



Biotech Daily

Friday March 12, 2021

Daily news on ASX-listed biotechnology companies

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- * **CELL CARE SELLS 6m CRYOSITE SHARES TO 0.2%**
- * **McRAE INCREASES, DILUTED TO 17.6% OF NEUROSCIENTIFIC**

MARKET REPORT

The Australian stock market was up 0.79 percent on Friday March 12, 2021, with the ASX200 up 52.9 points to 6,766.8 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 10 fell and seven traded unchanged.

Cyclopharm was the best, up 22 cents or 9.2 percent to \$2.60, with 50,828 shares traded. Paradigm, Proteomics, Universal Biosensors and Volpara climbed more than six percent; Optiscan was up 5.3 percent; Actinogen, Impedimed and Polynovo improved more than four percent; Alterity, Mesoblast, Oncosil and Opthea were up more than three percent; Compumedics, Dimerix, Medical Developments, Nanosonics, Neuren, Orthocell, Pro Medicus and Starpharma rose two percent or more; Cochlear and Telix were up more than one percent; with Cynata up by 0.8 percent.

Osprey led the falls, down 0.2 cents or 10 percent to 1.8 cents, with 1.9 million shares traded. Resonance retreated 8.6 percent; Amplia and Prescient fell four percent or more; LBT and Patrys shed more than two percent; Clinuvel, Next Science and Pharmaxis were down more than one percent; with CSL, Kazia and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: AUSCANN + CANNPAL

By TIM BOREHAM

ASX codes: AC8 (Auscann), CP1 (Cannpal)

Share prices: Auscann 14.5 cents; Cannpal 17 cents (Cannpal ceased trading March 11)

Market caps: \$45.97 million (Auscann), \$16.15 million Cannpal (at the close on March 12, combined entity about \$??? million)

Shares on issue: Auscann 317,047,357; Cannpal 95,000,000

Shares on issue (post-merger): 440,547,357 (123,500,000 to be issued to Cannpal holders)

Chief executive officer (merged entity): Layton Mills

Board (proposed for merged entity): Max Johnston (chair), Chris Mews, Krista Bates, Bruce McHarrie, Geoff Starr*, Robert Clifford*, Dr Kathryn Adams* (*Cannpal directors)

Finances (December half 2020):

Auscann: sales \$39,364 (previously nil), loss of \$4.6 million (previously \$3.4 million deficit), cash of \$15.23 million (down 20%)

Cannpal: sales \$16,655 (previously nil), loss of \$273,000 (previously a \$512,000 deficit), cash of \$1.4 million (down 26%)

Substantial shareholders (merged entity): Merchant Opportunities 15 percent, Layton Mills 2.3%, Tania Vidovic 2%, Mal Washer Nominees 1.6%

After years of talk about a pending rationalization of the underachieving ASX-listed cannabis sector, the first full-blown merger of two locally listed pot stocks has been duly implemented.

At a virtual meeting on Monday, Cannpal shareholders agreed to a scheme of arrangement that sees the company subsumed by Auscann.

Given the tight nature of the Cannpal register the union was never really in doubt and was duly approved by holders accounting for 99.9 percent of the shares and 94 per cent of the participating investors.

(Schemes of arrangement require consent from at least 50 percent of voting holders by numbers and 75 percent of shares by value).

The scrip-based deal melds Cannpal's veterinary drug program with Auscann's two-legged one.

As well as generating the usual cost benefits, the proponents argue the union will imbue greater liquidity, attract more institutional investors and meld two complementary product portfolios.

The union is also expected to expand the company's presence not just locally, but in the US, the Middle East, Asia and Germany.

While Cannpal has more advanced programs, Auscann delivers a crucial element - cash - to the table.

A key aspect is that while Cannpal disappears from the ASX boards, the new Auscann will be headed up by Cannpal founder and CEO Layton Mills.

Auscann chief Nick Woolf handed in his resignation in early January, but committed to keep running the show until the merger is complete.

What Auscann brings to the table

The greater Auscann will have two products on market and two to be launched in the next 12 months.

On the Auscann side, Neuvis, is a hard-shell capsule containing a controlled dose of cannabidiols (CBD) and the psychoactive tetrahydrocannabinol (THC) in equal parts.

Neuvis has been available under the local Therapeutic Goods Administration's special access scheme and the network of approved prescribing doctors.

The company recently completed a phase I study of 28 volunteers and plans a phase IIa trial for chronic neuropathic pain. This 60-patient effort is expected to start at local sites this year.

Meanwhile, what Auscann isn't bringing is its joint venture with Chilean grower Dayacann, entered into in 2016.

After the Chilean government last year banned the export of cannabis products, Auscann sold its stake to two offshore parties in November last year, for \$US1.5 million (\$A1.9 million). Of this, Auscann received \$US200,000 upfront.

And Cannpal?

Cannpal brings along CPAT-01, a liquid medication for canine inflammation. The company carried out a phase I study that enrolled 100 dogs, including 46 with osteoarthritis.

Cannpal has lodged an investigational new drug application with the US vet regulator, the Food and Drug Administration's Centre for Veterinary Medicine. This is something to crow (or howl) about, given no other drug company has this status for a CBD-related application.

But Cannpal's's closest path to commercialization is with Dermacann, a CBD derived food additive to promote healthy skin and immune functions. A liquid oral version has been tested on some willing hounds = or at least their owners consented on their behalf - for atopic dermatitis.

Cannpal intends to seek regulatory approval for Dermacann in “key markets”, with first sales targeted for this year in the US and South Africa.

“We are in the final stages of working through a distribution agreement with a major partner in South Africa.” Mr Mills says.

The US approach harnesses the recent liberalization of products containing CBD derived from hemp, which makes getting to market easier in at least some states. The regulatory framework is still complex, but in effect the company can market Dermacann as a food additive if it makes the right claims (and does not over reach).

If approved in Australia, Dermacann would be the only approved veterinary cannabis therapy and only the third approved cannabis drug overall (the others are Epidiolex for epilepsy and Sativex for multiple sclerosis).

Cannpal also has Micromax, a canine food additive based on encapsulation technology developed by the venerable CSIRO (Cannpal acquired the rights to the tech in 2019).

Cannpal plans a pilot launch in the US of a non-prescription dietary supplement for hip and joint health.

A pot-ted history of Cannpal

Cannpal was founded by Mr Mills and listed in October 23, 2017, raising \$6 million at 20 cents a pop.

It was - and remains - the world’s only listed, pure-play, pet, pot stock.

In early 2017 Cannpal entered a term sheet with the then Zelda Therapeutics to bestow Zelda with the first use of its clinical data for human purposes. But the deal lapsed after Zelda merged with Ilera Therapeutics of the US and became Zelira Therapeutics.

Earlier on, Cannpal and Auscann had a chat about the latter taking on the former’s human health research and development, but nothing eventuated.

With a background in consumer goods, Mr Mills zeroed-in on the work on alternative health therapies spearheaded by Californian researchers. In the pain space, that meant alternatives to opioids.

“In the animal space there hadn’t been so much innovation,” he says.

As a result, non-steroidal anti-inflammatory drugs remain the key treatment for canine osteo, despite myriad side effects.

Initially Cannpal targetted an alternative therapy for doggy bone cancer, but accessing the beasts proved to be difficult.

Lest we be seen as specie-ist, Cannpal is also interested in cats, but as we all know they are more finicky and have trickier metabolisms.

The full dope on Auscann

Auscann listed on February 3, 2017, by way of a reverse takeover of TW Holdings and a \$5 million capital raising at 20 cents apiece. Auscann wasn't the first ASX pot stock - that honor went to Perth based peer Phytotech, now owned by Canada's Harvest One - Auscann was a fast follower.

Initially, Auscann was run by the 'A-team' of Dr Stewart Washer and Elaine Darby, the son and daughter of former Federal MP Dr Mal Washer (who not only chaired the Joint House Committee on Environment and Climate Change, but later chaired Auscann).

The company's plans first focused on growing the stuff in Chile and producing pharmaceutical grade product, but things never quite clicked.

Ms Darby resigned in September 2018, to be replaced by former Teva executive Ido Kanyon on an eye watering base salary of \$420,000 a year. Mr Kanyon lasted less than a year and the board then decided it was time for Mr Woolf.

The movers and shakers behind the deal

Under the deal, Cannpal holders receive 1.3 Auscann shares for each Cannpal shares. At the time of the November 16, 2020 announcement, the implied valuation of 18.4 cents per Cannpal share and was a 54 percent premium over the weighted average price of Cannpal shares (11.95 cents) for the previous five trading days.

A key driver of the merger was the assent of the ubiquitous Merchant Funds, which held 19.88 percent of Cannpal and 13.6 percent of Auscann, a stake acquired in 2019 from original Auscann investor Canopy Growth (a leading Canadian pot stock).

Post-merger Merchant will own 15 percent of the entity.

As an aside, Merchant was also a common shareholder of cancer diagnostic houses Bard1 and Sienna, which merged last year.

The odds of a 'yes' vote were also enhanced because Mr Mills owns 8.4 percent of Cannpal and Tania Vidovic, another friendly party and former Cannpal director accounts for another 7.4 percent.

Finances and performance

Both companies could be politely described as pre-revenue: Auscann managed \$13,000 of receipts in the December quarter, while Cannpal chalked up \$11,000. The companies lost \$1.8 million and \$553,000 respectively.

As of December 30, Auscann had \$16.8 million of cash, with a further \$US1.5 million to flow from the Dayacann divestment. Cannpal had \$1.4 million in the kitty (or doggy, if you prefer) with an R&D Tax Incentive to come, but still copped a 'going concern' comment from audit firm BDO.

Auscann's loot is courtesy of a \$33 million placement in a July 2018 placement. Earlier, in May 2017, the company pocketed \$15 million from a placement to poppy grower Tasmanian Alkaloids.

Auscann shares are well off their January 2018 peak of \$1.74, while Cannpal shares hit their high of 21 cents in early December last year.

Elsewhere ...

The merger is in keeping with the popular trend of cannabis 'vet' plays seeking human cannabis exposures, or vice versa.

For example, hemp play Ecofibre has been focused on food additives but is expanding into pet care markets.

The owner of vitamins giant Suisse, the Hong Kong based Health & Happiness Group (H&H Health) owns 17 percent of ASX pot stock BOD Australia. H&H has acquired the Solid Gold pet nutrition brand and will access CBD formulations from BOD.

Creso Pharma plays in both the human and fur-clad sectors with Anibidiol, a hemp-based CBD complementary feed for companion animals.

Mr Mills notes that it makes perfect sense to leverage the veterinary trial data with the human side of things, given human drug development also requires animal-based studies.

Dr Boreham's diagnosis:

Generally speaking, mergers have a habit of disappointing, at least initially. But at the very least, we can't see this one doing any harm.

We won't know for some time whether one plus one equals more than two, and the union is a howling success. But at the very least the merger looks like it will do no harm and save money at corporate HQ level, as well as in the labs (laboratories, not the golden or tan varieties).

Personally, we're more excited about the veterinary side, given the near-term promise for Dermacann and the longer-term prospects for CPAT-01.

The local human medical cannabis sector is growing, but from a low base and, if anything, there's an oversupply.

What's really paws for thought is the veterinary sector, given the lower regulatory hurdles and the ever-expanding market as our fur-babies work their way up the evolutionary chain to true household dominance.

Disclosure: Dr Boreham is not a qualified medical practitioner. He does not possess a doctorate of any sort but does own a dopey hound who has never inhaled.

[VOLPARA HEALTH](#)

Volpara says it has a record contract of more than \$US400,000 (\$A512,957) of annual recurring revenue for its breast cancer risk assessment software.

Volpara said the contract was signed through its wholly-owned subsidiary CRA Health with an unnamed Indiana, US-based organization which had sites in more than 20 states and operated an electronic health record system.

Last year, the company said its revenue for the six months to September 30, 2020 was up 38.3 percent to \$NZ9,465,000 (\$A8,979,966), including \$NZ8,816,000 from its breast mammography software and subscription contracts, with \$NZ19.9 million in annual recurring revenue (BD: Nov 25, 2020).

Today, Volpara chief executive officer Dr Ralph Highnam said that while the company “would not normally announce individual deals, this is the Volpara Group’s highest value contract signed to date”.

“Not only does it enable us to help many more women across the United States benefit from early cancer detection, but it also sets us up for future sales of additional products to this organization,” Dr Highnam said.

“Further, the contract is validation of the decision to purchase CRA Health and validation that the world is rapidly moving towards personalised breast care, which includes analysis of risk and genetics,” Dr Highnam said.

Volpara was up eight cents or 6.1 percent to \$1.395 with 1.1 million shares traded.

[NEUROSCIENTIFIC BIOPHARMACEUTICALS](#)

Neuroscientific says it has raised \$12.26 million through investors’ exercise of more than 61.3 million options at 20 cents each prior to the expiry date on March 7, 2021.

Neuroscientific said that 93.7 percent of all the listed options were exercised by investors, with 4,112,615 options not exercised, which had lapsed.

The company said the exercise of options reflected “strong investor support from option holders”.

In its most recent Appendix 2A new share announcement, Neuroscientific said that after the exercise of options it had 143,471,643 shares available for trading on the ASX.

Neuroscientific was up half a cents or two percent to 26 cents.

[RESAPP HEALTH](#)

Resapp says it has a one-year licencing agreement with the Osaka, Japan-based Astrazeneca KK for its cough counting technology.

Resapp said Astrazeneca KK, a subsidiary of the Cambridge, UK-based Astrazeneca PLC, would integrate the Resapp technology into its asthma management smartphone application, which assisted patients in monitoring symptoms and managing their asthma at home.

The company did not disclose financial details.

Resapp managing-director Dr Tony Keating said that more than “one million people in Japan live with asthma and Astrazeneca’s [application] aims to help patients better manage their condition and adhere to their management plans, leading to a better quality of life”.

Last year, Resapp said it had licenced its cough counting software to Astrazeneca for a lung cancer clinical trial (BD: Oct 22, 2020).

Resapp was up one cent or 17.2 percent to 6.8 cents with 27.4 million shares traded.

CYCLOPHARM

Cyclopharm says it expects the US Food and Drug Administration to approve Technegas by June 26, with US sales to begin “early in the second half of 2021”.

Last year, Cyclopharm said its phase III Technegas lung imaging trial closed early, after data from 200 patients met the primary efficacy endpoint, and earlier this year said it hoped for FDA approval of its lung ventilation imaging agent for pulmonary embolism by July 2021 (BD: Sep 15, 2020; Jan 17, 2021).

Today, the company said it had received the FDA’s timetable for the approval of its new drug application for Technegas, with a pre-approval audit of Cyclopharm’s manufacturing facility scheduled for the week beginning March 29 and the provision of labelling requirements by early May 2021.

Cyclopharm said that on receipt of the labelling requirements, it would finalize the packaging and labelling of Technegas generators and patient administration sets for the US.

The company said the FDA timetable was “broadly in line with Cyclopharm’s expectations and reaffirms the company’s anticipation of commencing sales into the US market early in the second half of 2021”.

Cyclopharm was up 22 cents or 9.2 percent to \$2.60.

BARD1 LIFE SCIENCES, SIENNA DIAGNOSTICS

Bard1 says South Korea has registered its hTERT adjunct bladder cancer test as a class II in-vitro diagnostic medical device and it has an \$80,000 purchase order.

Bard1 said the South Korean Ministry of Food and Drug Safety approved the registration, which would allow the human telomerase reverse transcriptase (hTERT) urine test for bladder cancer to be distributed in South Korea.

In 2019, Bard1’s subsidiary Sienna Diagnostics said it had appointed the Seoul-based Mirax Corp to distribute the hTERT test (BD: Jan 22, 2019).

Today, the company said that it had received an initial purchase order for \$80,000 of tests from Mirax which would be manufactured and delivered “as soon as possible”.

Bard1 said that urological cancer accounted for more than eight percent of all cancers in South Korea in 2011 and the hTERT test could assist pathologists resolve indeterminate urine cytology to assist in bladder cancer diagnosis and improve patient outcomes.

Mirax chief executive officer Sang-Ju Bae said Mirax believed there was “a significant opportunity for hTERT to become a key product in the bladder cancer diagnostic market in Korea”.

Bard1 chief executive officer Learne Hinch said that “securing [South] Korean registration and our first order from Mirax is the culmination of the Bard1 team’s dedication and effort to expanding the geographical footprint for hTERT in Asia”.

Last year, Bard1 said it had acquired Sienna Cancer Diagnostics (BD: Jul 20, 29, 2020).

Bard1 was up 36 cents or 9.9 percent to \$3.99 with 1.1 million shares traded.

INCANNEX HEALTHCARE

Incannex has requested a trading halt pending an announcement “regarding the launch of a sixth research program” for its cannabidiol-based IHL-675A.

Trading will resume on March 16, 2021 or on an earlier announcement.

Incannex last traded at 20.5 cents.

CRYOSITE

Cell Care Australia says it ceased its substantial shareholding in Cryosite, reducing from 6,913,807 shares (14.75%) to 74,065 (0.16%)

The Melbourne-based Cell Care said that between March 9 and 11, 2021 it sold the shares at prices ranging from 16.91 cents to 17.01 cents.

In February, Cell Care announced it had sold Cryosite shares for the first time since 2015 and continued to sell shares, reducing from 9,229,995 shares or 19.69 percent on four previous dates (BD: Nov 26, 2015; Feb 17, 24, Mar 8, 10, 2021).

Cryosite was up 7.5 cents or 44.1 percent to 24.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

McRae Investments says its substantial holding in Neuroscientific has increased and been diluted from 24,343,954 shares (26.9%) to 25,255,262 shares (17.6%).

The Perth-based McRae said that between February 10 and March 11 it bought and sold shares, with the largest acquisition 3,883,712 shares for \$776,742 or 20 cents a share, through the exercise of options.

McRae said it was diluted on March 11, 2021 following the exercise of options by unrelated parties (see above).