



Biotech Daily

Friday November 9, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: BIONOMICS UP 11%; AIRXPANDERS DOWN 11%**
- * **DR BOREHAM'S CRUCIBLE: ALLEGRA ORTHOPAEDICS**
- * **COCHLEAR, DENMARK'S GN GROUP EXPAND COLLABORATION**
- * **PROTEOMICS SHIPS 1st COMMERCIAL PROMARKERD KIDNEY TEST**
- * **IMUGENE RECEIVES \$1.85m FEDERAL R&D TAX INCENTIVE**
- * **BVF, MARK LAMPERT TAKE 18% OF OPTHEA**
- * **NZ HARBOUR ASSET MANAGEMENT BELOW 5% OF VOLPARA**

MARKET REPORT

The Australian stock market fell 0.11 percent on Friday November 9, 2018 with the ASX200 down 6.4 points to 5,921.8 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and five were untraded.

Bionomics was the best, up 1.5 cents or 10.7 percent to 15.5 cents, with 2.0 million shares traded.

Mesoblast climbed more than five percent on next week's news; Reva and Universal Biosensors improved more than four percent; Immutep and Oncosil rose more than two percent; Cochlear, Optiscan, Resmed and Starpharma were up more than one percent; with Nanosonics, Neuren and Opthea up by less than one percent.

Airxpanders led the falls, down 0.4 cents or 10.0 percent to 3.6 cents, with 2.1 million shares traded.

Osprey lost 6.45 percent; Avita and Paradigm fell four percent or more; Prescient was down 3.3 percent; Actinogen, Compumedics, Ellex, LBT, Medical Developments, Orthocell and Pro Medicus shed more than two percent; Clinuvel, Pharmaxis and Telix were down more than one percent; with CSL, Cynata, Genetic Signatures and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: ALLEGRA ORTHOPAEDICS

By TIM BOREHAM

ASX code: AMT

Share price: 21 cents; **Shares on issue:** 99,559,052; **Market cap:** \$20.9 million

Chief executive officer: Jenny Swain

Board: Peter Kazacos (chairman), Dr Nicholas Hartnell, Anthony Hartnell, Sean Mulhearn

Financials (year to June 30 2018): revenue \$4.7 million (down 5.1%), net loss after tax \$604,144 (previously \$501,048 profit), cash of \$1.6 million (down 12,6%).

Identifiable holders: Robinwood Investments (Dr Nicholas Hartnell) 39.66%, Netwealth Investments 9.2%, Welsh Super Pty Ltd (Peter Welsh) 7.15%, Andrew and Skye Leicester 5.65%, Marie and Dawson Carroll 5.66%, Cryptych Pty Ltd (Dr Greg Roger) 5.02%. (CLJE Investments reported a 10.1% holding in 2017, but is not listed in the annual report.)

If Allegra has its way, one of Australia's premier faunal symbols will be hopping into service to restore the stride of millions of patients with ligament and tendon issues.

In a deal announced in August, Allegra and its two collaboration partners won Innovative Manufacturing Cooperative Research Centre funding of \$2.4 million to develop kangaroo-derived ligaments to address the growing demand for reconstructive ligament material.

As anyone who has grappled with a big red would attest, 'roo tendon is three times stronger than the human variety.

Allegra hopes this xenograft material will redefine ligament construction, providing a unique solution for orthopaedic surgeons to treat ligament injuries.

"This project could have the ability to disrupt the billion-dollar orthopaedic ligament repair market with new and uniquely Australian bone and ligament material," the company says.

Indeed - one does not get more uniquely Australian than the bounding macropods. The company adds it is "several years away from bringing a product to market."

About Allegra

Then known as Advanced Surgical Design and Manufacture, Allegra listed in late November 2007, a debut uncannily matching the Australian stock market's historical peak and the onset of the global financial crisis.

At the time, the company's main product was its Active Knee cement-free total knee replacement system made out of metal and polyethylene, with a cruciate retaining design. It continues to be so.

Allegra was founded in 1994 by Sydney physician Dr Greg Roger, based on a collaboration with Dr Mervyn Cross. Dr Roger was a founding director and chief executive officer, but resigned these positions in March 2012 and continues as a major shareholder.

The company initially had manufacturing operations in Wollongong, but in 2003 relocated to its current digs in St Leonards, Sydney.

Later the company was backed by New South Wales orthopaedic surgeon Dr Nicholas Hartnell who is on the board and accounts for 38 percent of the company. Touchingly his old man Tony is also on the board. Lawyer Tony has a claim to fame of his own, having been inaugural head of the Australian Securities Commission (now the Australian Securities and Investments Commission).

Tech whiz Peter Kazacos has been chairman since the company listed. Mr Kazacos is famed for founding the dot-com era Kaz Computing and then selling it to Telstra for \$330 million in 2004 (in 2009, Fujitsu acquired the operation from Telstra for \$200 million).

Advanced Surgical changed its name to Allegra - Italian for joyful or lively - in late 2014.

Bounding ahead in the lab

For Allegra, the kanga tendons are another application for its bone substitute product in development, called Sr-HT-Gahnite. The novel additive is composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite, a zinc-aluminium-oxide.

A 3-D-printed biodegradable ceramic scaffold, Sr-HT-Gahnite has “outstanding potential for supporting bone regeneration in load bearing applications.” Allegra holds an exclusive licence from Sydney Uni to use the Sr-HT-Gahnite technology.

Allegra is divided into two divisions: innovation (as in the kangaroo tendons) and distribution of products including lower limb hip and knee replacements prosthetics (artificial material to replace a worn or damaged part of the body).

The company also distributes the associated blades, wires, pins and screws.

In a December 2017 deal, Allegra became exclusive local distributor for German international supplier Waldermar Link GmbH & Co to deliver its complete portfolio of medical devices in Australia. The three-year deal has an option to extend to five years.

Allegra is working to commercialize its latest product: an interbody cervical spinal cage using the Sr-HT-Gahnite bone substitute material and in April this year secured an MTP Connect grant of \$891,000 to support the venture.

Financials and performance

Earnings-wise, Allegra was a tale of two divisions in the 2017-'18 year with orthopaedics recording an earnings before interest, taxation, depreciation and amortization (Ebitda) of \$434,000 (previously \$633,000) but the innovation division losing \$681,000.

The orthopaedics performance was affected by the Federal Government's mandated reduction of benefits for prostheses paid by the private health insurers. A 7.5 percent cut was effective in February last year, with a further 3.0 percent reduction in March this year.

"These reductions directly impacted product sales and commission revenues for hip and knee implants plus other related products," the company intoned.

In late 2017, Allegra raised \$2.5 million in two separate private placements, both at 15 cents apiece.

In 2018-'19, the company will remain loss-making because the investment in the innovation division is expected to exceed the profits from the orthopaedic arm.

Still, investors are undeterred: Allegra shares in mid-September were trading around eight cents, but then bounded to current levels on not much news. We'll attribute the surge to the infectious animal spirits pervading the whole biotech sector.

Since listing Allegra shares have traded as high as 54 cents in late 2009 and as low as 4.7 cents in October 2015.

Dr Boreham's diagnosis:

Allegra can hardly be accused of using its ASX disclosures as a marketing tool, having issued a mere 10 notices to the bourse this year.

After last month's annual general meeting, the company disclosed the voting results - and not a single vote against any of the routine motions.

But the chairman's and CEO's soaring rhetoric was to be enjoyed only by those of the company's 389 shareholders who bothered to show up.

Attempts by Crucible to interview the company in a timely way were unsuccessful.

So is Allegra one of those shy, publicly-listed companies that's hiding its light under a bushel?

Allegra clicks over decent revenue - and in a good year, earnings - from the meat-and-potatoes distribution of existing products while chipping away at the innovative stuff.

The company doesn't go the market to raise funds every two seconds - which is a tick for us - although its end-of-year cash balance of \$1.6 million looks a tad sparse.

The company has been around for a fair while and the real interest lies in its ability to develop its own products.

If Skippy's the answer, management had better hop to it.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He may well have a 'roo loose in the top paddock.

COCHLEAR

Cochlear says it will expand its smart hearing alliance collaboration with Copenhagen's GN Group (originally Great Northern Telegraph).

Cochlear said that GN was "the global leader in intelligent audio solutions" and the alliance was established in 2015 to develop the most integrated, best-in-class hearing products, giving hearing aid and cochlear implant recipients access to the latest in connectivity and wireless technology, and allowing bimodal recipients to achieve seamless connectivity between a cochlear implant in one ear and a GN hearing aid in the other. The company said the relationship included joint research and development, shared technology and strengthened commercial collaboration with GN Group's hearing aid division GN Hearing and would "focus on fast-moving connectivity and wireless technology to allow for closer integration between Cochlear and GN Hearing technologies ... [and the two companies would] leverage research and development investment to jointly develop firmware and software technologies".

GN Hearing chief financial officer Marcus Desimoni said the strengthened alliance was "an important step forward for the millions of people around the world with disabling hearing loss, making the most advanced technology more accessible and simplifying the experience with more integrated solutions".

Cochlear chief executive officer Dig Howitt said the expanded collaboration would "bring the latest in connectivity and wireless technology to our implant recipients more quickly". "As two leaders in our areas of hearing health, this collaboration demonstrates our commitment to design and bring to market the best hearing solutions available," Mr Howitt said.

Cochlear climbed \$3.11 or 1.8 percent to \$176.13 with 178,548 shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says the first commercial batches of the new Promarkerd immunoassay kit will be shipped this month following the presentation of performance verification data.

Proteomics said the first batches of the diabetic kidney disease diagnostic would be shipped on November 20, 2018 following presentation at the Diabetes Technology meeting in North Bethesda, Maryland, November 8 to 10, 2018.

The company said it had completed production of the key antibody reagents in Puerto Rico and the manufacture of the kit in certified facilities in California, in partnership with licence partner Omics Global Solutions.

Proteomics said the kit would be used "to target new commercialization deals in Japan and India, opening the door to further commercialization discussions around the world".

The company said that its Promarkerd mass spectrometry laboratory developed test (LDT) had been licenced in the US, Mexico and Spain.

Proteomics said the test for predicting the onset of diabetic kidney disease was licenced to the Austin, Texas-based PHDX for launch in the US and was due to launch in Mexico and Spain in 2019.

Proteomics said that an abstract, titled 'Promarkerd: A Novel Test for Predicting Rapid Decline in Renal Function in Type 2 Diabetes' would be presented at the conference and the results "further validate the performance of Promarkerd and its power in predicting kidney decline, which is not possible with the existing diagnostic tests".

Proteomics managing-director Dr Richard Lipscombe said that Promarkerd "could save the US healthcare system up to \$US100 billion per year in direct costs associated with treating end-stage kidney disease".

Proteomics was up 4.5 cents or 16.1 percent to 32.5 cents with two million shares traded.

IMUGENE

Imugene says it has received \$1,852,597 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imugene said that the tax incentive was for research and development programs for the year to June 30, 2018.

Imugene was unchanged at two cents with 9.9 million shares traded.

OPTHEA (CIRCADIAN TECHNOLOGIES)

BVF Partners and Mark Lampert say they have increased their holding in Opthea from 32,488,784 shares (15.74%) to 39,305,918 shares (17.65%).

The San Francisco, California-based BVF Partners, Biotechnology Value Fund and Mr Lampert said they acquired the 6,817,134 shares on November 7, 2018 through the exercise of listed 27 cents options.

Opthea was up half a cent or 0.9 percent to 57 cents with 1.7 million shares traded.

VOLPARA HEATH TECHNOLOGIES

The Wellington, New Zealand-based Harbour Asset Management says it has ceased its substantial shareholding in Volpara.

Last month, Harbour Asset Management said it had become a substantial shareholder in Volpara with 9,271,332 shares or 5.174 percent, acquiring 899,000 shares for \$1,010,431 or an average price of \$1.12 a share between August 3 and October 6, 2018 (BD: Oct 9, 2018).

In October, the Harbour substantial shareholder notice said the shares were held by TEA Custody, Citibank Nominees JP Morgan Nominees, BNP Paribas Nominees and HSBC Nominees.

Today, the company said it bought and sold shares between October 9 and November 8, 2018 with the single largest sale 476,000 shares for \$630,510 or \$1.325 a share.

Volpara fell half a cent or 0.3 percent to \$1.445.