



Biotech Daily

Friday November 2, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.14 percent on Friday November 2, 2018 with the ASX200 up 8.4 points to 5,849.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and five were untraded. All three Big Caps rose.

Pro Medicus was the best, up 83 cents or 8.7 percent to \$10.40 with 254,131 shares traded. Airxpanders was up 8.5 percent; Starpharma climbed 7.4 percent; Orthocell was up 6.4 percent; Clinuvel, Cynata and Mesoblast improved more than three percent; CSL, Immutep, LBT, Medical Developments and Prescient rose more than two percent; Compumedics, Impedimed and Nanosonics were up one percent or more; with Cochlear, Genetic Signatures, Opthea, Polynovo and Resmed up by less than one percent.

Dimerix led the falls, down 0.7 cents or 6.7 percent to 9.8 cents, with 1.1 million shares traded. Osprey lost 6.1 percent; Neuren and Oncosil fell five percent or more; Actinogen and Factor were down more than four percent; Bionomics was down 3.45 percent; Avita shed 2.2 percent; Volpara lost 1.5 percent; with Telix down 0.6 percent.

DR BOREHAM'S CRUCIBLE: CRYOSITE

By TIM BOREHAM

ASX code: CTE

Share price: 6.4 cents

Market cap: \$3.0 million

Shares on issue: 46,859,563

Chief executive officer: Mark Byrne

Board: Bryan Dulhunty (chairman), Andrew Kroger, Nicola Swift

Financials (year to June 30 2018): revenue \$5.92 million (up 0.67%), loss of \$1.24 million (\$225,000 profit previously), underlying profit \$259,441 (\$89,986 loss previously), and cash of \$4.68 million (down 8%)

Identifiable major holders: Andrew Kroger (and related entities) 36.95%, Cell Care Australia 19.7%, Alistair David Strong 4.27%, Jane Susan Milliken 2.78%, Tootcan Superannuation Services 2.15%, Stephen Roberts 2.07%.

The country's first private repository for blood stem cell material sourced from umbilical cords, Cryosite can lay claim to one weird fact and one less welcome 'first'.

The weird is that the company has revenue and is trading significantly below cash-backing.

The unwelcome first is that Cryosite is the first Australian company to face an action by the Australian Competition and Consumer Commission for allegedly 'jumping the gun' and engaging in cartel behavior before its proposed merger with a rival could be approved.

More on that later.

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

But cord blood banking has become a difficult business, with a rival called Stemlife going into administration in March 2016.

Cryosite nobly stepped into the breach and offered to be the freezer service for Stemlife's 2,000 plus punters.

Citing declining profits and lack of demand, Cryosite in August last year said it would close its cord blood banking facility for new customers and only store samples for existing ones under long-term or annual contracts.

“We were spending more money building and investing in the business but the number of contracts were declining,” says Cryosite CEO Mark Byrne.

It doesn't help that there's a free alternative: birthing mothers at nine participating hospitals (of which five are public) are able to donate their bub's cord blood to Auscord, which keeps the material for other compatible uses.

Cryosite is now largely focused on storing (freezing) and transporting biological material for other uses, such as in clinical trials and university research activities.

Cryosite is 37 percent owned by former stockbroker and Cryosite board member Andrew Kroger, whose older brother Michael is better known as a Victorian Liberal Party heavyweight.

Cryosite unthawed

The country's only repository of cord blood stem cells at the 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).

(Those with an elephantine memory may recall Peter Walker's Private Blood Bank of Australia, which listed in 1987 as a repository for normal blood amid paranoia about AIDS and HIV. Being a 1980s company it eventually collapsed).

Specifically, Cryosite held itself out as the only collector, processor and storer of cord blood stem cells with the requisite Therapeutic Goods Administration seal of approval.

But more broadly Cryosite is about the ultra-low temperature storage of other biological material including cells, microorganisms, proteins and genes.

With the cord blood bank side of the business frozen, Cryosite's main activity is handling material for offshore pharma companies or contract research organizations seeking to do trials in Australia.

While big pharma companies routinely doing multiple trials are likely to have their own facilities, the business is profitable.

Cryosite has two key rivals: Pharma Packaging Professionals in Melbourne and Adelaide's Flinders Clinical Trials.

Management merry go round

Cryosite is one of those companies that changes its management almost as regularly as (most) people change their underwear.

Joseph Saad was appointed CEO in late January 2015, replacing 12-year managing director Gordon Milliken, but in October resigned for personal reasons.

Andrew Shine was then appointed in June 2016, but quit in May last year to be replaced by chief finance officer Mark Byrne on an interim basis. Mr Byrne was appointed permanent head honcho in January this year.

Executive director Graeme Morris was interim CEO on two occasions, but left in October 2016.

In March this year chairman Stephen Roberts resigned after a two-and-a-bit year reign, to be replaced by company secretary Bryan Dulhunty.

Jumping the gun?

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

Well, that one got a bit messy. The Australian Competition and Consumer Commission reviewed the transaction, but then discontinued its public review process without giving a yea or a nay.

Given Cryosite and Cell Care are the only cord blood bank providers, ACCC approval was a condition of the transaction and given Cell Care was unwilling to waive it, the deal foundered.

At the time ACCC commissioner Rod Sims expressed his displeasure at the failure of the parties to seek dialogue with the regulator beforehand, even though the companies were not legally obliged to do so.

In its first “gun jumping” action, the ACCC in July this year launched Federal Court legal action against Cryosite for alleged cartel conduct.

The regulator contends that Cryosite acted illegally by referring all customer enquiries to Cell Care after the agreement was signed, but before the acquisition was completed.

The ACCC alleges this !!! ese amounts to cartel conduct because it restricted or limited Cryosite’s supply of cord blood and tissue banking services and allocated potential customers from Cryosite to Cell Care.

Cryosite pulled the plug on new collections in August last year, citing declining demand and diminishing profits.

At least Cryosite, which is still considering its stance on the ACCC proceedings, pocketed the \$500,000 upfront payment from Cell Care.

Financials and performance

Cryosite racked up what chairman Bryan Dulhunty dubs a “disappointing” loss of \$1.24 million in the year to June 30, 2018 (the deficit compared to a \$225,000 profit previously).

The half a cent dividend paid in 2016-'17 now looks a distant memory.

The closure of the company's South Granville lab in Sydney (the processing business for new blood samples) resulted in \$995,743 of costs and write downs.

And the bottom line number was further blemished by a \$169,416 legal settlement pertaining to a former director and employee who argued for extra payments.

Of Cryosite's 2017-'18 revenue of \$5.92 million, \$5.3 million was derived from the trials and biorepository side and only \$553,313 from the long term cord blood contracts.

Because of the ACCC action, the company expects to incur "significant legal costs and the potential to incur financial penalties in the 2018-'19 financial year."

Cryosite was also affected by a large customer who moved warehousing logistics management of a commercial product to an international distribution business.

As a result, the company expects a "significant negative impact on revenue and profits" in the first half, but hopes to have made up lost sales by June 30, 2019.

Cryosite's troubles have weighed on the share price, which has steadily declined from 18 cents a year ago.

Dr Boreham's diagnosis:

To paraphrase Julia Gillard, Cryosite looks like a company that had lost its way. But at least it still has decent top-line revenue to work with ... and is "moving forward".

The company says there remains "significant opportunities" from long-term cold, frozen and cryogenic storage logistics and distribution.

"It's a modest growth business, maybe five to 10 percent a year," Mr Byrne says. "But that can change very quickly. The amount of investment going into the biotech industry is huge and we've seen a lot of activity in this space."

Should there be a surge of storage requests, the South Granville facility has adequate spare capacity to cope.

With the ACCC action weighing on the company, we expect Cryosite's prospects could remain in deep freeze for some time.

But with a \$3 million market cap, the company is not exactly burdened with the weight of investor expectations.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Late one night he went looking for a cord blood bank ATM, but his blood ran cold when he ended up in a bar with Bram Stoker and Mary Shelley.

LIVING CELL TECHNOLOGIES

Living Cell says that 18-month follow-up of its 18-patient, phase IIb trial of NTCell for Parkinson's disease shows statistically significant benefit for the 80 capsule dose.

Last year, Living Cell fell 88.8 percent to 2.3 cents on news that there was no statistical significance for NTCell treatment efficacy for Parkinson's disease (BD: Nov 10, 2017).

The company said at that time that three of the four primary endpoints were met, with no product or procedure adverse events and no evidence of xenogeneic infection in patients and their partners.

Living Cell said that at 26 weeks post-implant, there was "not a statistically significant difference between the groups who received the encapsulated pig choroid plexus brain cell NTCell and the patients who had sham surgery, as measured by the change in the unified Parkinson's disease rating scale (UPDRS).

Today, the company said that 80 weeks there was statistical significance for the patients implanted with the midrange dose of 80 capsules of NTCell encapsulated pig brain choroid cells ($p < 0.05$).

Living Cell said the study was designed to confirm the most effective dose of NTCell, define any placebo component of the response and identify the initial target Parkinson's disease patient sub-group.

The company said that the study consisted of three groups of six patients, with two patients from each group having sham surgery with no NTCell implanted, while the active cohorts received 40 microcapsules, 80 microcapsules and 120 microcapsules of NTCell implanted on each side of the brain.

Living Cell said that no benefit was observed in the 120 NTCell group, with evidence of inflammation "which may have compromised efficacy in this group".

Living Cell principal investigator at New Zealand's Auckland City Hospital Dr Barry Snow said that "the statistical improvement seen at 12 months has been sustained; variation between recipients is expected with the small number of subjects".

"The next step is further in-depth analysis to understand the data on all efficacy measurements both on and off normal symptomatic treatment," Dr Snow said.

Living Cell chief executive officer Dr Ken Taylor said that when the company had the in-depth data analysis "and have had appropriate discussions with the New Zealand regulatory authorities, [the company] will be able to confirm its ongoing strategy for NTCell."

Living Cell was up 0.3 cents or 5.9 percent to 5.4 cents with 61.8 million shares traded.

RHINOMED

Rhinomed says it has raised \$5 million in a placement to institutional and sophisticated investors at 21 cents a share and hopes to raise a further \$1 million in a share plan.

Rhinomed said that the placement raised the maximum of \$5 million and both the chairman Ron Dewhurst and chief executive officer Michael Johnson would participate in the placement, subject to shareholder approval.

The company said that the record date for the share plan November 1, 2018.

Rhinomed said that the proceeds would "drive growth of the company's Mute snoring and sleep technology platform ... support further development and working capital needs".

The company said that the placement was managed by Bell Potter Securities and Morgans Corporate who acted as joint lead managers.

Rhinomed fell 1.5 cents or six percent to 23.5 cents.

BIOCURATE PTY LTD

Biocurate says Novartis is the first bio-pharmaceutical company to collaborate on early stage drug discovery projects.

Last year, Biocurate said it was a venture launched in 2016 by Monash University and the University of Melbourne and supported by the Victorian Government, with former Victoria Treasurer and Premier John Brumby as its chair (BD: May 2, 2017).

Today, Biocurate said the Novartis collaboration aimed “to provide expert industry-focused scientific advice and expertise” to the company.

Biocurate said that the collaboration provided an opportunity to identify and translate research from Monash University and the University of Melbourne.

The company said that the agreements focussed on identifying early stage innovation and academic research which addressed unmet patient needs

Biocurate chief executive officer Dr Glenn Begley said the company recognized the importance of early engagement with a range of leading industry partners to ensure new drug development programs are informed and aligned with addressing unmet patient and market needs.

“We are hopeful this collaboration will ultimately lead to better health outcomes for the global community and continue to build Australia’s expanding innovation economy,” Dr Begley said.

Dr Begley said the Novartis collaboration was “the first in a number of similar arrangements currently under discussion with other potential industry partners”.

Novartis Australia chief scientific officer Dr Simon Fisher said the collaboration “opens the door to overcome barriers that limit the translation and commercialization of early stage research progressing to new medicines and providing benefits to patients”.

CELLMID

Cellmid says the New South Wales Supreme Court has ordered it to pay \$939,056 plus interest to Ikon Communications Pty Ltd.

In 2016, Cellmid said that Ikon Communications Pty Ltd had filed a legal action for \$939,056 against its wholly-owned consumer health subsidiary Advangen International Today, Cellmid said that the Court ruled that Ikon was entitled to its claim and that the cross claim by Advangen should be dismissed and the parties had 14 days to agree on costs or the matter will be relisted.

Cellmid said it was “disappointed” with the Court’s decision and maintained its position that Ikon failed to provide the services agreed in the contract which, in the board’s view, caused the failure of the campaign.

The company said that “the learnings from the Ikon contract have long been implemented and as such the company is confident there will be no negative bearing on the business today or in the future as a result”.

Cellmid said that with its consumer health products being sold in four countries, with additional territories pending, it had “experienced substantial growth and a tripling of revenue in the past three years ... [and was] in a strong position to implement its growth plans.

The company said that the conclusion of the matter would allow it “to fully focus on those plans”.

Cellmid said that it had already expensed its legal costs to date in the relevant financial years and made an allowance and noted it as a contingent liability in its 2018 financial accounts.

Cellmid requested a trading halt before the open and last traded at 34 cents.

ORTHOCELL

Orthocell says it has been granted Mexican and Hong Kong divisional patents for its Celgro collagen scaffold.

Orthocell said the patents were titled 'Method for Producing a Collagen Membrane and Uses Thereof' and provided "additional important intellectual property to protect the platform for soft tissue regeneration and repair applications" until June 12, 2033.

Orthocell managing-director Paul Anderson said the company had "secured 11 patent families covering its portfolio of breakthrough regenerative medicine products, comprising 102 separate patents/applications, of which 72 are granted".

The company said that Celgro was a customizable collagen medical device "with numerous competitive advantages over existing synthetic and biologic tissue repair devices, particularly in the areas of cell compatibility, tensile strength and the promotion of quality tissue in growth and repair".

Orthocell said that Celgro could improve tissue in-growth and repair bone regeneration within the jaw and rotator cuff tendon repair and was being assessed for performance in re-joining of severed or damaged nerves and articular cartilage repair in the hip.

Orthocell was up 1.5 cents or 6.4 percent to 25 cents.

OPTISCAN IMAGING

Optiscan has requested a voluntary suspension to follow the trading halt requested on Wednesday October 31, "pending an announcement ... in relation to a regulatory approval" (BD: Oct 31, 2018).

Optiscan last traded at 5.5 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it will acquire Telerhythmics LLC cardiac diagnostic monitoring service "membership interests" for \$US1,950,000 (\$A2,692,200).

G Medical said that the Memphis, Tennessee-based Telerhythmics was a 24-hour cardiac diagnostic monitoring service used by hospitals and physician offices, providing services throughout the eastern US.

The company said it would acquire "all the outstanding membership interests of Telerhythmics from ... Digirad Corp for a total up-front consideration of \$US1,950,000, subject to working capital adjustments", subject to customary conditions.

G Medical said Telerhythmics booked revenue from January 1, to September 30, 2018 of \$US3.2 million.

The company said that the Telerhythmics acquisition, along with the acquisition of Cardiostaff Diagnostic Services Inc would "create a sizable player in the cardiac diagnostic US monitoring space and ... provide [it] with a solid base of business across the Southeast and Southwest territories" (BD: Oct 30, 2017).

G Medical said the Telerhythmics acquisition would increase insurance coverage providing about 100 commercial payor agreements across local, regional and national markets and an additional 30 million to 35 million "covered lives" or individuals insured, taking the aggregate to about 100 million covered lives.

The company said it would gain access to several health systems including Baptist, Ochsner and HCA, as well as existing agreements with providers such as Blue Cross and Blue Shield.

G Medical was up 1.5 cents or 4.4 percent to 35.5 cents.

THE HYDROPONICS COMPANY

Hydroponics says it has begun supply of marijuana-based Endoca cannabidiol (CBD) products to its first Australian patients.

Hydroponics said it had “verified its supply line from manufacturer through to patient under Federal [Government] authorized prescriber and special access schemes as well as relevant state regulations”.

The company said it was importing four products from Endoca’s range, CBD oil and CBD and CBDa oils in three and 15 percent concentrations.

Hydroponics said that documentation for doctors to prescribe marijuana products could be accessed through the Medicinal Cannabis Medicines Portal at: <https://mcmp.com.au/>.

Hydroponics chief executive officer Ken Charteris said that “the ability to secure supply of high-quality ... certified medicinal cannabis products to domestic patients is a key bridge to implementation of [our] farm-to-pharma model”.

Hydroponics was up half a cent or 0.9 percent to 55.5 cents.

GENERA BIOSYSTEMS

Genera says the Australian Securities and Investments Commission has granted an extension for its annual general meeting from November 30 to 14 December 2018.

Genera said that in July it requested a voluntary suspension pending a capital restructure “to strengthen [its] financial position and support the planned rollout of [its] test menu operating on the new automated Beckman Coulter system (BD: Jul 4, 2018).

The company said it expected to despatch its annual report and notice of meeting “shortly” with the meeting scheduled for December 13, 2018.

Genera said it was finalizing a prospectus for a four-for-five non-renounceable rights issue to raise up to \$11.2 million, expected to close in December.

Genera last traded at 16 cents.

MEDIBIO

Medibio says it has appointed David Kaysen as chief executive officer and managing director on \$US360,000 (\$A500,367) and has sacked US staff.

Medibio said Mr Kaysen’s base salary would be \$U360,000 with a short-term incentive of 50 percent of base salary in cash or shares pending performance milestones and a long-term incentive of 10,000,000 options exercisable at 45 cents each within five years.

In a separate announcement the company said it had “implemented cost reduction measures that included eliminating certain staff positions in Minneapolis, Minnesota”.

Medibio said that Mr Kaysen had more than 35 years of experience leading and managing emerging growth companies and had experienced in the US Food and Drug Administration approval process, leading products in revenue growth and had experience in Australia.

The company said that previously Mr Kaysen was Sun Biopharma and Uroplasty chief executive officer and had served as chief executive officer of Advanced Duplications Services LLC; Diametrics Medical Inc and Rehabicare Inc and continued as a director of Sun Biopharma, Interrad Medical and Spinal Singularity.

Medibio was up 0.1 cents or 2.6 percent to four cents.