Biotech Daily

Friday November 19, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.23 percent on Friday November 19, 2021, with the ASX200 up 17.3 points to 7,396.5 points. Eleven of the Biotech Daily Top 40 stocks were up, 23 fell and six traded unchanged.

Dimerix was the best, up two cents or eight percent to 27 cents, with 522,549 shares traded. Patrys climbed five percent; Uscom improved four percent; Actinogen was up three percent; Telix rose 2.3 percent; CSL, LBT and Pro Medicus were up one percent or more; with Medical Developments, Neuren, Osprey, Resmed and Volpara up by less than one percent.

Optiscan led the falls, down two cents or 9.1 percent to 20 cents, with 377,811 shares traded. Alterity lost 7.1 percent; Proteomics fell 6.8 percent; Cynata was down 5.5 percent; Nanosonics, Nova Eye and Prescient fell more than four percent; Avita, Polynovo and Universal Biosensors were down more than three percent; Amplia, Genetic Signatures, Oncosil, Opthea, Paradigm and Resonance shed more than two percent; Clinuvel, Cyclopharm, Next Science and Orthocell were down more than one percent; with Cochlear, Immutep, Mesoblast and Starpharma down by less than one percent.

[VALE BIOSHARES DAVID BLAKE (1.3.1962 – 18.11. 2021)]

Bioshares co-founder, David Blake died yesterday afternoon.

David Ronald Blake was born in Gympie, Queensland but having moved to Melbourne he became a tireless advocate for the biotechnology industry, co-founding Bioshares with Mark Pachacz in 1998.

When I started Biotech Daily in 2005, he had no hesitation in helping devise the original Top 40 for the BDI-40 Index and knew that the greater the focus on the sector, the better for the sector.

Unwittingly, we caused much confusion when Marc Sinatra joined Biotech Daily, with two Melbourne biotechnology publications run by David and Mark; and David and Marc.

Then I took my eldest son to his first parent teacher night at his new high school (University High) and ran into David.
"What are you doing here?" I asked in surprise.
"My daughter, Alethea, goes to this school," he said - a little indignantly.
We lived just a kilometre or two from each other.

In private conversations, David did not suffer fools gladly. He was very concerned with a few companies and their characters, who he thought were not helping the industry. But he championed the rest.
The strength of Bioshares, in maintaining a leadership role for our industry, cannot be under-estimated, and especially the Bioshares annual skiing conferences, which most unfortunately I was unable to attend.

David was a stalwart of the Australian biotechnology industry. We shall all miss him.
David is survived by his wife Sonya and daughter Alethea.

David Langsam

David was the voice of conscience of the sector.
Strongly passionate, highly knowledgeable and supportive, and openly and immediately critical when needed.
He was unwavering in his dedication to this sector.
And his friendship was a constant for 21 years.
Thank you, David, for all of this.
And especially for all the fun we had along the way...

Mark Pachacz, Bioshares

David has been a friend since the very early days of biotech in Australia, a true friend. We talked often and we had the greatest respect for each other.
I have missed his good counsel over the recent times due to his illness and I will continue to miss our chats, our lunches and our views over the future years.
David gave his time to many in the industry and this has also been reflected by the tributes coming in.

Leon Serry

In our constellation, occasionally we detect a light so bright for outshining others, for energy so kinetic heating those he encounters, for thoughts so lucid enlightening us all.

David is so inquisitive, engaging and aspirational that he continuously leaves one wondering about oneself.

Such a luminary simply radiates on.

Dr Philippe Wolgen, CEO, Clinuvel

David was generous in his support to all and freely shared his informed and considered advice if asked. He treated everyone with interest and respect.

He would readily make introductions he thought would help and encouraged everyone to ‘give it a go’, and make the most of their skills and talents.

At the heart of his work was a belief in the ability of Australia’s biotech and medical technology sector to improve the world through innovation and knew that medical technology innovation and research in Australia was equal to, or better, than anything produced in Europe and the US.

David was unfailingly polite and courteous, even to individuals and companies he was never going to cover, when he knew there were governance and credibility issues.

His analysis delivered original and sometimes surprising insights informed by a deep understanding of the science and a genuine commitment and concern for the viability and growth of the sector in Australia.

Andrew Geddes

David’s leadership was unique and special because he truly cared about telling the stories of our sector.

He invested into what inspired him, and that made Bioshares - the publication and the annual event - personal; this passion is what has resonated with me, and with our community.

The publication gives invaluable and unique data to the sector, and the conference has grown into a go-to event that galvanized the sector with discussion and debate. It is an event that everyone looks forward to, and where friendships are formed. David’s commitment to seeing the sector flourish will be missed.”

The biotechnology, science and investment communities have experienced a great loss with the passing of David Blake, and his impact will remain in the companies, people, and in the industry that he worked tirelessly to promote.

Ausbiotech sends its condolences to David’s family, friends and colleagues during this difficult time.

Lorraine Chiroiu, CEO, Ausbiotech

DR BOREHAM'S CRUCIBLE: CRYOSITE

By TIM BOREHAM

ASX code: CTE

Share price: 36 cents; **Shares on issue:** 48,809,563; **Market cap:** $17.6 million

Chief executive officer: John Hogg

Board: Bryan Dulhunty (chair), Andrew Kroger, Nicola Swift and Steven Waller

Financials (year to June 30, 2021): revenue $10.1 million (up 12%), underlying profit $1.12 million (up 39%), net profit $652,574 (down 55.9%), cash of $3.9 million (down 4%)

Identifiable major holders*: Andrew Kroger (and related entities) 41.5%, BNP Nominees 12%, Gary Griffith Robins and Allan James Robins 6%, DMX Capital Partners 5%

***** Cell Care Australia disposed of its 15 percent stake in March 2021. Investors purchasing its stake included DMX Capital Partners and individual shareholders under the BNP Nominees banner.

Not too many companies would thank a competition regulator that both blocked a proposed merger and levied a $1 million fine on them, albeit in highly unusual circumstances.

But there's not much usual about Cryosite, which operates a Sydney storage facility for cord blood (stem cell) material and other biological samples for use in clinical trials.

The reason for Cryosite's gratitude to the Australian Competition and Consumer Commission is that by disallowing the sale of its cord blood business to Cell Care Australia in 2017, the company retained a low-growth, run-off operation that's become nicely profitable. And eventually the company recouped the $1 million penalty, not from the ACCC but from its external legal advisers.

The accidental breach of the law related to "jumping the gun" provisions. But we won't jump the gun with the narrative, we'll explain it further below.

Meanwhile, the pandemic has also proved an accidental boon for Cryosite, because pharmaceutical companies migrated many of their trials to (relatively) Covid-free Australia.

Frozen in time

Cryosite was founded in 1999 and listed in May 2002 after raising $8.5 million at 40 cents apiece (for a total market cap of $7.6 million). Back then Cryosite held itself out as the only collector, processor and storer of cord blood stem cells with its south Granville facility in western Sydney, winning Therapeutic Goods Administration approval.

More broadly, Cryosite is about the ultra-low temperature storage of other biological material including cells, micro-organisms, proteins and genes.

And klutzes such as your columnist can relax if they think the company has a massive electricity bill: the samples are stored in liquid nitrogen.

One of Cryosite’s many quirks is that its three-person board has remained unchanged for many years (until today – see above), but the CEO role has changed more times that Australia’s carbon emissions target. The CEO baton is now held by former production manager John Hogg.

Cryosite’s register is tighter than a Tasmanian family reunion, with former stockbroker Andrew Kroger (brother of Liberal heavyweight Michael) holding more than 40 percent.

Trial emphasis is no error

In the last financial year, Cryosite gleaned three-quarters of its revenue, $7.5 million, from storing material for research trials.

With the company traditionally spending little on capex (capital expenditure), management invested $1.3 million over the last two years and plans to splurge another $750,000 this year.

“Revenue is going through the roof,” Mr Dulhunty says. “We thought it would take years to get to maximum capacity, but it is full now.”

He says most of the large pharmaceutical companies treated Europe as one entity, so when borders closed, they struggled to ship between countries. The flow-on effect is they shipped the requisite material to Australia ahead of time.

Mr Dulhunty says taking on a large pharma client will involve 12 months of due diligence and mutual bottom-sniffing.

“But once you have the customer locked in, they are with you for a very long time.”

Laughing all the way to the blood bank

Speaking of bottom-sniffing, in a case of ‘man bites dog’ Cryosite’s sideline clinical trials business has become the main event over the years.

But the cord blood storage side of the business is fighting back.

Collected at birth, the stem cells in cord blood and tissues allegedly can be used to treat certain blood disorders - and also could come in handy for any number of emerging stem-cell treatments.

Cryosite has been storing cord blood samples for up to 20 years, under 18-year contracts. It does not accept new samples, having ceded this business to Cell Care and its superior marketing power.

But Cryosite hatched a cunning plan of contacting the legacy clients ahead of contract expiry, offering contracts of up to 10 years, renewed annually for $175.

The company expected to be throwing out most of the samples, or donating them to research organizations.

After all, the donors - now adults - legally own the material and how many 18-year-olds are interested in shelling out $175 of beer money every year?

But having paid thousands of dollars for the initial contract, parents (and grandparents) have stepped-in to fund the extensions. “They clearly believe in the future of stem cell science,” Mr Dulhunty says.

“We are getting an exceptionally high take-up rate. What was essentially a long-tail liability … over time will generate a very significant revenue flow at pretty much zero extra cost.”

Not just sprinters jump the gun

In June 2017, Cryosite said it would licence (in effect sell) the cord blood bank business to Cell Care Australia.

The ACCC reviewed the transaction, but then discontinued its public review process and the deal foundered.

In its first “gun jumping” action, the ACCC launched legal action against Cryosite for alleged cartel conduct.

“Jumping the gun” does not refer to overzealous sprinters but Cryosite advising new customers to go to Cell Care instead of themselves, ahead of the anticipated merger.

Cryosite reasoned those new customers ought to know the business was about to close its doors, but admitted to the unintended cartel behavior and copped the $1 million penalty plus $100,000 of legal fees (on a negotiated 10-year instalment plan).
The $1 million (less $41,000 of fees) was later recovered from the legal firm dispensing the relevant advice.

Founded by ex-Macquarie Bank types, Cell Care went on to buy a Canadian blood bank, before being acquired by private equity interests for $US100 million.

The group last year was taken over - again - for $US200 million.

Along the way, Cell Care retained a 19.9 percent holding but sold out in March this year after reducing the stake to around 15 percent.

“Cell Care wasn’t a natural holder,’ Mr Dulhunty says.

New competition?

Cryosite is an ‘orphan’ in ASX listed terms, but bears some similarities with Bluechiip which provides “cryogenic consumables” notably wireless trackers.

Meanwhile, a Ballarat mob called Vitrafy Life Science has raised $7.9 million ahead of a vaunted ASX listing in 2021. We’re yet to spy a prospectus, though.

The “biomedical cryo-preservation” company is supported by a cabal of institutions including Ryder Capital, Regal Funds Management and Thorney Holdings, as well as former Bellamy’s chairman Rob Woolley.

The raising was organized by Bell Potter, so there’s more heavyweights involved than a sumo wrestling final.

Finances and performance

In the year to June 30, 2021, Cryosite recorded a net profit of $652,574, which ‘officially’ was down 56 percent but up 39 percent discounting the previous year’s $1 million legal settlement.

For a small company, Cryosite’s balance sheet - and, consequently, profit and loss statement - is replete with complexities.

The balance sheet items include a $20 million deferred asset and a $18 million deferred liability.

Mr Dulhunty says investors should focus on the cash flow statement, which showed an inflow of $488,000 this year compared with last year’s $357,000 (excluding the legal settlement).

In the troubled 2017-’18-year, cash outflows were $200,000 and the company recorded an $800,000 pre-tax loss.

Over the last year the quasi-illiquid Cryosite shares have changed hands between 45 cents (January 29 this year) and 16 cents (March 10). This low point reflects a savage investor reaction after Cell Care’s share sell-down was revealed.

Management prepared to mount a share buy-back to mop up the share overhang. Instead, Cell Care organized a group of shareholders to acquire the scrip. This introduced DMX Capital to the register, as well as a gaggle of monied individuals represented by BNP Nominees

Frozen in time

Here’s a fun fact: When we last covered Cryosite in November 2018, the company had exactly 46,859,563 shares on issue and as of June 30 this year the company had - yep - 46,859,563 shares on issue

Way back in 2005 the company had - you guessed it - 46,859,563 shares on issue.

This highlights how the tightly-held company has survived by relying on internal funds generated.

This extraordinary stasis was interrupted only in September this year when Messrs Dulhunty and Hogg exercised 1.95 million in-the-money options, thus boosting shares on issue by 2.5 percent.

Dr Boreham's diagnosis:

Previously we opined that Cryosite had lost its way - and management didn't argue with that.

"Since then, we have refocused, reinvested in and revitalized the business," Mr Dulhunty says.

Given its patchy corporate history and tight register, Cryosite has not been an active self-promoter, but plans to sing its song more lustily over the next 12 months.

While management plans a trading update at its December 8 AGM, Mr Dulhunty has already flagged a "very strong" current year (to June 30, 2022).

"Cryosite is largely a fixed cost business," he says.

"Now the restructuring is pretty much behind us the revenue growth will pretty much all drop to the bottom line."

Clinical trials aside, Cryosite is eyeing expansion into other cold-storage activities, notably medical marijuana and oncology products (the company is licenced by NSW's health mandarins to store the former).

"We are doing some novel things which may prove very successful," Mr Dulhunty says.

The cord blood side is a slow burn, but there's significant value in a $175 annual fee over, say, 30 years and it's possible that someone like Cell Care will buy the company.

Your columnist believes Cryosite is materially undervalued with a $17 million market valuation, but we caution the business won't exactly become 10 times bigger.

As Mr Dulhunty says: "we are not trying to build an empire, we are trying to build a business with very strong cash flow and revenue growth."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He knows he doesn't have any umbilical cords stored in his freezer, but the old tomatoes look like they are growing their own children.

MTP CONNECT

MTP Connect says it is calling for proposals to deliver a pilot program to develop the innovation and commercialization skills of clinicians and healthcare professionals.
MTP Connect said it was looking for a single provider to deliver the program with the price to be determined by market forces.
The organization said that the Researcher Exchange and Development within Industry (REDI) Clinical Entrepreneur Program was based on the UK Clinical Entrepreneur Programme and would help equip healthcare professionals with the skills to translate and commercialize ideas and innovations into products and "effect cultural change within the healthcare system by encouraging entrepreneurialism".
The Federal Government-funded MTP said that it had reported on skills gaps in Australia and that "harnessing the potential of clinician entrepreneurs is pivotal to enabling the medical technology and pharmaceutical sector's growth".
MTP Connect managing-director Dr Dan Grant said that "nurturing the skills underpinning clinician-led entrepreneurism highlighted in the report will help set Australia apart in the medical products innovation stakes".
"Through our REDI program, we're looking to support the establishment of a pilot Clinical Entrepreneur Program in Australia to deliver bespoke training to clinicians to develop their innovative ideas into products and enterprises/businesses that benefit patients," Dr Grant said.
For more information go to: https://www.mtpconnect.org.au/programs/REDI/CEP.
Applications close on January 31, 2022.

TRAJAN GROUP

Trajan says it has bought Axel Semrau GmbH and Co KG and Semrau Immobilien GmbH and Co KG for EUR17.0 million ($A26.4 million).
Trajan said it paid EUR14.75 million ($A23.01 million) for Axel Semrau GmbH and EUR2.25 million ($A3.51 million) for Semrau Immobilien GmbH.
The company said that both enterprises were private businesses of the Sprockhövel, Germany-based Axel Semrau.
The company said adjustments, including accumulated undistributed profits of EUR2.85 million would be paid to Axel Semrau following the close, funded by cash and debt.
Trajan said Axel Semrau employed more than 50 staff in Europe developing and manufacturing laboratory automation and chromatography software and detection systems, and reported revenue for the year to September 30, 2021, of EUR14.9 million, with unaudited earnings before interest, taxation, depreciation and amortization (Ebitda) of EUR1.46 million.
Trajan said the two managing-directors at Axel Semrau, Frank Sasse and Andreas Bruchmann and all other employees would continue in their current roles as part of the Trajan group.
Trajan managing-director Stephen Tomisich said that his company's automation business and Axel Semrau had "worked in close cooperation for several years".
"Axel Semrau owns and develops the Chronos intelligent sequencing software platform upon which Trajan's automated workflows are built," Mr Tomisich said.
"We intend to further invest in Chronos in line with Trajan's goal to simplify and automate complex analytical workflows," Mr Tomisich said.
Trajan was up 26 cents or eight percent to $3.50.

RESAPP HEALTH

Resapp says a study it partly funded found that there is a need for better diagnosis and management of respiratory disease in children.

Resapp said the study, titled ‘Diagnostic Errors Are Common in Acute Paediatric Respiratory Disease: A Prospective, Single-Blinded Multicentre Diagnostic Accuracy Study in Australian Emergency Departments”, was co-authored by Resapp adviser Dr Paul Porter and published in the Journal of Frontiers in Paediatrics and available at: https://doi.org/10.3389/fped.2021.736018.

The company said the study used data from the Breathe Easy study.

In 2018, Resapp said the results from its 585-patient, paediatric trial of its cough-based smartphone application for respiratory illness diagnosis were “outstanding” with “excellent top-line results” using machine learning algorithms to diagnose respiratory disease from cough sounds recorded on a smartphone (BD: Sep 3, 2018).

Today, Resapp said the publication analyzed data from 620 paediatric patients and found that acute respiratory disorders were frequently misdiagnosed with more than 45 percent of focal pneumonia, 35 percent of isolated upper respiratory tract infection, 23 percent of croup and 33 percent of bronchiolitis cases “missed by the emergency department clinicians”.

Dr Porter said the “shines a light on the standard of care for acute respiratory disease diagnosis in the emergency department”.

“The differential diagnosis of childhood respiratory disease is challenging as it relies on a complex mix of clinical and interpretive skills, compounded by many diseases having similar clinical features such as breathlessness and wheeze,” Dr Porter said.

“Although these diseases represent the most common reasons for children to be taken to the emergency department, our study shows that they are frequently misdiagnosed,” Dr Porter said.

Resapp managing-director DR Tony Keating said the results “bring into focus the clinical value that Resappdx brings to the assessment of patients presenting with respiratory symptoms”.

“For example, in the same dataset, our cough-based pneumonia algorithm identified 87 percent of children with pneumonia without the need for clinical examination or investigations,” Dr Keating said.

“Not only does Resappdx offer clinicians an objective and accurate diagnostic tool, it has the potential to deliver high quality diagnosis, equal to, or better than what is achieved in a well-resourced emergency department, globally – making it more accessible and affordable for all,” Dr Keating said.

Resapp was up 0.1 cents or 1.85 percent to 5.5 cents with 2.1 million shares traded.

IMMUTEP

Immutep says it has dosed the last patient of 185 patients in the part A expansion of its phase II Tacti-002 combination study of IMP321, or eftilagimod alpha, for cancers.

Immutep said the phase II study Tacti-002 study of eftilagimod alpha with Keytruda, or pembrolizumab, enrolled first and second line patients with non-small cell lung cancer and second line head and neck small cell carcinoma.

The company said further data from Tacti-002, including data from part A of the study would be reported by July 2022.

Immutep chief executive officer Marc Voigt said the completion of recruitment was a “major milestone for Immutep”.

Immutep fell half a cent or 0.9 percent to 54 cents with 2.5 million shares traded.

UNIVERSITY OF QUEENSLAND, UNIQUEST

The University of Queensland says it has licenced Sol-Gel for marijuana delivery to the Vancouver, British Columbia-based Preveceutical Medical.
The University said that the licence to the Sol-Gel technology was through its commercialization company Uniquest.
The University said that Sol-Gel was invented at the School of Pharmacy by Dr Harendra Parekh and his team and was “a liquid solution that converts to a gel upon contact with the internal membranes of the human body, such as the nose … [and could deliver] cannabinoids to all regions and membranes of the human body”.
Uniquest chief executive officer Dr Dean Moss said the deal “a great testament to the strength and willingness of … researchers to engage with industry and work together to create impact through the development of potential new treatments”.
Preveceutical executive chair Stephen Van Deventer said the company had been “been developing the cannabinoid Sol-Gel delivery system … since 2017, with a focus on nasal delivery” and would investigate other product formats to deliver cannabinoids using Sol-Gel, including through the skin.

MICRO-X

Micro-X says it withdrew its 10 percent placement capacity prior to its annual general meeting and faced up to 13 percent opposition to the issue of performance rights.
The resolution for the approval of a 10 percent placement capacity was a special resolution, requiring 75 percent to pass.
The company did not provide an explanation for the withdrawal of the resolution.
Micro-X said five resolutions to provide a total of $108,000 worth of performance rights to five non-executive directors were opposed by up to 20,688,390 votes or 13.44 percent.
The company said other resolutions such as the adoption of remuneration report, the increase in directors’ fee pool from $300,000 to $700,000, the re-election of directors, and the issue of shares to five directors in lieu of fees were passed easily.
According to its most recent filing, Micro-X had 460,127,745 shares on issue, meaning the 20,688,390 votes against the issue of performance rights amounted to 4.5 percent of the company, not sufficient to requisition an extraordinary general meeting.
Micro-X was up 1.5 cents or five percent to 31.5 cents.

GENETIC SIGNATURES

Genetic Signatures says it faced nearly 14 percent opposition to the remuneration report and the re-election of Michael Aicher.
Genetic Signatures said that 10,090,378 votes (13.9%) opposed the adoption of the remuneration report with 62,519,675 votes (86.1%) in favor.
The company said 10,243,284 votes (13.52%) opposed the re-election of Michael Aicher as a director with 65,537,543 votes (86.48%) in favor.
Genetic Signatures said the resolution to elect Neil Gunn as a director and to issue Mr Gunn options were passed easily.
According to its most recent filing, Genetic Signatures had 143,036,246 shares on issue, meaning that that votes against the election of Mr Aicher amounted to 7.16 percent of the company, sufficient to requisition extraordinary meetings.
Genetic Signatures fell 3.25 cents or 2.4 percent to $1.3075.

BIONOMICS

Bionomics says it will not proceed with a capital distribution to shareholders in connection with its right to receive royalties from Merck & Co.
In August, Bionomics said it was planning a Nasdaq initial public offering, as well as a capital distribution of royalties, if any, from Merck & Co for BNC375 (BD: Aug 2, 2021).
Today, Bionomics said a distribution would “not be in the best interest of shareholders”.
Bionomics was up one cent or 9.1 percent to 12 cents.

EMYRIA

Emyria has requested a trading halt pending an announcement “regarding a proposed strategic placement of shares”.
Trading will resume on November 23, 2021, or on an earlier announcement.
Emyria last traded at 32.5 cents a share.

OVENTUS MEDICAL

In an Appendix 3Z, the Oventus’ founding chair Dr Melvyn Bridges said he had resigned as director, effective from November 18, 2021.
The company did not publish a separate announcement regarding Dr Bridges’ departure, but included it in the notice of meeting and chair’s address.
Oventus was up 0.1 cents or one percent to 9.7 cents.

CRYOSITE

Cryosite says it has appointed Steven Waller non-executive director, effective from November 19, 2021.
Cryosite said Mr Waller previously worked for Aspen Pharmacare, Sigma Healthcare and Johnson & Johnson.
According to his Linkedin profile, Mr Waller held a Bachelor of Pharmacy from the University of Sydney and a Master of Business Administration from the Macquarie Graduate School of Management.
Cryosite was untraded at 36 cents.

PRESCIENT THERAPEUTICS

Prescient says it has appointed Mofitt Cancer Centre’s Dr Marco Davila and the University of Pennsylvania’s Prof Andrew Tsourkas to its scientific advisory board.
Prescient said Dr Davila was a medical oncologist and his research included chimeric antigen receptor-T (Car-T) therapies for cancer.
The company said Dr Davila held a Doctor of Medicine and Doctor of Philosophy from the Durham, North Carolina-based Duke University.
Prescient said Prof Tsourkas was a professor of bioengineering in the University of Pennsylvania and co-invented the patents licenced by Prescient to form Omnicar.
Prescient said Prof Tsourkas held a Bachelor of Science from New York’s Cornell University and a Doctor of Philosophy from Atlanta’s Georgia Institute of Technology.
Prescient fell one cent or 4.1 percent to 23.5 cents with 2.3 million shares traded.