Biotech Daily

Thursday January 25, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 19%; COMPUMEDICS DOWN 8%**

*** DR BOREHAM'S CRUCIBLE: ACTINOGEN MEDICAL**

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*** LIVING CELL SELLS ITS 50% JV SHARE TO OTSUKA FOR $3m**

*** AIRXPANDERS RECEIPTS UP 419% TO $3.5m**

*** MEDADVISOR H1 RECEIPTS UP 49% TO $3m**

*** GENETIC SIGNATURES H1 RECEIPTS UP 46% TO $1.5m**

*** REVA IMPLANTS 1st ITALIAN FANTOM PATIENT**

*** AURORA TAKES 23% OF CANN**

*** MGC MEDICAL MARIJUANA PLANT WINS INTERIM GMP CERTIFICATION**

*** COGSTATE JOINS GLOBAL ALZHEIMER'S PLATFORM RATER PROGRAM**

MARKET REPORT

The Australian stock market slipped 0.08 percent on Thursday January 25, 2018, with the ASX200 down 4.7 points to 6,050.0 points. Ten of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and one was untraded.

Uscom was the best, up four cents or 19.05 percent to 25 cents with 529,160 shares traded. Genetic Signatures climbed 10.3 percent; Starpharma was up 8.3 percent; Acrux and Oncosil were up more than three percent; LBT and Nanosonics rose more than two percent; Clinuvel and Osprey were up more than one percent; with Resmed and Volpara up by less than one percent.

Compumedics led the falls, down 3.5 cents or 7.5 percent to 43 cents with 35,888 shares traded. Airxpanders and Viralytics lost more than six percent; Universal Biosensors fell 5.1 percent; Benitec, Dimerix and Factor Therapeutics were down four percent or more; Admedus, Reva and Telix lost more than three percent; Actinogen, Medical Developments, Optiscan and Pro Medicus shed more than two percent; Avita, Bionomics, Impedimed, ITL, Mesoblast, Neuren, Orthocell and Pharmaxis were down more than one percent; with Cochlear, CSL and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: ACTINOGEN MEDICAL

By TIM BOREHAM

ASX code: ACW

Share price: 4.0 cents

Shares on issue: 747,193,558

Market cap: $29.9 million

Chief executive officer: Dr Bill Ketelbey

Board: Dr Geoff Brooke (chairman), Dr Jason Loveridge, Dr Ketelbey, Dr George Morstyn

Financials (September quarter): income nil, cash burn $1,590,000, cash on hand***** $2,404,000, estimated December quarter cash burn $1,739,000

Identifiable holders:** Edinburgh Technology Fund 6.77%, JK Nominees (Kim Hogan) 6.5%, Sari Warambi (Dr Loveridge) 3.5%, Sunset Capital 3.2%, Martin Rogers 3.2%, Ben Dark Holdings 2.5%

***** Boosted post-balance date by a $1.2 million R&D Tax Incentive and a $5.28 million share placement (pre-expenses)

****** As of 2017 annual report. Some holdings may have been diluted subsequent to the November share placement.

The sobering news about Alzheimer's disease is that while it's emerging as the world's number one killer disease, there is no drug that cures or alleviates the ailment.

That's not for wont of trying, either. The www.clinicaltrials.gov site lists 1810 Alzheimer's related trials. Of these, 336 are actively recruiting, 967 have been completed and 137 terminated (some with extreme prejudice).

The trials include a heroic but ultimately forgettable attempt to evaluate the therapeutic effect of coconut oil.

All up, the failure rate is 99.6 percent, with only between 10 to 27 percent of patients trial-eligible in the first place.

Joining the list of those seeking to crack a cure is Actinogen, which is carrying out the biggest Alzheimer's dementia study ever done by an Aussie biotech.

Actinogen chief Dr Bill Ketelbey was involved in developing Aricept, which remains the leading Alzheimer's treatment despite being developed 25 years ago.

Chairman Dr Geoff Brooke is well known as founder of venture capital firms Medvest Inc and GBS Venture Partners.

In December the company's petite board was bolstered with the inclusion of Dr George Morstyn, former chief medical officer at US pharma Amgen.

And for a company whose technology evolved from the Edinburgh University, what better time for us to visit Actinogen than on January 25?

For proud Scots, it's not Australia Day/Invasion Day Eve but Burns Day, the Scots' day of celebration of poet laureate and Auld Lang Sine creator Robert Burns.

Scary trends

Alzheimer's is already the leading cause of death for women in Australia and second overall behind heart disease.

Within five years Alzheimer's will be the leading cause of death, partly because of progress with preventing heart disease and killer cancers.

Globally there are 50 million people with Alzheimer's disease and the number is expected to double every 20 years.

Almost one-third of 85-year olds have the disease, although in the past we used to think gran and pop were just a bit senile.

"Everyone's now looking to novel approaches for treating the disease and that's where Actinogen comes to the fore," Dr Ketelbey says, adding that any developed drug is likely to be used in combination with existing drugs

Actinogen's approach

Actinogen's work revolves around the novel drug candidate Xanamem, which is designed to inhibit production of the naturally occurring stress hormone cortisol in the brain.

A growing screed of research links excessive cortisol with the development and progression of Alzheimer's.

Xanamem aims to negotiate the blood-brain barrier - something other drugs can't do properly - and thus deliver the active ingredient more effectively.

In short, Xanamem has the potential to modify the disease, which no other drug has managed.

“If we can demonstrate (that) in our trials, we have a world-beating product beyond a doubt,” Dr Ketelbey says.

(Like everything in biotech trials, note the use of the word “if”.)

Recruiting now

In May 2017, Actinogen started recruiting for its headline clinical trial, called Xanadu. This has nothing to do with one of Olivia Newton John’s forgettable recording efforts, Kublai Khan or even Orson Welles, but is a 174-patient phase II trial for mild Alzheimer’s sufferers.

Xanadu is constructed as a double-blinded, 12-week, randomized, placebo-controlled study. Previous animal models showed “significant cognitive improvement’ with Xanamem after 28 days.

The trial will enrol a total of 174 patients across the 20 research sites here and in the US and the UK. To date, 66 patients have been recruited and in early September the first patient completed a 12-week treatment, plus four-week follow up.

Top-line results are due in early 2019, which sounds like a long way away, but time will fly.

Management also expects the data safety monitoring board to review the first 50 patients by June, which is not too many sleeps away at all.

“The feedback from the data safety monitoring board will help shape current and future trials,” Dr Ketelbey says.

To gauge efficacy, patients will be subjected to a number of widely used cognitive tests, such as the mini mental state examination (MMSE) and the ADAS-Cog14.

For example, patients might be asked to remember three unrelated terms such as ‘apple’, ‘boat’ and ‘chair’. They are then guided to another topic and asked to recall the words a few minutes later.

Such measures aren’t exactly perfect, because on a bad day anyone could struggle to remember their chairs and their pears (or apples).

But given the absence of biomarkers - signals in the body to flag the presence of a disease - such tests will have to suffice.

Fully-funded

The Xanamem trial is fully-funded after the company raised $5.28 million in an oversubscribed placement in December.

At a general meeting last Thursday (Jan 18), shareholders voted ‘aye’ to the two-tranche placement, done at 4 cents (a then 22 percent discount) and accompanied by a one-for-two options issue exercisable at 6 cents a share.

Should Actinogen raise more moolah - and never say never - the company enjoys the support of a phalanx of local investors including Perth’s Forrest Capital, Sunset Capital and Tony Grist (Perth man about town and co-founder of Amcom Telecommunications).

Xanadu and beyond

Xanamem’s opportunities lie with diabetes-related cognitive impairment, post-traumatic stress disorder, Parkinson’s disease, epilepsy, schizophrenia and post myocardial infarction. All of these are related to elevated levels of the cortisol ‘stress hormone’.

The Uni of Edinburgh, Actinogen’s biggest holder, is interested in substantially funding diabetes and cognitive impairment trials, so never accuse Scots of being tight with their money.

It’s possible that Actinogen would go it alone on a lengthy phase III Alzheimer’s trial - a high-risk, high-reward route.

Dr Boreham’s diagnosis:

Dr Ketelbey reckons that, globally, a phase II Alzheimer’s triallist attracts an average market valuation of $US800 million.

Given Actinogen’s lowly $30 million market capitalization, he contends the company is undervalued. Then again, everyone thinks their own baby is cuter than the one in the crib next door.

Actinogen shares peaked at 15 cents in April 2015 and then made an assault on the nine cent level in April last year. Post-placement, the stock is now trading at 14-month lows.

Dr Ketelbey reckons the Xanadu trial is not a binary outcome because of Xanamem’s other potential applications.

Still, Alzheimer’s is clearly Actinogen’s main focus and last year’s demolition of Living Cell, Innate Therapeutics and Resapp shares show how unforgiving investors are in the wake of failed clinical trial results.

As we sit down to Burns Supper, let’s drink a cup of kindness to the boffins from Actinogen (and Edinburgh) as they strive to cure this cruel disorder.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is also wondering why he put his car keys in the fridge.

MEDLAB CLINICAL

Medlab says it has raised $24 million in a “heavily oversubscribed” placement at 90 cents a share to sophisticated and institutional investors in Australia and Asia.
Medlab said the placement was managed by Bell Potter Securities and was co-managed by APP Securities.
Medlab chief executive officer Sean Hall said the support for the placement had been “extremely pleasing and appreciated”.
Mr Hall said that the funds put the company in a strong financial position and allowed it to accelerate the commercialization of its cannabis-based Nanabis under the Government’s Special Access Scheme by up to 18 months.
Mr Hall said the funds would help Medlab “accelerate its research and development program of other areas in chronic disease, including obesity, diabetes and depression”.
Medlab was up 10.5 cents or 10.3 percent to $1.12 with 1.8 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it will sell its 50 percent holding in joint venture company, Diatranz Otsuka, to partner Otsuka Pharmaceutical Factory Inc for $3 million.
In 2011, the two companies formed the joint venture to further develop the Diabecell encapsulated pig-derived islets of Langerhans cells for type 1 diabetes, with Living Cell transferring $25 million of assets to the company and Otsuka depositing $25 million in cash (BD: Nov 2, 2011).
In 2012, Living Cell said a 14-patient phase I/IIa clinical trial showed that Diabecell reduced unaware hypoglycaemic events in type 1 diabetes, but the treaemtne was non-significant in HbA1c reduction (BD: Sep 26, 2012).
The company said at that time that a single implant of Diabecell at doses of 5,000 islet equivalents per kilogram of body weight (IEQ/kg), 10,000 IEQ/kg, 15,000 IEQ/kg and 20,000 IEQ/kg demonstrated that Diabecell was a safe and effective treatment
Today, Living Cell said that on completion of the sale, expected on January 31, 2018, it would exclusively licence Diabecell for Australia, Argentina and New Zealand when it was US Food and Drug Administration approved and supply product on favorable terms.
The company said that in October 2014 Diatranz Otsuka licenced Otsuka to use Diabecell in US and Japan, with Otsuka undertaking development product in the US.
“However, this is taking much longer than originally anticipated,” Living Cell said.
The company said that Diatranz Otsuka had an exclusive right to manufacture and market Diabecell in the rest of the world, but did not have the capacity to manufacture product and the price to purchase it from Otsuka had not been agreed, but Otsuka said it would support Diatranz Otsuka to meet its responsibilities under the Living Cell licence.
Living Cell said it was “not in a position to add value to [Diatranz Otsuka, so] it has decided to sell its shareholding and utilise the resulting funds to further develop its own product pipeline”.
Living Cell chief executive officer Dr Ken Taylor said that the extra funds were “projected to extend our cash runway out to approximately 2.5 years”.
“In that time, we believe NTCell and products in our pipeline, which include pericyte protective agents, can be funded to generate an exit position favorable to shareholders,” Dr Taylor said.
Dr Taylor said the right to market Diabecell in Australia, Argentina and New Zealand, where it had clinical connections and support would be of value when the product had received FDA approval.
Living Cell was up 0.1 cents or 3.6 percent to 2.9 cents with 3.1 million shares traded.

AIRXPANDERS

Airxpanders says that customer receipts for the year to December 31, 2017 was up 419.2 percent to US$2,845,000 (A$3,529,790) compared to previous corresponding period.
Airxpanders said it had cash and cash equivalents of US$22.6million at December 31, 2017 consisting of liquid US Treasury securities at December 31, 2017 compared to US$11,507,000 at December 31, 2016.
Airxpanders fell 4.5 cents or 6.5 percent to 65 cents.

MEDADVISOR

Medadvisor says that receipts from customers for the six months to December 31, 2017 was up 48.5 percent to $3,068,000 compared to previous corresponding period.
Medadvisor chief executive officer Robert Read said the quarter was “momentous … with the rolling out of our Plusone platform”.
Mr Read said “the $9.5m investment from [the Melbourne and Christchurch, New Zealand-based] Ebos provides additional capital to enable us to accelerate patient acquisition, extend into the hospital channel and to further support our international expansion activities” (BD: Oct 24, 2017).
Medadvisor was up 0.2 cents or 4.1 percent to 5.1 cents with 2.3 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says that receipts from customers for the three months to December 31, 2017 was $1,250,000.
Genetic Signatures said total receipts from customers for the six months to December 31, 2017 was up 46.4 percent to $1,492,000, compared to the previous corresponding period.
Genetic Signatures chief executive officer Dr John Melki said the company’s “consistent strong revenue growth is the direct result of our focus on strong product development and the commencement of our sales expansion strategy”.
Dr Melki said the company’s “US and EU teams continued to make headway into these major markets, with several new trials underway including the first paid trial for a pre-release stage product that has not yet completed commercial trials”.
Genetic Signatures was up three cents or 10.3 percent to 32 cents.

REVA MEDICAL

Reva says that its first Italian patient has been implanted with its Fantom bioresorbable scaffold for coronary artery disease at Fatebenefratelli Hospital in Milan.
In April 2017, Reva said the Fantom stent received Conformité Européenne (CE) mark approval with the first Swiss patient implanted in October (BD: Apr 4; Oct 16, 2017).
Reva fell 1.5 cents or three percent to 48 cents.

CANN GROUP

Aurora Cannabis Inc says it has increased its substantial shareholding in Cann from 28,762,314 shares (21.8%) to 31,956,347 shares (22.9%).
The Vancouver-based Aurora Cannabis said that on January 24, 2018 it bought 3,194,033 shares for $7,985,082 or $2.50 a share, the same price as the recent $78 million capital raising (BD: Nov 30, 2017, Jan 21, 2018).
Cann was up seven cents or 2.2 percent to $3.30.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has been granted interim good manufacturing practice certification for its European medicinal cannabis production facility.

MGC said the certification prepared it for production of the first batch of its Cannepil adult medical cannabis epilepsy product at the European production and compounding facility.

The company said that the first batch of Cannepil produced at the facility would undergo validation of manufacturing, analysis and, on meeting the required protocols, it expected the facility would be granted full certification.

MGC said that Cannepil targeted drug-resistant epilepsy, which accounted for about 30 percent of the estimated 240,000 people diagnosed with epilepsy in Australia each year.

MGC was up one cent or 9.5 percent to 11.5 cents with 29.8 million shares traded.

COGSTATE

Cogstate says it has been selected by the Global Alzheimer's Platform Foundation to support its rater training and certification program.

Cogstate said the program would qualify and train clinical trial staff to administer cognitive and functional assessments required for Alzheimer's disease studies.

The company said the program is intended to increase the quality and shorten the duration of Alzheimer's disease trials by up to two years.

Cogstate chief executive officer Brad O'Connor said the company was "proud to have been selected to support such a visionary organization as the GAP Foundation".

Mr O'Connor said the Foundation's selection of his company for the program was "further commercial validation of Cogstate's expertize and trials".

Cogstate was unchanged at 87 cents.