



# Biotech Daily

Friday November 15, 2019

*Daily news on ASX-listed biotechnology companies*

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- \* **RESPIRI: SMEDLEY CHAIR, BLAIR-HOLT OUT; BOARD SPILL WITHDRAWN**

## MARKET REPORT

The Australian stock market was up 0.87 percent on Friday November 15, 2019, with the ASX200 up 58.6 points to 6,793.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and one was untraded.

Oncosil was the best, up three cents or 20 percent to 18 cents with 13.0 million shares traded. LBT climbed 12.9 percent; Cynata, Impedimed, Imugene and Osprey improved more than seven percent; Amplia, Paradigm and Volpara were up five percent or more; Alterity was up 4.35 percent; Clinuvel, Genetic Signatures, Patrys and Pro Medicus rose more than two percent; CSL and Mesoblast were up more than one percent; with Cochlear, Next Science and Polynovo up by less than one percent.

Proteomics led the falls, down 1.5 cents or 4.35 percent to 33 cents, with 168,391 shares traded. Opthea fell four percent; Pharmaxis, Prescient and Universal Biosensors shed more than two percent; Compumedics, Medical Developments, Neuren and Starpharma were down more than one percent; with Avita, Cyclopharm, Ellex, Nanosonics and Resmed down by less than one percent.

## [DR BOREHAM'S CRUCIBLE: USCOM](#)

**By TIM BOREHAM**

**ASX code:** UCM

**Market cap:** \$17.8 million

**Share price:** 12.5 cents

**Shares on issue:** 142,436,287

**Executive chairman:** Prof Rob Phillips

**Board:** Prof Phillips, Brett Crowley, Christian Bernecker

**Financials (September quarter 2019):** customer receipts \$727,101 (up 128%), loss of \$469,724 (previously \$700,064 deficit), cash of \$1,828,237 (up 3.5%), estimated current quarter outflows \$1,325,000

**Key identifiable shareholders:** Prof Phillips 19%, Smart Top (Xianhui Stephen Meng) 19%, Gary Davey 4.6%, John Gleeson 4.99%, Jetan (Greg Plummer) 5.4%.

We hate to sound like an old school report, but it's been a year of steady and solid progress for the maker of non-invasive cardiac and pulmonary measuring devices, especially in its key target market of China.

Achievements include record revenues and increased sales for Uscom's existing product suite, "despite an increasingly difficult and unpredictable international commercial environment".

Uscom also expanded its reach, notably in China where it has two products approved (one of them re-approved), with seven more applications lodged.

Uscom has established a Chinese subsidiary, expanded its manufacturing facility in Budapest, created a European sales hub and cheerfully participated in all school activities (sorry).

"Our products address diseases responsible for 75 percent of the world's mortalities: heart failure, sepsis, hypertension, asthma and [chronic obstructive pulmonary disease]," Prof Phillips says.

"This is stuff that the world spends billions on."

But there's one key aspect in which Uscom misses an A-plus - the share price. While Uscom's sales have grown at a 30 percent compound rate, the shares have drifted by 15 percent or more over the last year and the company is now valued at a mere \$18 million.

Prof Phillips is philosophical.

“Australians don’t get biotech as they do mining,” he says.

“I’ve always joked that if I put a shovel and pick across our logo and said we were digging for lithium and we would be a \$1 billion company.”

(Actually, the lithium price has tanked, but we take your point Rob).

We’ll put the share malaise down to the disruptive ratbag investors in the back row.

### **Just to recap**

Uscom (as in Ultra-Sonic Cardiac Output Monitors) listed in December 2003 after being founded by Prof Phillips, ultrasound specialist and University of Queensland professor of medicine.

The best thing to come out of Coffs Harbour since Ladyfinger bananas, Prof Phillips saw a better way of measuring blood flows in and around the heart than a highly invasive pulmonary artery catheter.

“Blood pressure measurement techniques have almost always got it wrong because they measure the wrong things using the wrong devices,” Prof Phillips says. “It’s about the circulation - and blood pressure is only a part of that.”

“Furthermore, blood pressure in the arm is less accurate and predictive than pressure at the heart, which we measure [with the company’s BP+ product].”

Uscom currently has three approved products (and several iterations of these devices).

The lead product, Uscom 1A, is a cardiac output monitor for sepsis, fluid, heart failure, hypertension and pre-eclampsia, or hypertension in pregnancy.

BP+, a central blood pressure monitor, was owned by New Zealand’s Pulsecore, and bought by Uscom in 2013.

Acquired via the purchase of the Budapest based Thor Laboratories in 2015, Spirosonic is an ultrasonic spirometer for asthma and chronic obstructive pulmonary disease.

All three are approved in Europe (Conformité Européenne, or CE mark) and by the Australian Therapeutics Goods Administration, while Uscom 1A is also approved by China’s National Medical Products Administration and cleared in the US (as a 510K device) by the Food and Drug Administration.

BP+ and Spirosonic are subject to FDA submissions. In China, BP+ has been pre-approved while Spirosonic awaits final testing.

## **Sweet new product suite**

Uscom is developing Spirosonic Air, a wireless home testing device for asthma and chronic obstructive pulmonary disease. This one is still undergoing European certification.

In late August, the company said it had won CE Mark approval for three Spirosonic iterations: Flo, Smart and Mobile. Technically they were re-approvals, because the relocation of manufacturing to Budapest required a fresh application.

This process also interrupted manufacturing (and sales) for three months.

Prof Phillips notes the CE Mark imprimatur allows the company to sell into most South East Asian countries as well as Middle Eastern markets.

“We have a number of partners keen to advance sales in these jurisdictions who have been waiting on the CE approvals,” he says.

Despite Uscom specializing in non-invasive technologies, Prof Phillips says the approval processes have become more complex and time consuming.

## **On board the slow boat to China**

Unusually for a biotech, more than half of Uscom’s revenues are already gleaned from China, where the company has created a Beijing subsidiary.

Hanging out the shingle wasn’t just a matter of renting an office and some pot plants, with 13 regulatory steps along the way. It also took more than a decade’s work.

“The secret is process and patience and relationships,” Prof Phillips says. “You need to be prepared to take time with those relationships.”

While China is a notoriously difficult market, Prof Phillips says the country has a more stable and growing health system than the US, where of course Uscom also operates.

“In China there are a lot of things that could go wrong but you have stable fixed objectives and goals,” he says. “They have a long-term plan, not a day-to-day plan.”

Uscom’s Chinese push was driven by its recently appointed director of China operations, Teresa Guo, a master of pharmacy from University College London.

“She prepared and guided all of our approvals and operations, and set up a new distribution system and arranged partners,” Prof Phillips says.

Notably, the company has restructured and expanded from 10 Chinese distributors to nearly 40, allowing a “more direct pathway” to 10,000 hospitals.

“We will control our entire product delivery pathway,” Prof Phillips says. “We are doubling our margin and doubling our number of distributors.”

“Previously we had to sell to a master distributor, who sold to a distributor, then a sub distributor who then sold to a sub sub distributor. Now we have our own system.”

“This approach should more than double our margin and it should more than double our volume.”

While Uscom sells mainly to hospitals, it is also targeting the Chinese home market with products such as BP-plus and Spirosonic.

The company is also eyeing acquisitions in related fields. “There’s a company we are looking at the moment,” Prof Phillips says. “It’s very inexpensive and has very good technology. Technically they’re great and will fit our new distribution nicely.”

Uscom’s equal biggest shareholder Stephen Meng is also a key weapon in opening doors in China, having been a founder and marketing director for the \$10 billion Beijing-based, Hong Kong-listed Sihuan Pharma.

### **Tackling the western world markets**

Prof Phillips notes that China spends about five percent of its GDP in health, but Beijing wants to get this proportion to 12 percent “because that is the metric of an advanced economy.”

The US in contrast spends 18 percent of its national income on health - but is striving to reduce this to 12 percent.

While highly controlled and protected, the US remains an attractive market to Uscom, if only because of its sheer size.

Prof Phillips expects the FDA to approve both BP+ and Spirosonics.

He describes Europe as a “big blancmange”, with different regulatory settings in every jurisdiction. “You do your best there and get what you can out of it, but we are starting to grow that too.”

### **Finances and performance**

Uscom boosted sales by 29 percent in the 2018-'19 year, to \$2.84 million. In the September quarter it generated customer receipts of \$727,101, up 128 percent and reported a \$469,724 deficit.

While losses are narrowing, management warns operating costs are likely to remain high as global regulatory and marketing initiatives are finalized.

As of September, Uscom had \$1.83 million of cash after a placement that raised \$1.05 million at 10 cents a share.

The takers? Prof Phillips put up his hand for 3,000,000 shares (\$300,000), while Uscom China boss Ms Guo said “shi” to 4,000,000 (\$400,000) of scrip.

Major shareholder Meng Xianhui has been invited to subscribe for 3,500,000 shares (\$350,000).

Post raising, both Prof Phillips and Mr Meng have emerged with about 20 percent of the company.

Over the last 12 months Uscom shares have traded between 18 cents (late March 2019) and 9.5 cents (late August 2018). A decade ago, the shares peaked at 80 cents.

### **Dr Boreham’s diagnosis:**

With established sales and a promising route to China, Uscom is a clear candidate for dux of the class (specialist medical device stream).

The company’s digital offerings are especially suited to the electronic health sector, which is now being vigorously pursued by the likes of Google, Microsoft, Apple and -speaking of China - Tencent and Huawei.

But as the good professor notes, global conditions are choppy at the moment and this one needs time. The company doesn’t exactly have the field to itself, either: Uscom 1A competes with about 11 other products, four of them non-invasive.

Prof Phillips argues the company could make itself profitable now by shelving its growth plans, but he is striving for earnings of perhaps \$40 million rather than, say, \$4 million.

“Because we have high margin products, profitability will come quite quickly,” he says.

“We don’t need to spend any more. We have acquired companies, built offices and established international manufacturing. All of our stuff is done. Our costs should diminish and our revenue should grow.”

Uscom’s lowly market cap makes for an intriguing comparison with the ASX-listed Respiri (formerly Isonex and Karmelsonix) which is seeking European approval for its ‘Wheezo’ asthma device.

The last time we looked, the pre-revenue Respiri was valued at \$36 million and a few months ago was worth close to \$100 million, despite almost continuous board and management changes.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But all his vital signs are tickety-boo and not so wheezy.***

## RESEARCH AUSTRALIA, GLAXOSMITHKLINE

Research Australia says Burnet Institute director Prof Brendan Crabb has won the \$80,000 Glaxosmithkline award for research excellence for his work on malaria.

Media releases from Glaxosmithkline and Research Australia said that Prof Crabb won the top award at last night's presentation in Melbourne.

Glaxosmithkline said that Prof Crabb "won the award for his research to better understand the DNA of the malaria parasite".

"His work has transformed how scientists explore malaria prevention and treatments globally," Glaxosmithkline said.

The company said Prof Crabb was involved in DNA transfection of the malaria parasite, enabling scientists to manipulate the genome of the malaria parasite and discover which mutations were responsible for drug resistance and what could be targeted by medicines and vaccines.

Glaxosmithkline said that malaria was one of the leading causes of death and disease and was responsible for more than 430,000 deaths in 2017, with 1,200 children dying every day from the disease.

Research Australia said that Murdoch Children's Research Institute director Prof Kathryn North won its "flagship award" the Peter Wills medal, "recognizing her outstanding leadership in genomic medicine".

The organization said Prof North had "a key role in integrating genetic testing and diagnosis into standard healthcare ... to shorten diagnosis times, enable early intervention, and provide access to treatment for people with genetic disorders".

Research Australia said University of Wollongong Prof Jeremy Micah Crook and his team won the inaugural frontiers research award for their work using electrical stimulation to produce advanced living human neural tissue, with potential applications for neurological disorders such as epilepsy, schizophrenia and Parkinson's disease.

The organization said the Walter and Eliza Hall Institute's Dr Christine Keenan won the Griffith University discovery award for epigenetics work suggesting an existing anti-cancer drug can switch-off and reverse the inflammation that caused asthma, potentially paving the way for the first targeted treatment addressing asthma's cause.

Research Australia said Pamela Galli won the great Australian philanthropy award, recognizing the Lorenzo and Pamela Galli Medical Research Trust.

The organization said that the University of Melbourne's Prof Gordon Lynch won the advocacy award for his 18-year commitment to the ABC's Overnights program, translating scientific and medical research into "clear messages that can transform people's health, inspiring millions of Australians to engage with research and recognize the importance of lifestyle factors in better long-term health".

Research Australia said the University of Adelaide's Prof John Lynch won the Bupa private health insurance data innovation award for developing the South Australian Early Childhood Data Project providing information for policy makers and agencies.

The organization said that University of South Australia Prof Libby Roughead won the Victorian Government Health Services Research Award for leadership in improving medicine use within our national health services

Research Australia chief executive officer Ms Nadia Levin said the calibre of the finalists "demonstrated the strength of Australia's research sector".

"Almost every day, Australian researchers uncover new insights that can change the way we treat or prevent disease," Ms Levin said.

"Through incredible dedication and skill, these amazing scientists are making an indelible mark on the journey of human progress, with tangible results for the health and wellbeing of us all," Ms Levin said.

### PALLA PHARMA

Palla says its two-for-five entitlement offer at 70 cents a share has raised \$10.1 million, taking the total raised in its underwritten \$31.1 million capital raise to \$30.7 million. Last month, Palla said the institutional placement raised \$8.4 million, the institutional rights offer raised \$12.2 million and it expected to raise a further \$10.1 million in its retail entitlement offer, in the underwritten \$31.1 million capital raise (BD: Oct 17, Oct 21, 2019). Palla said the shortfall shares would be allocated to Morgans Corporate and Shaw and Partners as the underwriters and lead managers to the offer. Palla was down 0.5 cents or 0.6 percent to 85 cents.

### PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has raised \$3.0 million in a “heavily oversubscribed” placement at 28 cents a share.

Proteomics said the issue price was a 13.9 percent discount to the 20-day volume weighted average price.

The company said the funds would be used to upgrade facilities, strengthen its balance sheet, advance the commercialization of its Promarkerd test for diabetic kidney disease, for analytical services and development of its intellectual property.

Proteomics said Alto Capital was lead manager and Adelaide Equity Partners was corporate advisor to the placement.

Proteomics fell 1.5 cents or 4.35 percent to 33 cents.

### ALLEGRA ORTHOPAEDICS

Allegra says it will start a trial of its biodegradable strontium-hardystonite-Gahnite (Sr-HT-Gahnite) spinal fusion cage for bone neck fusion in sheep.

Allegra said the US Food and Drug Administration-approved study would be conducted in Lyon, France in an undisclosed number of sheep, was a “significant milestone” and would assess safety, efficacy and performance of the device in sheep at three, six and 12 months to represent early, mid and long-term implantation, with the aim to demonstrate the load bearing capability of its Sr-HT-Gahnite spinal fusion cage.

Allegra said the sheep model was closely translatable to the human spine and it expected fusion to occur by six months, with full “degradation” expected from years four to five.

The company said the study would be undertaken by an Australian orthopaedic spinal surgeon, and if successful at six months would “lead to a small confirmatory human clinical trial in Australia, the final step before commercialization”.

Allegra was unchanged at 19 cents.

### PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica says its work with Genentech to find bacteria penetrating peptides to deliver an anti-microbial cargo was not successful and the collaboration has been “concluded”.

Phylogica said Genentech confirmed the ability of its bacterial penetrating peptides (BPP) to deliver a cargo across the target bacterial membrane, but the drug cargo Genentech wanted to deliver into the target bacteria “did not retain its anti-microbial efficacy after conjugation (joining) to the BPP, meaning that the collaboration has not progress further and has now concluded” (BD: Aug 18, 2014).

Phylogica fell 0.1 cents or 1.75 percent to 5.6 cents with 7.8 million shares traded.



## RESAPP HEALTH

Resapp says it will collaborate with Sanofi to build a smartphone application using its cough-based respiratory disease diagnostic algorithm to provide at-home support.

Resapp said it would allow Sanofi to use the outcomes generated from the Start-up Creosphere incubatory program under the exclusive licence.

The company said Sanofi would have the option to negotiate and acquire the rights to develop, manufacture and commercialize a respiratory disease self-assessment application specifically for consumers until March 7, 2020.

Resapp said Sanofi would have six months to negotiate licencing terms if it exercised the option.

Resapp was unchanged at 27 cents with 2.4 million shares traded.

## DORSAVI

Dorsavi says operational and staff cuts have reduced costs and the board expects to raise further capital by the end of the year, "subject to market conditions".

Dorsavi said it would explore alternative options to achieve a cash flow neutral position if a capital raising was unsuccessful and would continue to evaluate licencing and other product line acquisitions to increase the growth rate of its recurring revenue.

The company said it had reduced full-time equivalent staff by 25 percent and reduced chief executive officer Andrew Ronchi's salary from \$US221,500 (\$A325,937) to \$US201,500 (\$A296,507).

Dorsavi said it expected these changes to reduce cash expenses to \$5.4 million a year, a 30 percent reduction from \$7.7 million for 2019.

The company said it had cash and cash equivalents of \$1.66 million, estimated cash outflows for the quarter remained at \$1.58 million and an estimated \$600,000 in cash receipts from operations.

Dorsavi was untraded at 3.4 cents.

## OBJ

OBJ says the Australian Patent Office has issued it a patent for its Bodyguard microarray technology products for joints.

OBJ said the patent, titled 'Device and method to treat or prevent joint degeneration' would protect its intellectual property until June 10, 2035.

OBJ was untraded at 1.5 cents.

## ELIXINOL GLOBAL

Elixinol has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price fell 22 cents or 17.3 percent from \$1.275 on November 13 to \$1.055 on November 14, 2019 and noted a "significant increase" in the trading volume.

Elixinol said that on October 23 it announced non-compliance of its Japan subsidiary but was unable to confirm that the price change was related to this matter (BD: Oct 23, 2019).

Earlier this month, Biotech Daily reported that the 18 companies claiming to be medical marijuana companies fell 29.4 percent in October, down 42.3 percent from the July 31 high of \$1,913 million to \$1,103 million (BD: Nov 1, 2019).

Elixinol was up 6.5 cents or 6.4 percent to \$1.08 with 2.3 million shares traded.

## [NOVITA HEALTHCARE](#)

Novita has told the ASX it received a National Disability Insurance Agency email about Tali Health registration on November 11 and published it on November 12, 2019.

The ASX said the announcement, titled 'National Disability Insurance Scheme expands access to Tali' was released on its announcements platform at 10:43am on November 12, 2019 and asked the company if it would be information that a reasonable person would expect to have a material effect on the price or value of its securities and if so when it became aware of the information.

Novita said it believed the information would be material and managing director Glenn Smith first became aware of the information on November 11, 2019 through an email from the NDIS Commission.

The company said Mr Smith received the notice at 2.49pm (AEDT) in Perth, en route to the airport for a flight to Sydney and did not have time to log-in to the BDIS portal to confirm the information until he was in Sydney at 10.30pm that night.

Novita said that Mr Smith confirmed the information at 11.45pm on November 11 and distributed it to the board at 9.13am on November 12 and it was lodged with the ASX "within 90 minutes".

At the close on November 11, Novita fell 12.8 percent and a further 3.7 percent on November 12, 2019.

According to Commsec data, Novita has been heavily traded with a 40 percent rise on November 6, a 55.2 percent increase on November 1 and a 30.4 percent rise on October 30, with falls on all other trading days in November.

Novita was up 1.2 cents or 19.05 percent to 7.5 cents with 198.3 million shares traded.

## [HERAMED AUSTRALIA](#)

Heramed has requested a trading halt "pending a response to a follow up by the ASX on the price and volume query of November 14, 2019".

Yesterday, Heramed told the ASX a paid article typographical error may have pushed its price up as much as 51.7 percent to 22 cents (BD: Nov 14, 2019).

Trading will resume on November 19, 2019 or on an earlier announcement.

Heramed last traded at 21.5 cents.

## [TELIX PHARMACEUTICALS](#)

Elk River Holdings as trustee for the Behrenbruch family says its 24,675,000 share-holding has been diluted from 12.5 percent to 9.74 percent.

In a change of substantial holding signed by Telix co-founder and chief executive officer Dr Christian Behrenbruch, the Melbourne-based Elk River said it was diluted on August 22, 2019 following a \$40 million oversubscribed placement and \$5 million share plan at \$1.30 a share (BD: Jul 17, Aug 19, 2019).

Telix was unchanged at \$1.85.

## [TELIX PHARMACEUTICALS](#)

Gnosis Verwaltungsgesellschaft and Telix co-founder Andreas Kluge says their 24,675,000 share-holding in Telix has been diluted from 12.5 percent to 9.74 percent.

The Dresden-based Gnosis Verwaltungsgesellschaft said that it was diluted on August 22, 2019 following the \$40 million placement and oversubscribed \$5 million share plan at \$1.30 a share (BD: Jul 17, Aug 19, 2019).

## [PARADIGM BIOPHARMACEUTICALS](#)

Paradigm chief executive officer Paul Rennie says he has increased and been diluted from 23,414,935 shares (12.18%) to 23,612,290 shares (12.14%).

The West Beach, South Australia-based Mr Rennie said he acquired 197,355 shares on November 7, 2019 for \$578,250 or \$2.93 a share as part of an employee share plan. Paradigm was up 16 cents or 5.4 percent to \$3.14 with 945,677 shares traded.

## [ANTEOTECH \(FORMERLY ANTEO DIAGNOSTICS\)](#)

Anteotech says it has changed its name from Anteo Diagnostics to Anteotech.

Anteotech was up 0.3 cents or 20 percent to 1.8 cents with 9.35 million shares traded.

## [RESPIRI \(FORMERLY ISONEA, KARMELSONIX\)](#)

Respiri says Nicholas Smedley has replaced chairman Ross Blair-Holt and the request for a board spill meeting has been withdrawn.

Last month, Respiri said Mr Smedley was appointed as a director, company secretary Alastair Beard replaced former chief executive officer Mario Gattino as interim chief executive officer and Mr Gattino continued as a director (BD: Oct 30, 2019).

On the same day, the company said it had received a board spill meeting request from shareholders with more than five percent of the company to elect Mr Smedley and remove Mr Blair-Holt, Mr Gattino and any new directors (BD: Oct 30, 2019).

The request notice included eight holders with 39,667,573 Respiri shares (7.1%).

According to an 'Annual report updated to include shareholder information', gambling machine operator and major shareholder Bruce Mathieson and Investment Holdings held 72,008,027 shares (12.88%) at September 17, 2019 (BD: Nov 13, 2019).

Today, Respiri said Mr Smedley had been appointed as executive chairman, Mr Blair-Holt had resigned as a director and Alastair Beard would step down as interim chief executive officer, but continue as company secretary.

In October, Respiri said it had lost Mr Gattino as chief executive officer, who continued as a director (BD: Oct 9, 2019).

In 2018, the company said it had appointed Mark Ziirsens and Brendan Mason as directors, replacing Leon L'Huillier and John Ribot-de-Bresac, with Mr Ziirsens later appointed chairman (BD: Jun 14, 2018).

In October 2018, Respiri said it had appointed Dr Thomas Duthy as a director and in November, replaced Mr Ziirsens, Mr Mason and Dr Duthy with Mr Blair-Holt and Prof Bruce Thompson (BD: Oct 24, Nov 27, 2018).

Respiri 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 Isonesa lost its fourth chief executive officer in a year and later said one issue with the diagnostic was it did not detect breath sounds (BD: Jan 23, Aug 6, 2015).

The company changed its name to Respiri at the end of 2015 and in 2017 lost the services of its founding company secretary, the CFO Solution (BD: Oct 11, 2017).

Last year, Respiri said Mr Blair-Holt was a director and chief executive officer of all Bruce Mathieson private family companies and was previously a Respiri director from November 28, 2014 to October 26, 2016, replacing Mr Mathieson (BD Dec 1, 2014; Nov 27, 2018).

Respiri fell 0.4 cents or 4.6 percent to 8.3 cents.