



Biotech Daily

Friday September 15, 2017

Daily news on ASX-listed biotechnology companies

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- * **FDA APPROVES CSL PRIVIGEN FOR CIDP**
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- * **CSL 2nd STRIKE REM REPORT, \$7m MORE CEO 'RIGHTS' AGM**
- * **CONSONANCE TAKES 5% OF AIRXPANDERS**
- * **BRUCE HIGGINS TO REPLACE NOVITA CHAIRMAN IAIN KIRKWOOD**

MARKET REPORT

The Australian stock market fell 0.76 percent on Friday September 15, 2017 with the ASX200 down 43.7 points to 5,695.0 points.

Ten of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and three were untraded.

Actinogen was the best, up 0.3 cents or 5.8 percent to 5.5 cents with 12,000 shares traded, followed by Airxpanders up 5.2 percent to 81 cents with 121,751 shares traded.

Admedus, Impedimed and Prana climbed more than three percent; Ellex, Factor Therapeutics and Pharmaxis were up more than one percent; with Medical Developments, Nanosonics and Resmed up by less than one percent.

Compumedics led the falls, down 3.5 cents or 8.3 percent to 38.5 cents with 133,188 shares traded.

Atcor lost 7.1 percent; Acrux and Psivida retreated more than five percent; Benitec, Cellmid and Reva fell four percent or more; LBT, Opthea, Starpharma and Viralytics were down more than three percent; Orthocell, Osprey and Sirtex shed more than two percent; Bionomics and Polynovo were down more than one percent; with Clinuvel, Cochlear, CSL, Mesoblast and Pro Medicus down by less than one percent.

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

By TIM BOREHAM

ASX Code: RNO

Market cap: \$16.85 million

Share price: 18 cents

Shares on issue: 93,637,159 *

Chief executive officer: Michael Johnson

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

Financials (year to June 30, 2017): revenue \$1.7 million (up 70 percent), loss of \$4.4 million (down 26 percent), cash burn \$3.0 million (down 51 percent), cash \$1.7 million, expected current quarter cash burn \$1.4 million.

Major holders: W Whitney George 17.7 percent, Kroy Wen (Ron Dewhurst) 7.5 percent.

* post one-for-10 share consolidation

To lay folk, Rhinomed's devices are simply lumps of moulded plastic shoved up one's nose.

In fact, there's an underlay of high falutin' scientific theory: the company employs Poiseuille's law, a rule of physics that determines flow rates based on factors such as viscosity, temperature, pressure gradient, length and diameter of the tubing.

In the case of schnozzes, if the diameter of the nose increases by a factor of one, the volume of the airway increases by a power of four.

In practical terms: if a cyclist bungs on Rhinomed's plastic clip-like Turbine device to keep the nostrils open, he'll soon be winning the Tour de France without any fear of a random urine test.

In Rhinomed-speak the devices are "individually customisable dilators that enhance breathing and reduce nasal congestion without putting pressure on the septum".

Detractors can stick it up their nose

Your columnist admits to being sceptical of Rhinomed, the former Consegna Group (and previously Helicon Group) that morphed into its current guise in 2013.

The work of Frenchman Jean Léonard Marie Poiseuille aside - and there's a 19th century physicist who needed to get out a bit more - Rhinomed's intellectual property seems unsophisticated.

But in simplicity often lies beauty: Somnomed, for instance, has built a \$50 million a year global market for its sleep apnoea devices that look like glorified mouth guards.

The Turbines also work for four times Tour de France winner Chris Froome, who has endorsed them from day one.

While the pedal-pusher is a paid ambassador these days, the first time chief executive officer Michael Johnson knew of Froome's initial unsolicited endorsement was on Twitter.

Mr Johnson says the Turbines were more about "socialising" people to the idea of wearing an appendage on their snout.

He says one in four people have trouble breathing through their nose.

"Snoring is a symptom of nasal obstruction so we thought we would start with that opportunity rather than creating a technology and then finding an application," Mr Johnson says.

The story so far

The Turbines were launched in 2014, paving the path led by Glaxosmithkline's successful Breathe Right strips that adhere to the nose and also force the nostrils open.

The Mutes - a variant for sleep disorders such as obstructive sleep apnoea (OSA, or snoring) - were launched online in December 2014 and in the Australian physical market in March 2015.

The Mutes and the Turbines are pretty similar, but the Turbines are made of more robust material with "retention features" so they won't fall off while you're cycling, jogging or even farnarkling.

As with the Turbine, Mute is sold over the counter for a recommended \$US24.95 (\$A31.20) for a pack of three although they tend to sell for \$US20 to \$US24.

They can be re-used up to 10 times - snot for too long.

Last financial year Rhinomed notched up \$1.7 million in revenue with 150,000 units (80 percent Mutes) sold in Australia, the US, Canada and the UK.

Across the four geographies the two devices are sold in 7,000 retail outlets - mainly pharmacies - with a pipeline of 20,000 more.

Since June 30, Walgreens has expanded its stocking of Mutes from 891 shops to 4,389.

US distributor Hamacher Resource has also included Mutes on its 'planogram', a recommended store layout that reaches 10,000 US pharmacies.

Rhinomed distributes directly and also through Amerisource Bergen, McKesson, Vittoria Industries, Linde Group and our own Sigma Healthcare and Symbion.

The Mutes have regulatory approval in each of the four markets and the company recently won assent to sell in Taiwan.

A good night's sleep

Rhinomed's greater fortunes lie in the \$US7 billion sleep disorders market and the company's variant model Mute.

Specifically, the company is targeting the 70 percent of patients with mild to moderate obstructive sleep apnoea, with Mute used as a potential adjunct to oral (mouth guard-style) or continuous positive airways pressure (CPAP) devices.

The latter (sleep masks and air pumps) have a notoriously low level of compliance, partly because users look like Hannibal Lecter and they are expensive.

Rhinomed is undergoing phase II trials of a Mute variant, called an intra-nasal positive expiratory air pressure device (IPEAPD).

The IPEAPDs are Mutes that contain a valve, so that users can breathe in, but not out. When exhaling through the mouth, pressured airflow is created in a similar way to a CPAP device.

While the Mutes would remain over the counter it is expected the advanced snore-busting tool will be a prescription-only product, selling at a higher price.

And there's nothing like the gravitas of a white-coat doc pulling out his prescription pad and adorning it with scrawl translatable only by the apothecaries.

Rhinomed is also undergoing pre-clinical studies for over-the-counter variants for congestion, hay fever and anxiety.

Dr Boreham's diagnosis:

Rhinomed has stuck to its two-product strategy and has established a broad distribution footprint.

This should help the company to keep its nose in front of any rivals and spur meaningful revenue.

Mr Johnson is loath to commit corporate hara-kiri by citing a revenue target.

But as a handy guide, the \$1.7 million revenue in 2016-'17 was from a base of 2,600 shops (with about 25 percent sold online).

Rhinomed pockets an average per-pack wholesale margin of \$US9 to \$US10.

By the end of the year the company hopes the devices will be based in 10,000 to 13,000 outlets.

“Based on that, we would like to see revenue increase in parallel to the store count,” Mr Johnson says.

We concur that the greater potential lies in the expansive sleep disorders market.

Having hit a peak of 62 cents in late 2013, Rhinomed shares have been on downward peak ever since, trading in a range of 14 cents to 27 cents in the last 12 months.

(These prices have been adjusted for the company’s share consolidation that reduced shares on issue by nine-tenths.)

Two notable investors reckon the only thing on the nose about Rhinomed is the device itself.

US investor W Whitney George has built a 17 percent stake while chairman Ron Dewhurst accounts for about seven percent through his innovatively named, reverse cryptic crossword clue, Kroy Wen.

George is a head honcho at the New York-based fundie Sprott Asset Management.

Having tried the device he had a Victor Kiam moment and bought the sizeable stake in his own right.

On our proboscis - er, prognosis - Rhinomed shares are set for a breath-taking run if the sleep apnoea potential can be achieved.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He also nose nothing about nasal airflow dynamics.

MESOBLAST

Mesoblast says it has completed its \$50.7 million fully-underwritten, one-for-12 entitlement offer.

Mesoblast said that including net proceeds from the offer, it had \$US84.0 million (\$A105.1 million) in cash “on a pro-forma basis as of June 30, 2017” and the proceeds and existing cash reserves would ensure it was fully funded to complete and advance its near term objectives.

The company said that the retail entitlement offer was fully underwritten by Bell Potter Securities and there was strong take up by eligible shareholders.

Mesoblast fell half a cent or 0.4 percent to \$1.375 with 865,571 shares traded.

CSL

CSL says the US Food and Drug Administration has approved Privigen for adults with chronic inflammatory demyelinating polyneuropathy to improve neuromuscular disability. CSL said that chronic inflammatory demyelinating polyneuropathy was a rare autoimmune disorder that affected the peripheral nerves and could cause permanent nerve damage. CSL chief scientific officer and director of research and development Dr Andrew Cuthbertson said the FDA approval of Privigen was “a significant milestone for individuals with this debilitating and progressive disease”.

“As we focus on building a leading neurology franchise, we continue to advance clinical research to determine innovative and improved uses of immunoglobulin therapy that can benefit patients and improve their quality of life,” Dr Cuthbertson said.

The company said that the incidence of chronic inflammatory demyelinating polyneuropathy was up to two per 100,000 people a year, with a prevalence of 40,000 people affected.

CSL said Privigen was “the first and only 10 percent, ready to use, room-temperature stored, liquid [intravenous immunoglobulin] stabilized with proline” and was approved for chronic inflammatory demyelinating polyneuropathy (CIDP) in Europe in 2013.

CSL said Privigen was also approved in the US for primary humoral immunodeficiency and chronic immune thrombocytopenic purpura in patients aged 15 years and older and Privigen was available in more than 70 countries for these and other rare diseases.

CSL fell 29 cents or 0.2 percent to \$130.96 with one million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says the Australian Therapeutic Goods Administration has approved Monurol, and it has launched Urorec, both for urinary tract infections.

Mayne said that Monurol, or 3gm fosfomycin trometamol granules, was a single dose antibiotic for acute uncomplicated urinary tract infections in females over 12 years old and Urorec, or 8mg silodosin capsules, was indicated for the relief of lower urinary tract symptoms associated with benign prostatic hyperplasia in adult men.

The company said that both products were new chemical entity approvals from the TGA and the first two approvals of this kind for Mayne Pharma.

Mayne said it licenced Australian rights to Monurol from the Bresso, Italy-based Zambon SpA and was approved in more than 80 countries, including the US, Germany, France, Italy and Spain with global brand and generic sales of \$220 million.

Mayne said it licenced the Australian rights to Urorec from the Milan, Italy-based Recordati SpA and it was approved in more than 50 countries including US, Canada, France, Spain and Italy with global brand and generic sales of \$750 million.

Mayne was up one cent or 1.35 percent to 75 cents with 19.0 million shares traded.

OBJ

OBJ says Proctor & Gamble's cosmetic brand SK-II has launched the SK-II Magnetic Booster in Taiwan, following launches in Japan and China.

OBJ said the SK-II Magnetic Booster, containing its magnetic micro-array transdermal and Soft Touch switching and vibration technologies, had been released in Singapore, Japan and China, with launches planned for Hong Kong, Malaysia and Indonesia.

The company said that the SK-II Magnetic Booster was the second successful collaboration between SK-II and OBJ.

OBJ was unchanged at 4.3 cents with 1.96 million shares traded.

CSL

CSL will vote on a potential second strike board spill, along with up to \$US5,428,100 (\$A6,786,729) more 'performance' shares for chief executive officer Paul Perreault. Last year, CSL's remuneration report earned a first strike with the meeting voting 26.02 percent against the report and 73.98 percent in favor (BD: Oct 12, 2016).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.

In 2016, CSL said that 33.82 percent of voting shareholders opposed the 33.3 percent increase in total director remuneration with 66.18 percent in favor.

Today, CSL said the meeting would vote to re-elect chairman Prof John Shine and directors Bruce Brookand Christine O'Reilly as well as to accept the remuneration report and approve Mr Perreault's performance shares.

In previous years, resolutions to issue 'performance' stock to Mr Perreault have been passed but the resolutions have faced opposed from up to 19.5 percent of voting shareholders (BD: Oct 16, 2013; Oct 15, 2014; Oct 15, 2015).

The meeting will be held at the Function Centre, National Tennis Centre, Melbourne Park, Batman Avenue, Melbourne on October 18, 2017 at 10am (AEDT).

AIRXPANDERS

The New York-based Consonance Capital Management says it has become a substantial shareholder in Airxpanders with 14,899,767 shares or 5.18 percent.

Consonance said that Goldman Sachs was a registered holder of the shares with Mitchell Blutt, Kevin Livingston and Benny Soffer as associated holders.

Consonance said it bought the shares between July 27 and September 14, 2017 with the single largest acquisition 6,931,401 shares for \$4,926,216 or 71.1 cents a share.

Airxpanders was up four cents or 5.2 percent to 81 cents.

NOVITA HEALTHCARE (FORMERLY AVEXA)

Novita says it has appointed Bruce Higgins as a director, from today, and replacing executive chairman Iain Kirkwood when he retires on October 30, 2017.

Novita said that Mr Higgins was an experienced non-executive director, chairman and former chief executive of private and listed companies, with more than 25 years' experience with companies ranging from engineering, manufacturing and professional services to larger contracting businesses, including Raytheon and Honeywell and was currently a director of Hub24 and Legend Corporation.

The company said that Mr Higgins held Bachelor of Engineering and a Masters of Business Administration.

Novita said that Mr Kirkwood would not seek re-election at the October 30 annual general meeting and would retire after serving seven years on the board.

The company thanked Mr Kirkwood "for his considerable contribution and commitment".

Novita was up 0.2 cents or 6.9 percent to 3.1 cents with two million shares traded.