



Biotech Daily

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Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.68 percent on Friday October 25, 2019, with the ASX200 up 45.6 points to 6,739.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and two were untraded. All three Big Caps were up.

Resmed was the best, up \$2.05 or 11.0 percent to \$20.65, with three million shares traded. Orthocell climbed nine percent; Clinuvel and Paradigm were up more than five percent; Alterity and Imugene improved more than four percent; Immutep and Neuren were up more than three percent; Cochlear, Cynata, Mesoblast and Proteomics rose more than two percent; CSL, Prescient and Telix were up more than one percent; with Cyclopharm, Nanosonics and Starpharma up by less than one percent.

Oncosil led the falls, down 0.75 cents or 6.7 percent to 10.5 cents, with 1.4 million shares traded. Antisense lost 6.1 percent; Actinogen was down 5.1 percent; Avita, Dimerix and Osprey fell more than four percent; Amplia, Impedimed, Next Science, Opthea, Pharmaxis, Universal Biosensors and Volpara shed more than two percent; Medical Developments was down 1.4 percent; with Compumedics, Ellex, Polynovo and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: ELIXINOL GLOBAL

By TIM BOREHAM

ASX code: EXL

Share price: \$1.70

Shares on issue: 60,023,540 (with a further 77,870,572 escrowed until December 2020).

Market cap: \$234.4 million

Chief executive officer: Stratos Karousos

Board: Andrew Duff (chairman), Paul Benhaim, Mr Karousos, Greg Ellery

Financials (half year to June 30, 2019): revenue \$17.45m (up 17%) loss of \$9.8m (previously \$299,000 profit), cash of \$48.1m (up 238%).

Major identifiable holders: Paul Benhaim (Raw With Life) 56%, D&G Health (David Neman and Gabriel Ettenson) 10.2%

Given it's chock full of omega acids and other goodies, hemp is acknowledged as one of nature's finest super foods.

But how much of a good thing is too much? The issue has been occupying the collective minds of the US Food and Drug Administration, which is determining the safe levels of cannabinoids in food (hemp contains only minute levels of the 'whoopie' ingredient tetrahydrocannabinol, or THC).

For Elixinol, one of the world's biggest producers of hemp ingredients, the key thing is not so much the decreed level - 20 milligrams a day is the best guess - but the fact that the agency has made a formal call on the safety aspect.

So far, the biggest food supplements and cosmetics companies have been rearing at the bit to use hemp ingredients, but have held back pending the agency's guidance.

"It's the next inflexion point for our industry, possibly the last," says Elixinol founder Paul Benhaim. "Companies like Nestle and Pepsi have done their due diligence on the sector and are waiting to act."

In the meantime, hemp in food is a legislative grey area in the US, as are the country's baffling cannabis laws. "We are selling it [hemp foods] today," Mr Benhaim says.

"It's not that it's illegal, it's just that there hasn't been clarity offered by the FDA."

The FDA's former commissioner Scott Gottlieb recently reminded everyone that hemp additives remained illegal Federally, but called for coherent regulation to address the "patchwork" of state-based laws. But he seemed more concerned about anything containing THC, so go figure ...

While the company grapples with US regulators, Japan is providing its own headache after the company's 50.5 per cent subsidiary Elixinol Japan was discovered to be selling non-compliant hemp (that is, not derived from stems and seeds).

With an internal investigation afoot, the stock dropped 11 percent, or 24 cents.

Elixinol Japan accounted for \$1.6 million of Elixinol's June half revenue, 8.7 percent of the total.

Chicken, beef or hemp?

The US-focused Elixinol has already benefited from last year's passing of the Hemp Farming Act Bill, which removed hemp from the controlled substances schedule and allowed it to be regulated likely any other agricultural commodity.

Mr Benhaim says the liberalization led to an immediate revenue uptick. "It's also allowed us to have conversations with much larger fast-moving consumer goods companies - multinationals who have been watching this space for some time."

However, the Farm Bill had some unintended consequences as well.

"Many people thought they could jump on board the magic wave and make a quick buck," he says. "I have never seen any farmer grow hemp for the first time successfully - it usually takes five attempts."

As a result, the market was flooded with low-quality material containing only one CBD isolate rather than the full range of whole-plant cannabinoid and terpene goodness.

Elixinol - a potted history

Arguably, Elixinol is the most successful ASX-listed pot stock, with a track record of selling its product in 40 countries (notably the US).

Elixinol was founded by Mr Benhaim, a Briton who became a global hemp expert after travelling the world to enhance his knowledge of the complex plant.

He ended up in Australia and in 1999 founded Hemp Foods Australia, which is a wholesaler retailer, manufacturer and exporter of ingredients and finished products.

These include hemp seeds, flour, oil, and nut butters, while its hemp burgers are available through Woolworths.

While the company is based in Sydney its spiritual home is at Bangalow near Byron Bay in New South Wales, where it grows the stuff.

In 2014, Mr Benhaim founded Elixinol LLC in the US and then took Elixinol world-wide.

Based in Colorado, the US arm makes and distributes industrial hemp-based dietary supplements and skincare products.

The company listed in January last year, having raised \$20 million at \$1 apiece.

In April last year, the company entered an equal joint venture with the growing group Northern Colorado High Plains Producers, which doubled Elixinol's growing capacity.

In June this year, Elixinol entered a joint venture with Infusion Strategies with RFI Ingredients, a 40-year old hemp supplier that services the likes of Nestle and Pepsi Cola.

Elixinol holds 60 percent of the joint venture, called Infusion Strategies and is the exclusive cannabidiol (CBD) supplier to that venture.

In 2014, the company formed a subsidiary, Nunyara Pharma, to participate in the emerging Australian medical cannabis sector. Nunyara holds a manufacturing licence and has applied to the Office of Drug Control for cultivation licence (a decision is pending).

At the heart of Elixinol's medical dope plans is a 24-hectare property in the northern rivers district of NSW, acquired for \$2.6 million in February.

Once permitted, the facility will serve as an integrated growing, cultivation and manufacturing facility.

In the meantime, Elixinol's medical products are available in New Zealand, which recently changed the law to allow low-THC level cannabis medications.

Elixinol also owns 51 percent of Pet Releaf, the "most widely distributed hemp and CBD pet product in the market".

Musical chairs

Despite its success, Elixinol has not been averse to pulling the trigger on some changes at executive and board level.

In July, Mr Benhaim ceded the CEO role to the company's chief commercial officer Stratos Karousas (who also joined the board).

Mr Benhaim became chief innovation officer but remains on the board. Given he accounts for almost 40 percent of the register, would anyone argue?

Director Linda McLeod also ceded her seat, but resumed an executive role.

In a further refresh - as they say - US regional prez Gabriel Ettenson became global chief technology officer while global information technology director Greg Smith became global chief information officer ... not be confused with global chief technology officer, of course.

Hitherto the director of business development for the US, the aptly-named Leif Harrison became CEO for the Americas, while European sales director Ali Atcha became CEO for Europe and the UK.

Finances and performance

When your columnist last covered Elixinol in September last year, he waxed lyrical about Elixinol's refreshing status as a profit generating entity - \$120,000 in the 2017-'18 year - in a sector drowning in red ink.

Sadly, we have to retract that praise because Elixinol reverted to a loss of \$9.8 million for the (first) June half.

However, revenue is clocking over nicely: turnover of \$17.45 million for the six months, 17 percent higher than previously. The company generated \$38 million of revenue in calendar 2018.

The results show a skew to Elixinol's own brands rather than 'private label' arrangements, with the latter contributing 18 percent of revenue compared with 38 percent in the previous corresponding half.

Branded product sales rose 63 percent to \$7.5 million, or 41 percent of the total. They also account for 52 percent of US sales, compared with 36 percent previously.

Mr Benhaim attributes the operating loss to the costs incurred in expanding the business: operating expenses rose to \$19.9 million in the six months to June 30, from \$7.6 million previously, with marketing expenses accounting for 21 percent of revenue.

Full time equivalent staff numbers also swelled to 134, from 59 previously.

The company has been scaling up capacity for an expected surge in orders, including amassing a \$20 million inventory of raw material.

Mr Benhaim says Elixinol's costs will not be as high next year because the investment in facilities has largely been completed.

Elixinol has a bulging cash kitty of \$48.1 million, courtesy of a supersized \$50 million placement in June (at \$3.90 apiece).

Since listing, Elixinol shares have traded between \$5.69 (early April this year) and \$1.35 (mid-February 2018).

Dr Boreham's diagnosis:

With a market cap approaching \$260 million despite this week's Japanese hiccup, Elixinol is the biggest ASX-listed cannabis stock ahead of the \$170 million market cap Cann Group.

As the only member of 'cannabis corner' with a respectable revenue and earnings track record, it is a unicorn stock in a sector that is yet to live up to its promises.

Mr Benhaim expects 2020 to be a "pivotal year" for the company, not just in the US but elsewhere.

"We are gaining a reputation everywhere for being a quality supplier, but if the FDA comes on board [with the hemp food standard] we will see significant growth," he says.

Elixinol also appears to be overcoming the problem of widespread discounting in the US following enactment of the Farm Bill, which resulted in a flood of substandard hemp on the market. The company lost several bulk and private label customers, whose pleas for a discount fell on deaf ears. Since then, there's been a flight back to quality.

Mr Benhaim sees Europe as a key growth market, especially in hemp-happy Germany where growing the stuff remains verboten. European hemp demand is tipped to grow at a compound annual rate of 42 percent to be a \$1.7 billion market by 2023.

We shouldn't forget that while the health benefits of omega acids are well accepted, the advantages conferred by CBDs - such as pain, anxiety and insomnia relief - remain largely anecdotal.

But let's not forget that most of the stuff flogged by Blackmores and Suisse are clinically unproven as well - or should we say proven not to be harmful - and they have become billion dollar plus companies.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He always thought hemp was what New Zealanders called something on a camel and that CBD was the main business district of a large city.

CSL

CSL Behring and Pharming NV say Pharming will be dismissed from the case against Prof Joseph Dr Chiao regarding information “he intended to provide to Pharming”.

Last week, CSL said it had filed a lawsuit in the US District Court for the Eastern District of Pennsylvania against former senior scientist Prof Joseph Chiao and the Leiden, Netherlands-based Pharming Group NV alleging that Prof Chiao “deliberately downloaded highly sensitive, proprietary commercial information and trade secrets that we believe he intended to provide to Pharming Healthcare Inc, and where [Prof] Chiao recently began working” (BD: Oct 18, 2019).

Today, a CSL spokesperson told Biotech Daily that Pharming had been removed from the matter.

In a media release, Pharming said its dismissal “did not involve any fault, liability, or penalties against Pharming and the temporary court injunction against Pharming is now terminated ... [as was] Dr Chiao’s employment”.

Pharming said it had worked, and would work, with CSL through the issues central to CSL’s claims against Dr Chiao.

“The parties continue to jointly conduct a forensic review, which we are confident will not uncover any evidence of confidential information, including personally identifiable information, being shared with Pharming by Dr Chiao,” Pharming said.

Pharming chief executive Sijmen de Vries said the “voluntary dismissal by CSL Behring of Pharming in this legal case confirms our previous statement that Pharming did not induce or encourage Dr Chiao to breach any rules or contract terms or in any way to remove any data from his former employer, nor did Pharming or our colleague Dr Anurag Relan receive any of CSL Behring’s confidential information from Dr Chiao”.

CSL was up \$4.02 or 1.6 percent to \$256.77 with 491,468 shares traded.

RESMED

Resmed says revenue for the three months to September 30, 2019 was up 15.8 percent to \$US681,100,000 (\$A999,309,920) compared to the previous corresponding period.

Resmed said that non-generally accepted accounting principles (non-GAAP) net profit after tax for the three months was up 16.4 percent to \$US135,400,000 (\$A198,594,2700). The company said that non-GAAP diluted earnings per share was up 14.8 percent to 93 cents a share.

The company said it would pay a dividend of 3.9 US cents a share for the three months to September 30, 2019 for the record date of November 7 and to be paid on December 12, 2019.

Resmed was up \$2.05 or 11.0 percent to \$20.65 with three million shares traded.

IMAGION BIOSYSTEMS

Imagion says it will continue to defer good manufacturing practice production of its nanoparticle for magnetic resonance imaging until it has additional capital.

Imagion said it expected to spend about \$1.6 million for the seven to eight months form production, exceeding its current cash runway.

Imagion executive chairman Bob Proulx said, “we are well-placed to move into GMP manufacturing, pending availability of funds”.

“The FDA has recognized that our technology will be a breakthrough for breast cancer patients,” Mr Proulx said.

Imagion fell 1.5 cents or 37.5 percent to 2.5 cents with 8.8 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has raised \$4.5 million in an underwritten one-for-two rights offer at 0.4 cents a share, with shareholders applying for \$786,000 in shares.

Genetic Technologies said shareholders who took up their full entitlement would be eligible to apply for additional new shares not taken up by other shareholders and oversubscriptions would be scaled back on a pro-rate basis based on the application amount (BD: Oct 4, 2019).

Today, the company said the rights offer was underwritten by Lodge Corporate.

Genetic Technologies said the funds would be used to develop its Genetype genetics risk assessment platform for chronic conditions, to establish a deep pipeline of polygenic risk tests and to enable it to complete further tests and begin sales of its Genetype tests in Australia and to resume sales in the US.

Genetic Technologies was up 0.05 cents or 9.1 percent to 0.6 cents with 19.0 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has been cleared it to treat 10 former American football players with its Zilosul injectable pentosan polysulfate sodium for osteoarthritis and bone bruising.

Paradigm said the former National Football League players had been approved by an institutional review board and would be treated under the US Food and Drug Administration expanded access program.

The company said it had applied to the US Food and Drug Administration for a pre-investigational new drug meeting for December 2019.

Paradigm said it expected to meet with the Australian Therapeutic Goods Administration on November 11, 2019 regarding Zilosul for osteoarthritis.

Paradigm was up 15 cents or 5.6 percent to \$2.82 with 886,027 shares traded.

CYNATA THERAPEUTICS

Cynata says the Canadian Intellectual Property Office has allowed a patent for its Cymerus mesenchymal stem cell technology.

Cynata said the patent, titled 'Generation of clonal mesenchymal progenitors and mesenchymal stem cell lines under serum free conditions' was owned by the University of Wisconsin-Madison's Wisconsin Alumni Research Foundation (WARF), among the intellectual property licensed exclusively from WARF to Cynata.

The company said it expected the patent to be granted by April 11, 2020, and it would protect its intellectual property until March 16, 2031.

Cynata was up 2.5 cents or 2.1 percent to \$1.20.

USCOM

Uscom says it has consolidated 345,939 shares into a single holding and will sell the shares on market and return the funds to investors proportional to their holdings.

Uscom said the consolidation and sale would reduce the total number of shareholders by 25 percent.

Uscom was unchanged at 11.5 cents.

HERAMED

Heramed says it has extended its Consultus India agreement for the Heracare launch and has received a second purchase order for its Herabeat foetal heart rate monitor.

Heramed said the purchase order of \$US45,000 (\$A66,002) came from Consultus, who it would work with to identify partners for pilot trials and beta testing of its Heracare software as a service-based platform in India.

The company said it had a memorandum of understanding with Consultus and would enter into a binding licensing, sale and distribution agreement following a mutual assessment, which would automatically expire on December 31, 2020.

Heramed was up one cent or 6.1 percent to 17.5 cents.

ALTHEA GROUP HOLDINGS

Althea says it expects to have prescribed 4,000 patients in Australia by the end of 2019 and has extended its Aphria product supply agreement to 2027.

Althea said it had currently prescribed 2,705 medical marijuana patients through 348 Australian healthcare professionals.

Althea chief executive officer Josh Fegan said that given the Australian Therapeutic Goods Administration's "comprehensive regulatory system for medicinal cannabis at a Commonwealth level, other states including Victoria, will soon follow the lead of Queensland and New South Wales by removing state-based applications for patients seeking access to medicinal cannabis".

"This will certainly lead to a wider acceptance of medicinal cannabis treatment within the medical community and we believe will significantly increase Althea's patient base," Mr Fegan said.

Althea fell 12.5 cents or 23.8 percent to 40 cents with 12.2 million shares traded.

RESPIRI

Respiri says it had cash and cash equivalents of \$1,906,000 at September 30, 2019, retained an additional \$678,000 after that date and expects to spend \$2,167,000 for the three months to December 31, 2019.

Respiri said it had cash burn of \$2,049,000 for the three months to September 30, 2019.

Respiri was up 0.2 cents or 3.3 percent to 6.3 cents with 1.1 million shares traded.

RESPIRI

Respiri says remaining directors Ross Blair-Holt and Prof Bruce Thompson oppose the re-election of Mario Gattino as a director at its annual general meeting.

Respiri said that "in light of Mr Mario Gattino's departure as [chief executive officer], Mr Ross Blair-Holt and Prof Bruce Thompson do not believe ... [his] re-election is in the best interests of shareholders".

The company said the meeting would vote to re-elect Mr Blair-Holt and Prof Thompson as directors, vote to issue Mr Gattino 625,000 shares at eight cents a share, 500,000 shares at 10 cents a share, and to issue Mr Blair-Holt 500,000 shares at 10 cents a share.

The company said it would vote to adopt its remuneration report and on a special resolution to approve a 10 percent placement issue.

The meeting will be held at Computershare, 452 Johnston Street, Abbotsford on November 25, 2019 at 4pm (AEDT).

ADHERIUM

Adherium says its annual general meeting will vote on its remuneration report and face a potential second-strike board spill.

Last year, Adherium said its annual general meeting remuneration report resolution was opposed by 23,853,661 votes (33.2%), providing the first trigger for a potential board spill at this year's annual general meeting (BD: Nov 20, 2018).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election at a subsequent meeting.

Today, Adherium said it would vote to issue chairman Thomas Lynch and directors Jeremy Curnock Cook, Dr William Hunter, Bruce McHarrie, Prof John Mills, Bryan Mogridge and Matthew McNamara shares in lieu of half their director fees.

The company said it would vote to approve convertible notes worth an aggregate of \$1,800,000 and secured note deeds up to \$1.25 million, along with \$750,000 debt notes to entities associated with director Dr Hunter, be convertible into note securities.

The company said it would vote to elect directors Mr Lynch, Dr Hunter and Mr McNamara and approve an additional 10 percent placement facility.

The meeting will be held at K&L Gates, Level 25, Rialto South Tower, 525 Collins Street, Melbourne on November 25, 2019 at 11am (AEDT).

Adherium was untraded at 5.5 cents.

AVITA MEDICAL

Avita says its annual general meeting will vote to issue chief executive officer Dr Michael Perry 39,554,252 additional long-term incentive restricted security units.

Avita said the additional restricted security notes would be a long-term incentive, subject to vesting conditions and performance milestones.

The company said it would vote to adopt its remuneration report, to re-elect directors Suzanne Crowe, Louis Drapeau and Damien McDonald, and to approve its employee share plan.

The meeting will be held at the offices of K&L Gates, Level 25, 525 Collins Street, Melbourne on November 26, 2019 at 11am (AEDT).

Avita fell 3.5 cents or 4.9 percent to 67.5 cents with seven million shares traded.

NOVITA HEALTHCARE

Novita says its annual general meeting will vote to issue 14,377,766 options to managing director Glenn Smith and change the company name to Tali Digital Limited.

Novita said that Mr Smith's options to Mr Smith would be issued in two tranches, subject to operating profit vesting conditions, and would be exercisable at 3.0 cents each by October 3, 2022.

The company said the meeting would vote to renew proportional takeover provisions approve an additional 10 percent placement facility, approve the prior issue of 3,785,507 options to PAC Partners Securities, adopt the remuneration report and elect director Mark Simari.

The meeting will be held at the offices of Baker McKenzie, Level 19, 181 William Street, Melbourne on November 26, 2019 at 11am (AEDT).

Novita was up 1.9 cents or 70.4 percent to 4.6 cents with 589.7 million shares traded.

[GENETIC TECHNOLOGIES](#)

Genetic Technologies says its annual general meeting will vote to change its name to Genetype Limited.

Genetic Technologies said the meeting would vote to approve the issue of 125,000,000 sub-underwriting options each to director Peter Rubenstein and executive chairman Dr George Muchnicki, approve a proposed placement to raise approximately \$US5 million (\$A7,332,725) at a price no less than 80 percent of the five-day volume weighted average price, to Aegis Credit Corp retail and institutional investors.

The company said it would vote to adopt its remuneration report, elect directors Nick Burrows and Mr Rubenstein and approve an increased 10 percent placement capacity. The meeting will be held at the Australian Style Institute, Level 1, 60-66 Hanover Street, Fitzroy, Victoria on November 28, 2019 at 11am (AEDT).

[CYNATA THERAPEUTICS](#)

Cynata says its annual general meeting will vote on a resolution to provide all shareholder names and email addresses to any member requesting them.

Cynata said the company opposed the resolution to amend the company constitution and insert the new clause.

The company said it would vote to adopt its remuneration report and to re-elect directors Peter Webse, Dr Paul Wotton and Dr Geoffrey Brooke.

Cynata said it would vote to renew its employee option acquisition plan and to approve a 10 percent placement facility.

The meeting will be held at the board room, Level 2, 62 Lygon Street, Carlton South, Victoria on November 27, 2019 at 11am (AEDT).

[PALLA PHARMA \(FORMERLY TASMANIAN POPPY INDUSTRIES\)](#)

Washington H Soul Pattinson says it has increased its substantial shareholding in Palla Pharma from 16,176,097 (19.95%) to 25,040,465 (23.18%).

The Sydney-based Washington H Soul Pattinson said it acquired 2,393,929 shares in a placement and 6,470,439 through a rights issue, in the recent capital raising at 70 cents a share, which has raised \$20.6 million (BD: Oct 21, 2019).

Separately, the Sydney-based Brickworks said it owned 39.4 percent of Washington H Soul Pattinson and as a result was also a relevant interest holder of the new shares.

Palla Pharma fell five cents or 5.9 percent to 80 cents.

[RHYTHM BIOSCIENCES](#)

Rhythm says Shane Tanner has resigned as chairman and a director and will be replaced by Otto Buttula from the close of the October 28 annual general meeting.

Rhythm said Mr Buttula was previously the co-founder, chief executive officer and managing director of IWL, the founder and managing director of Investors Mutual and the co-founder and director of Lonsdale Securities.

Rhythm was up half a cent or three percent to 17 cents.