



# Biotech Daily

Friday September 7, 2018

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 0.27 percent on Friday September 7, 2018 with the ASX200 down 16.6 points to 6,143.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and three were untraded.

Immutep was the best for the second day in a row, up 0.4 cents or 10.8 percent to 4.1 cents with 33.0 million shares traded. Both Airxpanders and Dimerix climbed 9.5 percent; Clinuvel improved 5.6 percent; Imugene and LBT were up more than four percent; Orthocell, Pharmaxis and Uscom climbed more than three percent; Compumedics, Ellex, Oncosil, Osprey, Resmed and Universal Biosensors rose more than two percent; Cochlear, Polynovo and Starpharma were up more than one percent; with Pro Medicus and Volpara up by less than one percent.

Optiscan led the falls, down 0.8 cents or 15.1 percent to 4.5 cents, with 341,654 shares traded. Prescient lost 8.8 percent; Neuren retreated 7.4 percent; Avita, Cynata and Impedimed fell more than four percent; CSL, Medical Developments and Opthea were down three percent or more; Factor Therapeutics shed two percent; Telix was down 1.1 percent; with Mesoblast and Sirtex down by less than one percent.

## DR BOREHAM'S CRUCIBLE: BOTANIX PHARMACEUTICALS

**By TIM BOREHAM**

**ASX code:** BOT

**Share price:** 9.7 cents; **Shares on issue:** 757,424,658; **Market cap:** \$73.5 million

**Chief executive officer:** Matt Callahan

**Board:** Graham Griffiths (chairman), Matt Callahan, Dr William Bosch, Robert Towner

**Financials (year to June 30, 2018):** revenue (continuing operations) \$233,710, other income \$1.63 million, loss of \$11.01 million, cash balance \$17.23 million\*, expected current quarter outflows \$4.33 million

\* The company raised \$23 million in two placements, in February and June 2018

**Major identifiable holders:** Caperi Fund (Gayle McGarry) 9.3%, Shenasaby Investments (Catherine Callahan, Elise Horgan) 9.3%, Dr Henry William Bosch circa 2%.

Are investors who have weighed into the ASX-listed medical (or quasi-medical) pot plays a pack of dopes?

After all, the world's most powerful medical regulator has made his views crystal clear on the medical cannabis caper, warning that the only dinky-di route to market is via properly structured clinical trials.

"Advancing sound development programs that properly evaluate active ingredients contained in medical marijuana can lead to important medical therapies," intoned US Food and Drug Administration commissioner Dr Scott Gottlieb, MD.

"Controlled clinical trials, along with careful review through the FDA's drug approval process are the most appropriate way to bring marijuana-derived treatments to patients."

Dr Gottlieb also warned the regulator would take action when it sees "illegal marketing of CBD [cannabidiol] products with unproven medical claims."

The good doc was commenting after the FDA green-lighted the epilepsy drug Epidiolex, the first cannabis treatment to be approved by the regulator.

### **Botanix's zit-busting quest**

Both the approval of Epidiolex and Dr Gottlieb's firm stance are music to the ears of Botanix, which is one of the few ASX listed pot stocks to have a kosher clinical program for its two synthetic marijuana-based compounds.

In fact, Botanix highlighted Dr Gottlieb's words in its own material.

Botanix is working on topical treatments for skin conditions such as acne, psoriasis and atopic dermatitis (severe eczema).

The dreaded zits are a key target, given that 250 million people globally and 50 million Americans (mainly teenagers) are blighted by acne.

Botanix also has an exclusive licence to a device called Permetrex, a dermal delivery device allowing 10 to 20 times more of the active ingredient to get through the skin.

Cannabis has been crushed and used on the skin for thousands of years. “We know it works, but not why,” says Botanix chief executive officer Matt Callahan.

One barrier to understanding is that as only humans get acne, animal models aren't available.

Mr Callahan says cannabis has three mechanisms of action: it stops the sebaceous oils, reduces inflammation and kills bacteria. Interestingly, Botanix's material does not refer to the 'c' cannabis word but a “synthetic form of a widely-studied natural compound”.

As Mr Callahan argues, aspirin (acetylsalicylic acid, if you really need to know) derives from the bark of a willow tree but no-one calls it a tree drug.

“The cannabis plant is the inspiration. We are just using a chemical that happens to be found in the plant.”

Having said that, this column is the second of our three-part series on so-called 'pot stocks', so sorry about that, bud.

### **From old Bone to new hound on the block**

Botanix listed in July 2016 in a back-door raising using the shelf of Perth-based biotech Bone Medical. The company raised \$3.5 million at two cents apiece in the process.

Headquartered in Perth but based in Philadelphia, Botanix was founded by parties including Mr Callahan, Caperi (a financial investor) and scientist Dr Bill Bosch.

The short and the long of Bone was that it was established by Dr Roger New's Oxford UK-based Proxima to develop Caphymone for osteoporosis and BN006 for rheumatoid arthritis, licenced from Proxima. The trials showed the drugs didn't work, Bone went into a spiral dive with a La Jolla Cove facility paying fees to Proxima. Cornerstone's Robert Towner replaced chairman Dr New and went looking for something to backdoor and voila ! – a listing without a technology for a technology without a listing.

### **Very cute**

Mr Callahan is founding CEO of Iceutica Inc and Churchill Pharma, having co-invented Iceutica's drug delivery platform. Iceutica was due to list in 2011, but instead the backers sold the company for two times the expected listing value.

“It’s the most successful company no-one has ever heard of,” he says.

A lawyer, Mr Callahan has also been involved with two venture capital firms and is a director of Orthocell. Botanix chairman Graham Griffiths headed a listed Perth-based outfit called Ipernica, which initially focused on intellectual property but spawned a successful listed aerial mapping offshoot called Nearmap.

The Permetrex technology was developed by a dude called Dr Eugene Cooper, who has licenced its use to Botanix. Dr Cooper also developed another drug delivery mechanism, Nano Crystal, which is used in six FDA approved products.

### **News from the clinic**

In January, Botanix finished its initial trial of BTX1503 for acne. In June it recruited the first of 360 patients for a phase II trial to be completed by mid-2019.

The enrolled patients will have moderate to severe acne and will be treated for 12 weeks at dermatological clinics here and in the US.

Botanix also finished a phase Ib study for atopic dermatitis in June and is preparing for a phase II trial. A further phase Ib study for BTX1308 targeting psoriasis is due to start this month.

In the case of the phase I pimple trial, Botanix earlier this year reported that of the 21 subjects with moderate to severe acne, 18 completed the program.

On average, inflammatory lesions (papules and pustules, if you really want to know) declined by an average 47 percent after 28 days of treatment.

This compares with reductions of 42 percent and 38 per cent respectively for the two leading existing acne treatments: Allergan’s Epiduo and Aczone’s Galderma.

### **Financials and performance**

Botanix is nicely cashed up after raising \$23 million in two placements, both at 11 cents apiece. Both were oversubscribed.

The phase II studies are costed at \$6 million to \$8 million (each or combined) and are described by management as fully-funded.

With \$17 million in the bank and a \$3.5 million Federal R&D Tax Incentive in the offing, there’s more than enough of the other green stuff to cover the earlier-stage work !!!stuff and management has no plans to raise more.

Botanix shares peaked at 18.5 cents on May 31, having troughed at 4.3 cents on October 4 last year.

## **Dr Boreham's diagnosis:**

Mr Callahan says the acne market globally is worth \$US5 billion and dermatitis is worth \$US7 billion.

"What's interesting about these markets is there has been little innovation over the last 20 years," he says. "With acne, there has been no new approved drug for over 20 years."

An approved drug called Accutane (or Roaccutane) is the only one to reduce sebaceous oil levels, the underlying cause of acne.

But the drug's side effects include lymphoma, birth defects and suicide risks, which makes putting up with a blemished visage that little more acceptable. It's no wonder the generic versions, which remain on market after Roche pulled its branded product, bear a stern FDA 'black box' warning.

Atopic dermatitis is usually treated with steroids, but in the case of children there's the risk of stunting growth with prolonged use.

"Our goal is to develop a product with significant efficacy but without the baggage of many of the products in the market," Mr Callahan says.

He says Botanix could have gone the over-the-counter route, competing with non-approved CBD creams that sell for \$US50 to \$US100 a tube.

But by gaining Dr Gottlieb's seal of approval, Botanix is more likely to be able to sell its unguents for \$US2,000 to \$US5,000 a tube in the US market (if reimbursable).

GW Pharma, the owner of Epidiolex, last month revealed the cost of the drug would be around \$US32,500 a year.

Mr Callahan is heartened that big pharma Pfizer in 2016 bought Anacor - which was in phase III dermatitis trials - for \$US5 billion.

Botanix's serious clinical approach means a slower and costlier path to market than, say, developing an over-the-counter zit treatment.

But the eventual returns are higher as well.

Given that, Botanix's \$75 million market cap - modest for the pot sector, which of course Botanix isn't a part - means the company looks a decent punt.

Other pot stocks having pot shots at skin disorders are the Europe-based MGC Pharmaceuticals (MXC) and Zeldia Therapeutics (ZLD), which is carrying out Chilean based eczema trials.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Happily, teenage pimples only caused him a spot of bother.***

## [STANDARD & POORS, CLINUVEL PHARMACEUTICALS, IMPEDIMED, POLYNOVO](#)

The Standard & Poor's Dow Jones Indices says its quarterly rebalance has promoted Clinuvel and Polynovo into the S&P ASX300 and demoted Impedimed.

Standard & Poor's previously told Biotech Daily that the inclusions reflect market capitalization, meaning that Clinuvel and Polynovo were two of the 300 largest companies listed on the ASX (BD: March 10, 2017).

Standard & Poor's said the changes would be effective from September 24, 2018.

No other biotechnology companies were affected by the rebalance, which included the ASX100 and ASX200 and the ASX All Australian 50 indices.

## [OSPREY MEDICAL](#)

Osprey says it has hired consultancy Device Access UK to help sell its Dyevert Plus cardiac dye reduction system to the UK's National Health Service.

Osprey said the Southampton, UK-based Device Access would begin market access activities and seek "ultimate guidance recommendation" with the National Institute for Health and Care Excellence (NICE), which provided guidance to the UK's National Health Service (NHS) and hospitals on the adoption of medical technology and reimbursement. The company said it expected the NICE recommendation process to take about 12 months, and if successful, UK hospitals would receive payment for coronary angiographic procedures using kidney protection protocols with the Dyevert contrast reduction system. Device Access president Michael Branagan-Harris said that Osprey's Dyevert Plus had "proven results in the US market".

"Given the high rate of acute kidney injury and clinical interest in finding a solution to this problem within the NHS, it makes strategic and economic sense that the Dyevert Plus system is supported by the NHS and is fully adopted and implemented in the routine care of NHS [chronic kidney disease] patients undergoing endo-vascular heart procedures," Mr Branagan-Harris said.

Osprey said the North Yorkshire, UK-based Cardiologic would be its UK distributor.

Osprey chief executive officer Mike McCormick said that acute kidney injury (AKI) which could be caused by contrast dye use in heart imaging, cost the UK hospital system GBP1.02 billion (\$A1.84 billion) a year, about one percent of the NHS annual budget.

"This alone shows that if the Dyevert Plus system were introduced to the UK ... to impact AKI rates, it will have substantial health and economic benefits," Mr McCormick said.

Osprey was up half a cent or 2.4 percent to 21.5 cents.

## [SIRTEX MEDICAL](#)

Sirtex says it has received the \$1.7 billion balance of scheme consideration from CDH Genetech and China Grand Pharmaceuticals.

In June, Sirtex said it had terminated a proposed \$1.56 billion acquisition by the Palo Alto, California-based Varian Medical Systems and had agreed to the \$1.87 billion proposal from China's CDH Genetech and China Grand Pharmaceuticals (BD: Jun 15, 2018).

Today, the company said that if the proposed scheme of arrangement was approved and implemented, the funds would be used to pay the scheme consideration to Sirtex shareholders, and that if the scheme did not proceed due to certain other events outlined in the deed Sirtex would be entitled to retain \$200 million.

Sirtex fell four cents or 0.1 percent to \$32.80 with 484,351 shares traded.

### MICRO-X

Micro-X says it will receive \$2.4 million from the Australian Government's Department of Industry, Innovation and Science's advanced manufacturing growth fund grant.

Micro-X said the \$47.5 million advanced manufacturing growth fund was designed to encourage innovation, skills and employment in advanced manufacturing in Australia, with applications for funding capped at \$2.5 million for each project.

The company said the grant would support its investment in plant and equipment for a new manufacturing site in Adelaide's Tonsley innovation district, which was adjacent to its existing manufacturing capability.

Micro-X said the new site would improve supply stability, quality, productivity and lower cost of production through improved in-house manufacturing operations.

Micro-X was up half a cent or 1.5 percent to 34.5 cents.

### RESPIRI (FORMERLY KARMELSONIX, ISONEA)

Respiri says the Sydney-based SRX Global will manufacture its new breath and asthma wheeze detection sensor.

Respiri said SRX would begin manufacturing at its Dandenong, Victoria facility, before an anticipated move to a low-cost facility in Johor Bahru, Malaysia once designs for the new sensor were ready and volume production increased.

The company said the Melbourne-based Grey Innovation and Two Bulls were responsible for designing the hardware and user interface respectively and that Grey was finalizing the manufacturing package with 130 verification units for study, user testing.

The company said the new sensor included finger grips and a second microphone for noise cancellation and it was developing Google and Apple smartphone applications.

Respiri, and previously Isonea and Karmelsonix, has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006).

In 2015, the then Isonea said it had lost its fourth chief executive officer in 12 months and later said one of the issues with its asthma diagnostic was that it did not detect breath sounds (BD: Jan 23, Aug 6, 2015).

Last year, the company hired Grey Innovation to produce the "next generation breath sensor with a new creative design and superior ergonomics" (BD: Sep 12, 2017).

Respiri climbed 1.8 cents or 23.4 percent to 9.5 cents with 2.2 million shares traded.

### PHYLOGICA

Phylogica has requested a trading halt pending an "announcement to the market regarding a proposed capital raising transaction".

Trading will resume on September 11, 2018 or on an earlier announcement.

Phylogica last traded at three cents.

### RESONANCE HEALTH

Resonance director Simon Panton says he has increased his substantial holding in the company from 71,275,743 (17.71%) to 72,546,350 (18.02%).

The Perth-based Mr Panton said that through Southam Investments 2003 he bought

1,270,607 shares on market on September 6, 2018 for \$31,765.18, or 2.5 cents a share

The substantial shareholder notice said that the Design Council was a co-holder.

Resonance was unchanged at 2.5 cents.

## OVENTUS MEDICAL

Oventus says chief executive officer Dr Chris Hart will receive a \$400,000 base salary and chief technical officer Neil Anderson will receive a \$225,000 base salary.

Earlier this week, Biotech Daily reported that Dr Hart had replaced Mr Anderson as chief executive officer, with Mr Anderson continuing as the company's chief technology officer and both continuing as executive directors (BD: Sep 5, 2018).

Today, Oventus formally announced the change and said that Dr Hart would receive a \$400,000 base salary not including superannuation with an annual bonus of up to 30 percent of salary, pending performance hurdles, with Mr Anderson receiving a \$225,000 base salary not including superannuation, with up to 20 percent of salary as a bonus. Oventus fell three cents or 11.1 percent to 24 cents.

## AUSBIOTECH

Ausbiotech says its 2018 Biotech Invest event will be in Melbourne on October 30, followed by its national conference in Brisbane from October 31 to November 2.

Ausbiotech said the Biotech Invest and partnering seminar provided investment-seeking companies an opportunity to present to, and meet with, the investment community.

The industry organization said that the up to 40 companies would present at the event to an expected 350 investors, including representatives from major global pharmaceutical companies.

Ausbiotech said that delegates would be able to use the online Bioinvest Partnering System to plan meetings.

The organization said that last year's national conference had more than 980 delegates from 18 countries attend.

Ausbiotech said that this year's conference would feature an inaugural "early stage investment event".

Ausbiotech chief executive officer Lorraine Chiroiu said the organization was "excited to bring together world-leading biotech innovators together with Australia's investment community to fund the future of life sciences".

"This year we are helping to service new areas of the pipeline and will be hearing pitches from a wide range of pioneering companies," Ms Chiroiu said.

"At the National Conference we will hear from those at the beginning of their funding journey and at the Australia Biotech Invest and Partnering we will meet those who are further down the path to success," Ms Chiroiu said

Ausbiotech said that keynote speakers included CSL chief medical officer Dr Charmaine Gittleton, Walter and Eliza Hall Institute director, Prof Doug Hilton; Pfizer, head of oncology external science and innovation Dr Denis Patrick and Endpoints editor in chief John Carroll.

The organization said the conference would host trade exhibitions, networking events and a partnering platform for delegates to facilitating collaboration and partnership opportunities with other attendees.

For more information and to register go to [www.ausbiotechinvestment.com.au](http://www.ausbiotechinvestment.com.au) and [www.ausbiotechnc.org](http://www.ausbiotechnc.org) or contact [events@ausbiotech.org](mailto:events@ausbiotech.org).