



# Biotech Daily

Friday September 14, 2018

*Daily news on ASX-listed biotechnology companies*

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- \* **DIRECTOR DENNIS ECK TAKES 6.4% OF CELLMID**

## MARKET REPORT

The Australian stock market was up 0.6 percent on Friday September 14, 2018 with the ASX200 up 36.6 points to 6,165.3 points. Nineteen Biotech Daily Top 40 stocks were up, nine fell, five traded unchanged and seven were untraded. All three Big Caps rose.

Dimerix was the best on no news, up 1.9 cents or 19.8 percent to 11.5 cents with 239,743 shares traded.

Factor climbed 14.3 percent; Genetic Signatures was up 13.8 percent; Prescient improved 8.9 percent; Opthea rose 7.7 percent; Benitec was up 6.1 percent; Imugene climbed 4.55 percent; Actinogen and Impedimed were up more than three percent; Compumedics, CSL, Mesoblast and Resmed rose more than two percent; Avita, Bionomics, Cochlear, Pro Medicus, Starpharma and Volpara were up more than one percent; with Clinuvel, Ellex and Telix up by less than one percent.

Airxpanders led the falls, down 1.5 cents or 12.5 percent to 10.5 cents, with 211,009 shares traded.

Orthocell fell five percent; Immutep lost 4.65 percent; Neuren and Uscom were down more than three percent; Cynata and Optiscan shed more than two percent; Medical Developments lost 1.3 percent; with Paradigm down 0.5 percent.

## [DR BOREHAM'S CRUCIBLE: ELIXINOL GLOBAL](#)

**By TIM BOREHAM**

**ASX code:** EXL

**Share price:** \$1.825; **Shares on issue:** 102,928,540; **Market cap:** \$187.8 million

**Chief executive officer:** Paul Benhaim

**Board:** Andrew Duff (chairman), Linda McLeod (managing director), Paul Benhaim, Stratos Karousas

**Financials (first half to June 30, 2018):** revenue \$14.9m (up 111%), underlying earnings before interest taxation depreciation and amortization \$800,000 (\$100,000 loss previously), net profit after tax \$120,000 (\$700,000 loss previously) \*, cash on hand \$14.2 million (previously \$18.8 million)

**Identifiable major holders:** Raw with Life Pty Ltd (Paul Benhaim) 53%, D&G Health LLC (David Newman and Gabriel Ettenson) 12.3%, Tiverton Food Pty Ltd 3.6%, Robot Expert UG (Germany) 3.2%.

\* based on pro forma previous half results.

In the last of The Crucible's three-part trip around Cannabis Corner, we visit Elixinol with its trio of food, cosmetics and medicine. The manufacturer of hemp-based foods and aspiring medical cannabis producer last month chalked up a crucial first for the ASX-listed pot sector: a net profit of \$120,000 for the first half.

(Yes, MMJ Phytotech then reported an amazing \$34.1 million profit, but that was accounting flummery relating to deconsolidation of a subsidiary).

Elixinol's revenue of just under \$15 million is nothing to be sneezed at, either.

So far, Elixinol's turnover has been achieved from selling its hemp skincare and food products to 40 countries.

Fresh from its January ASX listing, Elixinol is planning clinical trials for hemp-derived cannabidiols.

### **About Elixinol**

Elixinol consists of three separate businesses: Hemp Foods Australia, the Colorado based medical hemp producer Elixinol LLC and the local fledgling medical cannabis business Elixinol Australia.

The US division is the third biggest seller of hemp cannabidiol (CBD) dietary supplements in the country.

The driving force behind Elixinol is chief executive officer Paul Benhaim, who has a 25-year history in the global hemp sector in industrial hemp legislation, cultivation, manufacturing and sales.

The Briton 'discovered' hemp while travelling through Asia (where else?). "I realised hemp contained omega 3 and 6 fatty acids, it's a highly nutritious food," he said.

Mr Benhaim studied food and nutrition but travelled the world to meet leading fats and oils doctors including the Polish-born Dr Udo Erasmus, who discovered the importance of essential fats derived from organic flax seeds.

Back in the UK, Mr Benhaim developed a hemp snack bar called 9-bar which is still sold in the millions by a Welsh company.

Mr Benhaim was lured to Australia and in 1999 founded Hemp Foods Australia, which is now the largest hemp food producer in the Southern Hemisphere. The company provides both bulk and branded raw material to other food makers, as well as finished product, exporting to 40 countries (notably the US).

In 2014 Mr Benhaim founded Elixinol LLC in the US and then Elixinol locally, with the aim of participating in the emerging market here.

Elixinol listed on the ASX in January 2018, raising \$20 million at \$1 apiece (it had only sought \$15 million). While the company is headquartered in Sydney its spiritual home is Bangalow near Byron Bay in northern New South Wales, where the hemp factory is based.

Mr Benhaim is a certified industrial hemp addict, having penned no fewer than nine books on the topic.

### **Navigating the shifting regulatory sands**

As with other pot plays, Elixinol has been a story of navigating the complex overlay of cannabis prohibitions and - increasingly - regulation of the partly-decriminalized activity.

When Elixinol in the US started, hemp foods were illegal - sort of - so the company supplied skincare products.

"Nothing has been black and white because the Constitution allows states to devise legislation in the US," Mr Benhaim says.

But the US Senate recently passed the Hemp Farming Act Bill, which removes the plant from the controlled substances schedule and means it will be regulated like any other agricultural commodity.

The reform presents several key benefits to the hemp producers: they can openly advertise and will obtain easier access to bank funding and water rights.

Championed by Senate majority leader Mitch McConnell, the Bill is yet to pass the lower house and obtain a signature from The Donald's Twittering hands.

In Australia, Hemp Foods Australia initially imported hemp for skincare products, thus circumventing the prohibitions on hemp foods, later removed in November 2017. The company launched its Sativa skincare range in April this year.

Also in April this year, Elixinol entered into a 50-50 joint venture with the aptly-named Northern Colorado High Plains Producers, to use 700 acres of land backed by leased water rights. The deal will double Elixinol's US growing capacity.

### **Medical cannabis push**

Industrial hemp is high in cannabinoids but is low in the high-inducing ingredient tetrahydrocannabinol (THC), so it's surprising that US authorities have taken so long to properly legalize it when they've been willing to do so for recreational dope.

"You could smoke a field of the stuff and get a headache and that would be about it," says Mr Benhaim.

But that's not necessarily the case with hemp-derived medical cannabis which may contain THC, which is the next area in which Elixinol wants to play. Indeed, developing a medical cannabis business was a stated aim of the ASX initial public offer and listing.

Locally, Elixinol has submitted a cultivation and manufacturing application to Australia's Office of Drug Control and expects to hear back by the end of this year.

Mr Benhaim is coy when it comes to the indications of interest, but points to "lots of anecdotal evidence" for hemp as an anxiety treatment. He also notes the US Food and Drug Administration recently approved the first cannabis-based drug - for childhood epilepsy - GW Pharma's Epidiolex.

"We are firming up our clinical trial strategy," Mr Benhaim says. "We are taking a studious approach but they can be very expensive and don't lead to expected returns."

With the Australian government removing the ban on medical cannabis exports last February, Elixinol plans to supply off-shore markets.

### **Financials and performance**

Having long covered the pot sector which tends to be high in promises but devoid of any top line or bottom line proof, Elixinol makes a refreshing change.

Elixinol reported a net profit of \$120,000 compared with a proforma \$700,000 loss previously and underlying earnings before interest taxation depreciation and amortization of \$800,000 (previously a \$100,000 loss). Strictly speaking, the result cannot be compared with previously because the company was only incorporated in September last year.

The company also broke the Biotech Daily Cannabis Corner record books by actually paying some tax: \$200,000.

Mr Benhaim says: “We have delivered exceptionally strong top line growth, which has seen the company more than double its size and enabled us to report our first profit.”

Of the first half revenue of \$14.9 million (up 110 percent), Hemp Foods Australia contributed \$2.3 million (up 71 percent), with bulk sales in particular increasing five-fold. Wholesale, the biggest sub-division improved sales by 39 percent.

Elixinol in the US chipped in \$12.5 million, up 119 percent on the half. “Segments including direct to consumer, wholesale and bulk were all strong performers,” the company says.

The thinly-traded Elixinol shares are trading at their record highs, having had a growth spurt since early September on no apparent ‘new’ news. The lowest they have traded was at \$1.30 on February 12.

### **Dr Boreham’s diagnosis:**

Until it develops a serious medical application, Elixinol is in that cosmeceutical-nutraceutical (really cosmetics and food additives) grey zone in terms of what you buy in a chemist rather than a health food shop.

“It’s a bit like fish oil,” Mr Benhaim says. “You can get a prescription but you can also buy it in a health food supermarket. They are both significant markets and we are playing in both of those fields.” (And the most recent evidence is that both the prescription and over-the-counter fish extracts actually do nothing, at all, but are generally regarded as safe - or GRAS, as we bio-people say.)

But does Elixinol want to be perceived as a food hemp or medical cannabis play?

“The answer is both and more,” Mr Benhaim says. “The difference between us and other listed cannabis companies is they are medical cannabis or hemp. We are both.”

Locally, Hemp Foods Australia plans new product offerings in late 2018 and 2019 including a hemp snack bar to be called Essential Hemp. Given Elixinol’s revenue traction to date, we would hazard a guess that some shareholders will stick with the industrial hemp side of things.

What’s for sure is that with 53 percent ownership of the company, Mr Benhaim will have the final say.

And speaking of final words, Mr Benhaim says: “The outlook for Elixinol is very bright. Very green, one could say.”

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He once wore a hemp shirt and deeply inhaled - with little effect.***

## OPTHEA

Opthea says that a new analysis from its 2017 phase I/IIa trial of OPT-302 for wet age-related macular oedema details pharmaco-kinetics and specific efficacy.

Opthea said the data was presented by study investigator Dr John Wells at the Retina Society meeting in San Francisco, September 12 to 15, 2018.

The company said that in patients receiving the combination of OPT-302 with Lucentis, the proportion gaining more than five 10 or 15 letters of vision from baseline to week-12 was 67 percent, 44 percent and 33 percent, respectively, in treatment-naïve subjects, while it was 53 percent, 16 percent and 0.0 percent for patients previously treated with multiple intravitreal anti-vascular endothelial growth factor A (VEGF-A) agents.

Opthea said that similar gains in vision were also seen at week-8 and were observed as early as four weeks following combination treatment with OPT-302 and Lucentis.

The company said that seven (54%) of the 13 participants who received OPT-302 monotherapy did not require anti-VEGF-A rescue therapy over the 12 weeks, with an additional five (38%) receiving only one anti-VEGF-A rescue injection, while one subject received two rescue injections.

The mean time to first intravitreal injection of rescue therapy was 57.7 days.

Last year, Opthea said that its first-in-human OPT-302 trial met its safety and efficacy endpoints for wet age-related macular degeneration (AMD), including biological activity at the low dose of 0.3mg of OPT-302 (BD: Apr 3, 2017).

The company said last year that as a monotherapy OPT-302 showed an increase in visual acuity of 5.6 letters on the early treatment diabetic retinopathy study (ETDRS) eye-chart at 12 weeks, whereas the previous phase III Lucentis (ranibizumab) 'Marina' trial showed that controls had a continuous decrease in acuity, while those receiving Lucentis had a response plateau at three months.

In 2017, Opthea said that 44 patients (89.8%) maintained or gained vision at 12 weeks, with 18 naïve patients having the best response of an increase in 10.8 letters at 12 weeks. Today, Dr Wells said the standard-of-care most commonly used to treat patients with wet AMD was intravitreal anti-VEGF-A agents, but there was "a significant unmet need".

"These initial phase I/IIa trial results suggest that dual targeting of VEGF-C and VEGF-D with OPT-302 and VEGF-A with standard-of-care agents is a promising strategy to treat wet AMD and other retinal vascular diseases," Dr Wells said.

Opthea said the pharmaco-kinetic analysis showed that OPT-302 had a short serum half-life of eight days, plus or minus two days, with "low circulating levels and no evidence for accumulation or influence from Lucentis on the [pharmaco-kinetic] profile".

The company said that no dose-related trends were observed.

Opthea was up 4.5 cents or 7.7 percent to 63 cents.

## QUEENSLAND BAUXITE

Queensland Bauxite shareholders have approved the acquisition of three marijuana entities, the issue of related shares and to change its name to Cann Global.

In August, Queensland Bauxite said it would acquire the remaining 45 percent of subsidiary Medical Cannabis Ltd, 100 percent of Medcan Australia and 100 percent of T12 Holdings Pty Ltd which included Hemp Hulling Co (BD: Aug 16, 2018).

Today, the company said that all resolutions passed easily with the greatest dissent against the issue of shares to Sebastian Edwards and Sam Edwards with about 280.1 million votes (93.55%) in favor and 19.4 million (6.45%) against.

Queensland Bauxite was untraded at 3.7 cents.

### KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia says it will issue \$1,250,000 in shares to Glioblast Pty Ltd as its phase II GDC-0084 for glioblastoma trial has begun dosing.

In 2016, the then Novogen acquired Glioblast for GDC-0084, and chief executive officer Dr James Garner told Biotech Daily that Glioblast was owned by Viralytics chairman Paul Hopper and Imugene chief executive officer Leslie Chong (BD: Oct 31, 2016).

Dr Garner said at that time that Ms Chong was Genentech's former clinical program lead for GDC-0084, with Glioblast acquiring GDC-0084 from Genentech

Today, Kazia said that progress in the GDC-0084 study was "extremely positive, with all seven sites now open and actively recruiting patients, clinician engagement has been very encouraging and several patients are at various stages of screening".

The company said it was "on-track" to report initial data early in 2019.

Kazia was unchanged at 43.5 cents.

### CSL

CSL will vote on the grant of up to \$US6,128,500 (\$A8,510,935) more 'performance' shares for chief executive officer Paul Perreault.

Last year, CSL saw 48,585,584 votes (18.3%) oppose the issue of \$6,786,729 performance shares to Mr Perreault (BD: Oct 18 2017)

In 2017, the company was facing a 'second strike' vote but a potential board spill motion was withdrawn, with votes filed before the meeting showing that a spill was opposed by 94.3 percent of proxy votes.

In 2016, CSL narrowly earned a first strike vote with 26.02 percent of votes opposing the remuneration report, with Mr Perreault's \$6,636,637 performance rights and options opposed by 27.25 percent and a 33 percent increase in directors' fees to \$4,000,000 opposed by 33.82 percent (BD: Oct 12, 2016).

In previous years, resolutions to issue performance stock to Mr Perreault were passed but with up to 19.5 percent opposition (BD: Oct 16, 2013; Oct 15, 2014; Oct 15, 2015).

Today, CSL said the meeting would vote to elect directors Dr Brian McNamee, Prof Andrew Cuthbertson and Abbas Hussein, as well as to accept the remuneration report, approve the employee share plan and the performance rights plan and renew the takeover provisions.

The meeting will be held at the Clarendon Auditorium, Level 1, Melbourne Convention Centre, 2 Clarendon Street, South Melbourne on October 17, 2018 at 1pm (AEDT).

CSL was up \$4.28 or 2.1 percent to \$210.62 with 1.5 million shares traded.

### LIFESPOT HEALTH

Lifespot has requested a trading halt "pending an announcement in relation to an acquisition".

Lifespot previously said it was in discussions with North American and Australasian marijuana companies to finance medicinal and recreational marijuana products, as well as discussion with potential clients in Israel to supply its marijuana vaporizer for clinical trials (BD: May 14, Jun 20, 2018).

Last year, Lifespot said it was in "advanced negotiations" with unnamed European companies to integrate its Bodytel monitoring platform with medical marijuana opportunities (BD: Apr 4, 2017).

Trading will resume on September 18, 2018 or on an earlier announcement.

Lifespot last traded at 8.1 cents.

### STARPHARMA

FIL Limited says it has reduced its substantial holding in Starpharma from 25,549,892 shares (6.90%) to 21,789,977 shares (5.88%).

The Bermuda-based FIL said it sold shares between June 29 and September 11, 2018 at prices ranging from \$1.12 to \$1.42.

Starpharma was up 2.5 cents or 1.7 percent to \$1.485 with 1.2 million shares traded.

### BLUECHIIP

Melbourne's Bellwether Super and director Jim Craig say they have increased their shareholding in Bluechiip from 22,134,081 shares (5.7%) to 32,500,000 shares (6.6%).

Mr Craig said the shares were held by Equitas Nominees Pty Ltd, with 365,919 shares bought in August 2017 for three cents a share and 10,000,000 shares acquired in a placement on September 12, 2018 for \$590,000 or 5.9 cents a share.

Earlier this week, Bluechiip said it raised \$5.5 million in an oversubscribed placement at 5.9 cents a share to sophisticated and professional investors (BD: Sep 10, 2018).

Bluechiip fell 0.1 cents or 1.5 percent to 6.5 cents.

### CELLMID

Cellmid's Las Vegas-based director Dennis Eck says that he has become a substantial shareholder in the company, with 5,331,579 shares (6.40%).

Mr Eck said that on December 19, 2017 he bought 2,700,000 shares for \$1,026,000 or 38.0 cents share and on September 12, 2018 acquired 2,631,579 shares for \$1,000,000 or 38.0 cents a share.

Cellmid fell one cent or 2.5 percent to 38.5 cents.