

Biotech Daily

Friday March 22, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.45 percent on Friday March 22, 2019, with the ASX200 up 28.0 points to 6,195.2 points. Nineteen Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and five were untraded. All three Big Caps were up.

Avita was the best for the second day in a row, up four cents or 17.8 percent to 26.5 cents, with 35.6 million shares traded. Antisense and Paradigm climbed more than five percent; Patrys and Prana improved more than four percent; Mesoblast, Nanosonics, Oncosil and Orthocell were up three percent or more; Compumedics, Immutep, Neuren, Optiscan and Resmed rose more than two percent; Cochlear, CSL, Medical Developments, Polynovo, Pro Medicus, Proteomics and Universal Biosensors were up more than one percent; with Volpara up 0.4 percent.

Airxpanders led the falls, down 0.3 cents or 8.8 percent at 3.1 cents, with 729,820 shares traded. Clinuvel and Cynata lost more than five percent; Kazia and Osprey fell four percent or more; Genetic Signatures and Uscom were down more than three percent; LBT shed 1.6 percent; with Opthea down 0.7 percent.

DR BOREHAM'S CRUCIBLE: RHINOMED

By TIM BOREHAM

ASX code: RNO

Share price: 17 cents; Market cap: \$24.1 million; Shares on issue: 141,933,281

Chief executive officer: Michael Johnson

Board: Ron Dewhurst (chairman), Mr Johnson, Brent Scrimshaw, Dr Eric Knight

Financials (December half): revenue of \$1.3 million (up 77%), loss of \$2.9 million (previously \$1.9 million loss), net tangible assets 3.3 cents (up 20%), cash of \$3.8 million (up 200%)

December quarter: revenue \$618,000 (up 132%), estimated March quarter cash outflows \$1.3 million.

Identifiable major shareholders: W Whitney George 23.4%, Kroy Wen (Ron Dewhurst) 6.6%, Paul H Stephens and Eleanor M Stephens 6.74%, Thirty Fifth Celebration (John McBain) 5.68%.

"We're locked and loaded," Rhinomed CEO Michael Johnson says of the nasal obstruction buster's plans to deepen its US penetration with a new vaporizer product tackling nasal congestion and insomnia.

It's apt that he deploys a military analogy: the company discovered that its Mute devices are being used by US troops in Afghanistan and Iraq, who had been buying them off the internet. The Mute is a low-cost treatment for sleep apnoea (snoring).

"I had no idea. They found us, not the other way around," Mr Johnson says. "We are now working on how to develop a formal relationship with the US military."

Just as soldiers march on their stomachs, they also need a good night's sleep. "If you have one person snoring in a barracks they are disrupting everything," he says.

From Turbines to Mutes

The Rhinomed story now has much more of a clinical flavor as the company evolves from its original offering, Turbine, to enhance the performance of athletes such as cyclists, without fearing a visit from the anti-doping police. Attached to the nose, Turbine is a plastic stent-like device that expands the nostrils to allow-in more air, and hence, oxygen to the brain.

While advocates such as Chris Froome raved about the Turbines, they never really gained traction and Rhinomed turned to the sleep apnoea market with the Mute which is pretty much the same as the Turbine but made from softer nostril-friendly material.

Under long-serving CEO Mr Johnson, the company has plugged away on building distribution channels with the perseverance of a long-distance runner.

As of December, Mute was stocked in 9,000 US outlets, compared with 4,000 in June. Approved as a class one medical device, Mute is also stocked in 2,000 outlets across Australia, New Zealand, the UK and Taiwan. The Mutes, which sell for about \$US25 for a pack of three, are meant to be discarded after 10 uses, but like a wiry toothbrush, they are used for longer than that, which is snot ideal.

Move over Vicks Vaporub

Due to be launched in the US in late May or June, Rhinomed's new product emits constant vapors from a reservoir of soothing elements. These are a combination of eucalyptus, menthol and peppermint for sleep and lavender, chamomile and valerian for congestion (valerian is a flowering plant, not a Game of Thrones dialect).

Rhinomed's Chinese facility has produced an initial 7,000 units of the device, which incorporates patent 'smarts' around the use of a reservoir for the liquids and the way the device is recharged. To be pitched at around \$US15, each unit lasts for 10 to 15 uses.

"We are steering clear of clinical claims but [the product] amplifies what a nasal dilator generally does," Mr Johnson says. "We think we have something really innovative and hopefully the retailers - and consumers - agree."

Initially the product will be available over-the-counter, with some scope for turning it into a higher-margin prescription product later.

He says he can't be sure how many stores will take the product, but he's buoyed by the likely increased recognition of Rhinomed winning the US Drug Store News retail excellence award (in the over-the-counter category), earlier this month. Given the gong was the first for an Australian company, the trophy sits proudly in Mr Johnson's pool room.

Inhaling marijuana

Rhinomed is also eyeing the medical marijuana sector, given the device is a potentially effective delivery system for the healing herb. In September, Rhinomed entered a 12-year deal with US house Colombia Care, to develop nasally delivered medical cannabis formulations. Colombia Care has licenced the Rhinomed platform, with Rhinomed entitled to double-digit royalties should a commercial product emerge.

Mr Johnson maintains that oral delivery misses the mark 95 percent of the time, while nasal sprays are only about 50 percent effective. "We can dictate the rate of release over a set period," he says. "The key is to have repeatable and predictable dosages."

While Colombia Care would do the formulation and Rhinomed wouldn't touch the cannabis itself, the parties would need to sort out regulatory issues such as US state border restrictions in transporting the substance.

Financials and performance

Rhinomed recorded revenue of \$1.35 million in the six months to December 31, 2018, up 77 percent. The company has also invoiced \$1.8 million for a record 112,682 units (and sold 400,000 packets of Mute to date). Of this, \$535,000 is expected to be recognized as revenue "in the short to medium term".

Rhinomed has \$3.8 million in cash, following a November placement that raised \$4.7 million at 21 cents apiece, with a further \$147,000 raised in a share purchase plan. The company lost \$2.87 million in the half year, compared with a \$1.92 million deficit previously and has expected cash outflows of \$1.29 million for the March quarter.

Over the last 12 months, Rhinomed shares have traded between 15 cents (March 1 2019) and 38c (October 1, 2018). Formerly known as Consegna Group (and previously Helicon Group), the company adopted its current guise in late 2013 and the stock peaked at 63 cents in November that year.

Dr Boreham's diagnosis:

Rhinomed has come a long way since your columnist last analyzed the stock in September 2017, just after the company reported 2016-'17 revenues of \$1.7 million and a loss of \$4.4 million. Sadly, though, the shares have merely marked time.

In the short term, Rhinomed's fortunes revolve around the company's ability to become a genuine standard-of-care for sleep disorders and a recognized alternative for the many nasal decongestants on market.

Ultimately, Mr Johnson hopes the new product can be used as a delivery platform for any number of drugs, such as glyceryl trinitrate (GTN) for angina sufferers. "People who think that Rhinomed only produces a plastic stent are wrong," he says. "We have a platform and we can put anything on that platform."

Achieving genuine scale could be a tough ask, but to Mr Johnson, not even the sky's the limit.

We're talking literally: given the lack of gravity, astronauts are well known to suffer nasal congestion problems and Mr Johnson hopes the new product will become the extraterrestrial remedy of choice.

"I'm not sure how we are going to achieve that but we will give it a shot."

Back on terra firma, Rhinomed has a true believing - and high flying - shareholder in investor W Whitney George. A fund manager at the New York-based Sprott Asset Management, Mr George upped his Rhinomed stake from 21.81 percent to 22.92 percent.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He tries to get to sleep by the time-honored method of counting sheep, but nose that there are better ways.

PROF ALAN TROUNSON, CARTHERICS PTY LTD, BIO-MELBOURNE NETWORK

Prof Alan Trounson says that despite Australian government encouragement for innovation out-of-date regulations and guidelines are a break on advances.

In an essay published on the Bio-Melbourne Network website Cartherics chief executive officer and Hudson Institute of Medical Research's Prof Trounson said that scientists wanting to develop cell therapies, in particular, faced these hurdles.

Prof Trounson said that at risk were "promising treatments designed to supercharge a patient's own immune system, helping it eliminate cancer - treatments beyond surgery, chemotherapy, biologicals and radiation".

Prof Trounson said that government support was insufficient to take promising new cell therapies from the laboratory to the marketplace.

"Yet perversely, there is a lack of acceptance that commercialization of medical research is essential to enable the investment [by the private sector] of the quantum of funds needed to bring these advances to patients in desperate need," Prof Trounson said. "For example, Cartherics scientists need access to blood samples from patients with rare cells, but guidelines developed for the donation of tissue and blood samples state such material is available only for research purposes and must be destroyed when the project ends," Prof Trounson said.

"Without the donor cells there can be no products," Prof Trounson said.

"And without the prospect of products rolling off the production line, there is no reason for biomedical companies to invest in the research," he said.

Prof Trounson said that governments and regulators need to rethink the process of biomedical innovation.

Prof Trounson's full statement is available at: https://bit.ly/2Wmuj5N . Cartherics is a private company.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$24.6 million to the Australian Clinical Trials Network's Trialhub in a Monash University and Alfred Health program for clinical trials. A media release from Federal Health Minister Greg Hunt said the program would create partnerships with regional hospitals to expand clinical trial reach and allow regional Victorian patients to access clinical trial treatments.

The Government said Rosebud, Casey and Bendigo hospitals would be the first to partner with the Trialhub in Victoria and initially would focus on rare cancers and other rare diseases, prostate cancer and melanoma.

The media release said the investment was made through the Government's Community Health and Hospitals Program.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has expanded its relationship with the Chicago, Illinois-based GE Healthcare to distribute its breast density software Volpara Density worldwide. Volpara said customers outside the US would now have access to its breast density assessment software, installed in more than 35 countries.

Volpara was up half a cent or 0.4 percent to \$1.185.

MEDADVISOR

Medadvisor says it has a 12-month digital partnership with the Burlington, Massachusettsbased Adheris Health to supply its prescription adherence programs.

Medadvisor said that the Syneos Health subsidiary would promote and sell its prescription reminder service to its 26,000 pharmacies and pharmaceutical clients and the company had relationships with the top 100 US retail pharmaceutical manufacturers and reached 197 million US patients a year.

Medadvisor was up 0.3 cents or 7.3 percent to 4.4 cents with 9.5 million shares traded.

PHARMAUST

Pharmaust says it has raised \$1,310,122 of a hoped for \$2,003,007 in a two-for-five non-renounceable rights issue at 2.5 cents a share (BD: Feb 18, 2019).

Pharmaust said that lead manager to the issue, the Perth, Western Australia-based Alto Capital, would place the shortfall.

The company said the funds would be used to complete phase I and II trials of monepantel for cancer in dogs.

Pharmaust was up 0.1 cents or 2.9 percent to 3.6 cents.

IMMUTEP

Immutep says the US Patent and Trademark Office has granted a patent for the use of eftilagimod alpha or IMP321 with a chemotherapy agent for cancer treatment. Immutep said the patent, titled 'Use of recombinant LAG-3 or the derivatives thereof for eliciting monocyte immune response' protected its technology until October 3, 2028. The company said IMP321 was used to generate a monocyte mediated immune response to enhance the chemotherapy agent treatment.

Immutep was up 0.1 cents or 2.9 percent to 3.5 cents with 5.75 million shares traded.

<u>USCOM</u>

Smart Top Overseas says it has increased its holding in Uscom from 23,158,475 shares (16.88%) to 24,608,482 shares (17.88%) (BD: Dec 18, 2017).

The substantial shareholder notice, signed by director Xianhui Meng, said the British Virigin Islands-based Smart Top acquired 1,450,007 shares for \$215,032 or 14.8 cents a share between March 12 and March 19, 2019.

Uscom fell half a cent or 3.1 percent to 15.5 cents.

ACTINOGEN MEDICAL

BVF Partners LP says it has increased its holding in Actinogen but been diluted from 187,122,994 shares (19.90%) to 217,200,000 shares (19.43%).

The San Francisco, California-based BVF said on July 9, 2018 it acquired 22,877,006 shares for \$1,143,850.30 in a placement at five cents a share.

BVF said on July 18, 2018 it bought 7,200,000 shares on market at five cents a share and on December 5, 2018 it bought 17,554,536 shares off market at 3.3 cents a share.

The shareholder notice said BVF was diluted in a March 19, 2019 placement of 147,876,233 shares, but an Appendix 3B New Issue announcement said the 147,876,233

shares were issued following the conversion of listed options.

Actinogen was unchanged at 5.6 cents with 2.6 million shares traded.

<u>NOXOPHARM</u>

Goodridge Nominees says it has become a substantial shareholder in Noxopharm with 9,713,964 shares or 7.95 percent of the company.

The Darling Point, New South Wales-based Goodridge said that between November 19, 2018 and March 19, 2019 it acquired the shares, with a single largest purchase of 5,432,825 shares for \$2,118,802 or 39 cents a share.

Noxopharm fell 1.5 cents or 3.5 percent to 41 cents.

MESOBLAST

Mesoblast says it has appointed director Joseph Swedish as its non-executive chairman, replacing Brian Jamieson who retires effective from March 31, 2019.

Mesoblast said Mr Swedish was the chairman, president and chief executive officer of Anthem Inc.

The company said he had been a board member since June 2018 and had been a director of IBM Corp, CDW Corp, Proteus Digital Health and Centrexion Therapeutics. Mesoblast was up four cents or three percent to \$1.385 with 851,451 shares traded.

PHYLOGICA

Phylogica says it has appointed Dr Rakesh Veedu to its scientific advisory board. Phylogica said Dr Veedu was currently the head of precision nucleic acid therapeutics research at Murdoch University's Centre for Comparative Genomics. Phylogica fell 0.1 cents or 4.2 percent to 2.3 cents.