negatives with a blood-based, molecular diagnostics-based test.

The desired endgame is reducing the number of painful biopsies, but also ensuring that the most vulnerable women have access to regular cost-effective screening.

The raw reality is that mammograms miss 20 percent of all tumors, while 80 percent of follow-up biopsies are not needed.

“The goal of the company is to get to market as quickly as we can within the data and compliance requirements for clinical validation and regulatory approvals,” says executive chair Jayne Shaw.

About BCal

Breast Cancer Associated Lipids (BCal) was founded by the Lancashire-born Ms Shaw, who is not only a career healthcare professional but an entrepreneurial dynamo.

“All the girls in my family were nurses and all the boys were engineers,” she said.

After migrating to Australia in 1990, Ms Shaw became the director of nursing and CEO of two NSW hospitals “at a reasonably young age”.

Along the way, she noticed the poor clinical outcomes for breast cancer patients - especially depending on where they lived.

In 2000, she co-founded the eyecare clinic consolidation play Vision Group, which listed on the ASX and eventually was acquired by Chinese interests.

After that foray she invested in the Sydney Breast Clinic, where she teamed up with former New South Wales Liberal Party Health Minister Ron Phillips.

“We both wanted to make a difference with early diagnosis of breast cancer, it was a meeting of minds,” she says.

Eventually Sydney Breast Clinic was sold to Healthscope, after which she turned her attention to a blood-based test being developed by a company working at the clinic.

“We bought the [intellectual property], recruited some scientists and funded some research with the backing of high-net-worth individuals, who knew it was high risk but could make a meaningful impact.”

Some of the intellectual property derives from Louisville University, which was replicating some of the scientific work. BCal has an exclusive licence agreement with the Kentucky’s University of Louisville for breast and lung cancer.

BCal listed on the ASX on July 19, 2021, having raised \$10 million at 25 cents apiece.

The company funded research in the US for six years, but in 2017 re-domiciled the program to the University of Sydney’s Charles Perkins Centre (which has the requisite mass spectrometry infrastructure).

A notable member of BCal’s five-strong scientific team is Dr Amani Batarseh, a molecular biologist and leading expert in lipidomic and mass spectrometry.

“We were blessed to be able to recruit her,” Ms Shaw says.

A towering inclusion on the board is experienced investment banker and company director Mark Burrows, who has been known more for playing at the big end of town.

“We have to take a few noughts off the numbers because he is used to much bigger figures,” Ms Shaw quips.

About the BCal test

The BCal test - which, like the horse in the desert, does not have a name - is based on an algorithmic software component.

The blood sample is drawn from the patient and then the extracellular vesicles (EVs) are enriched from the blood plasma that contain lipids (types of fats).

The blood is then matched against a panel of 18 biomarkers “characteristic of the presence of blood cancers”.

Initial studies at Charles Perkins suggests the tests are 91 percent accurate in identifying patients with the disease and 87 percent right in calling out those without a tumor.

Regulatory approach

The company’s regulatory and commercial approach is to tackle the local market first, through an application to the Therapeutic Goods Administration, in parallel with a laboratory-developed-test pathway to market.

The BCal test’s first market entry will be as an adjunct with mammography - certainly not a replacement for it.

Along the way, BCal is augmenting its database of 1,000 or so samples with blood specimens from the Sydney Breast Clinic, Lifehouse, the Specialist Cancer Breast Surgery Centre adjacent to Melbourne’s Epworth Hospital and New South Wales Breast Screening (controversially closed during the Sydney pandemic crisis).

“Our gold standard and purpose are to have a routine screening blood test for all women everywhere, but you need high volumes of clinical samples and clinical data,” Ms Shaw says.

“The aim is to get an Australian lab partner to work to develop that.”

BCal is also in discussion with US parties, which is not surprising given the US accounts for 60 percent of the breast cancer diagnostics market.

Of course, the proudly parochial US regulators prefer applicants with home-sourced samples that are as American as apple pie and annoying family sitcoms.

“We are realistic that there is only so much we can do in Australia and we need to start collecting clinical data in the US as well,” Ms Shaw says.

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.”

The problem with mammograms

Poor accuracy aside, the wider problem with mammograms is that 50 percent of eligible women opt not to have them, either because of the pain involved or because they are unwilling to bare their breasts for cultural reasons.

Screening is low among women of certain Asian, Middle Eastern and Mediterranean backgrounds. Breast cancer is also much more fatal in developing countries where healthcare is of lower quality due to later diagnosis.

In Britain, last year's prolonged Covid-19 lockdowns resulted in about one million fewer mammograms being carried out - and an uptick in late-stage cancers because of tardy diagnosis.

In 12 to 18 months' time, we will see if the same trend is evident here.

Accuracy aside, the problem with mammograms is that in Australia they are not funded for women aged under 40 (the cut-off used to be 50). So, unless they are deemed high risk because of a BRCA gene mutation, younger women must rely on inaccurate self-examination. Breast cancers in the under 40s tends to be more aggressive.

Finances and performance

BCal's initial public offer raised \$2 million more than the targeted \$8 million, but as is often the case the shares failed to ignite after some of the original investors availed of the opportunity to sell.

It didn't help that Cicada, Sydney University's commercialization incubator, had to sell its entire stake in BCal. Yep - times are tough in academia.

To date, BCal shares have traded between 25 cents (July 21) and 14 cents (August 23).

Ms Shaw estimates the Americans (Louisville University) spent about \$US20 million (\$A27 million) on the intellectual property, with the Australian end investing a further \$8 million to \$10 million.

She adds that the company has also benefited from pro-bono input, such as directors and lawyers working for nothing during six years of "hand to mouth" existence.

"We are very prudent with our cash; we treat every dollar as if it is our own," she says.

Sizing up the rivals

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

(Holmes is currently on trial on fraud charges relating to the \$US9 billion collapse of Theranos, which claimed to be developing a pin-prick test for multiple indications).

In the US, Provista Diagnostics has blood-based cancer tests on market.

BCal is being closely compared with the ASX-listed blood-based diagnostics peer Bard1, which merged with Sienna Diagnostics. Bard1 is targeting breast and ovarian cancers, but its tests are based on antibodies rather than lipids.

Ms Shaw admits that BCal is not alone, but adds that it's not a winner-takes-all race.

"As with prostate cancer or colorectal cancer there will be many tests on the market and that's why it's important to have good clinical data and the support of the medical community, and we think BCal is well positioned in this regard."

BCal is also 'competing' with deep-pocketed companies such as Grail and Guardant Health of the US, which are working on pan-cancer tests. There are other genomic tests, but so far, no blood test for breast cancer.

She suspects the molecular testing efforts eventually will consolidate in favor of the most accurate and cost-effective assays.

"It's going to come down to the specificity and sensitivity of the test, clinical utility and price," Ms Shaw says.

There's also the Kiwi-based, ASX-listed Volpara Health Technologies, which has tools to enable more accurate imaging of dense-breasted women (tumors on dense breasts do not show up as well as those on fatty breasts).

"We all have the same purpose that earlier diagnosis will lead to improved survivability rates for women with breast cancer."

Dr Boreham's diagnosis:

In a bout of rare honesty for a CEO, Ms Shaw describes the share performance to date as "very turbulent and disappointing".

C'mon Jayne, cheer up: we've seen a lot worse than a recently-listed stock trading at a 20 percent discount.

She adds: "I can't do anything about the share price, we can only deliver milestones and we are doing that."

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. In Australia 20,000 cases are detected annually, with 3,000 deaths.

The global testing market is worth about \$US5 billion and is forecast to rise to \$US8.7 billion by 2027, but Ms Shaw has no delusions about the odds of success.

"It's risky, there's no question," she says. "I'm a realist but we are very focused on getting a test to market."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he does possess man boobs and does his breast to makes sense of the technical stuff.

FEDERAL GOVERNMENT

The Federal Government says it has provided a \$4 million grant for traumatic brain injury research.

A media release from the Minister for Health Greg Hunt said the grants would be available in two streams, one of \$3 million over three years for “a national consortium to identify ways to improve care for mild traumatic brain injury” and the second worth up to \$1 million over three years to “develop and implement new approaches for the prevention, diagnosis and treatment of sports-related concussion”.

The media release said that the funding was part of the Traumatic Brain Injury Mission, investing \$50 million over 10 years to improve the lives of patients with traumatic brain injury.

The Federal Government said the goal of the Mission was to better predict recovery outcomes after a traumatic brain injury, identifying the most effective care and treatments and reducing barriers support people.

The Government said it had released the Traumatic Brain Injury Mission Roadmap and Implementation Plan today, developed by the expert working group led by Prof Melinda Fitzgerald.

The media release said the roadmap would guide the research investment strategy for the mission to help achieve its goal.

CRESO PHARMA

Creso says it has launched an on-line sales site for marijuana products under the Born to Move brand and sold \$80,141 worth of marijuana to Polvet Healthcare.

Creso said the three Cannadol products under the Born to Move portfolio included the Cannadol booster, Cannadol revitalize gel and Cannadol recovery for sports.

In May, Creso said it had a one-year non-exclusive agreement with the Orzesze, Poland-based Polvet Healthcare to market and distribute its marijuana-based animal health products in Poland (AVW: May 21, 2021).

Today, the company said Polvet ordered Creso’s hemp-flour based Anibidiol granule for use in animals treated in its clinics before and after surgery and to sell and distribute through its electronic commerce channels.

Creso was unchanged at 12 cents with 10.1 million shares traded.

EPSILON HEALTHCARE

Epsilon has requested a trading halt pending an announcement on “the first material order under the recently announced partnership ... [with] the Valens Company”.

Trading will resume on September 21, 2021, or on an earlier announcement.

Epsilon last traded at 15 cents

ATOMO DIAGNOSTICS

Ellerston Capital says it has increased its substantial shareholding in Atomo from 34,375,000 shares (6.13%) to 41,586,285 shares (7.31%).

The Sydney-based Ellerston said it bought and sold shares between April 20, 2020, and September 15, 2021, with the single largest purchase 4,555,796 shares for \$1,408,076 or 30.9 cents a share on October 16, 2020.

Atomo fell two cents or 5.4 percent to 35 cents with 11.0 million shares traded.

COGSTATE

Australian Ethical Investment says it has reduced its substantial shareholding in Cogstate from 26,775,141 shares (15.66%) to 24,208,118 shares (14.05%).

The Sydney-based Australian Ethical said between June 16 and September 15, 2021, it sold 2,567,023 shares for \$4,613,479 or an average price of \$1.797 a share.

Cogstate was up 10 cents or five percent to \$2.10.

IMRICOR MEDICAL SYSTEMS

Regal Funds says it has become a substantial shareholder in Imricor Medical Systems with 8,311,716 shares or 5.84 percent.

The Sydney-based Regal Funds said it bought shares between May 27 and September 14, 2021, with the single largest purchase 2,470,055 shares for \$2,470,055 or \$1.00 a share.

Earlier this month, Imricor said it had raised \$16.5 million in a placement at \$1.00 a share and hoped to raise a further \$1.0 million in a share plan (BD: Sep 8, 2021).

Imricor was up fell 11 cents or 9.7 percent to \$1.25.

OSTEOPORE

Osteopore says 39,230,438 shares and 9,700,000 unlisted options will be released from ASX escrow on September 23, 2021.

According to the company's most recent Appendix 2A application for quotation of securities, following the release from escrow, it would have 117,268,238 shares on issue and available for trading.

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

HEXIMA

Hexima says 3,559,437 shares will be released from ASX escrow on September 25, 2021.

Hexima told Biotech Daily that following the release, there would be 123,931,846 shares available for trading with a further 6,925,878 shares in ASX escrow.

Hexima fell 7.5 cents or 16.9 percent to 37 cents.

MICRO-X

Micro-X says it has appointed Charlie Hicks head of its Mobile Digital Radiography (DR) business unit as part of the expansion of its medical and security business.

Micro-X said the Rochester, New York-based Mr Hicks was previously Carestream Health's business director and X-Ray general-manager.

The company said Mr Hicks had more than 30 years' experience bringing innovative radiology products to market and had multiple patents in digital imaging.

Mr Hicks LinkedIn page said he held a Bachelor of Science from the Potsdam, New York Clarkson University and a Bachelor of Arts in Computer Science from the State University of New York College in Potsdam.

Micro-X was unchanged at 29.5 cents.

FEDERAL GOVERNMENT

The Federal Government says it has appointed four new members to the Australian Medical Research Advisory Board.

A media release from the Federal Minister for Health Greg Hunt said the Board advised the Government on research and innovation priorities for the \$20 billion Medical Research Future Fund.

Mr Hunt said that Prof Ian Frazer continued as the chair of the Board, with the Burnet Institute's Prof Caroline Homer appointed to the Board as deputy chair.

Mr Hunt said the other new directors were: Australian Institute of Tropical Health deputy director Prof Denise Doolan; South Australian and Northern Territory National Heart Foundation of Australia chief executive and Bellberry founding chief executive officer Imelda Lync; and Chancellor of the University of Canberra and the University of Sydney Professor of Practice (Indigenous Engagement) Prof Tom Calma.

The media release said that Prof Anne Kelso, Prof Douglas Hilton and Yasser El-Ansary continued as members.