



Biotech Daily

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Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market slipped 0.07 percent on Friday May 25, 2018 with the ASX200 down 4.3 points to 6,032.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, 12 traded unchanged and two were untraded.

Compumedics was the best, up six cents or 16.4 percent to 42.5 cents with 1.5 million shares traded. Uscom climbed 5.9 percent; Nanosonics and Prana improved more than four percent; Cynata, Immutep, Impedimed, Medical Developments, Oncosil and Volpara were up more than three percent; Factor Therapeutics and Universal Biosensors rose more than two percent; Mesoblast and Pharmaxis were up more than one percent; with Bionomics, CSL, Resmed, Sirtex and Viralytics up by less than one percent.

This week's yo-yo, Optiscan, led the falls, down 0.8 cents or 12.1 percent to 5.8 cents – down one cent or 14.7 percent from last Friday's close - with 402,393 shares traded. Airxpanders lost 8.05 percent; Ellex and Opthea fell six percent or more; Osprey was down 3.2 percent; Actinogen shed 2.1 percent; Dimerix lost one percent; with Clinuvel, Cochlear and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: ANTISENSE THERAPEUTICS

By TIM BOREHAM

ASX code: ANP

Share price: 2.5 cents

Shares on issue: 371,586,638

Market cap: \$9.3 million

Chief executive officer: Mark Diamond

Board: Robert Moses (chairman), Prof Graham Mitchell, Dr William Goolsbee, Dr Gary Pace, Mark Diamond

Financials (March quarter): revenue nil, cash burn \$392,000, cash \$562,000*, estimated current quarter cash outflows \$550,000

* A rights issue and placement in April raised \$5 million.

Identifiable holders: Australian Ethical 19.3%, Platinum Asset Management 5.7%, Opthea Ltd 2.77%, Bin Liu 2.72%, Glen Bull 2.3%, CVC Ltd 2.27%, Citicastle Pty Ltd 2.22%

Having spun-out from Circadian Technologies in 2001, Antisense rates as one of the oldest listed biotechs that have stuck to its original purpose (in this case, novel gene therapies).

Unusually, Mark Diamond has been CEO for all that time and he vies with Bionomics' Deborah Rathjen and Compumedics' Dr David Burton as the sector's longest serving biotech helmsperson.

Another oddity of Antisense is that as far as we're aware it's the only biotech headquartered in the leafy Melbourne suburb of Toorak. (Opthea, formerly Circadian, moved all the way to South Yarra a few years ago.)

But longevity and a toffy address aren't the reasons why institutional investors have taken a shine to Antisense. Rather, it's the company's focus on Duchenne muscular dystrophy (DMD), a genetic degenerative muscular condition that affects only boys.

DMD is a close cousin to multiple sclerosis (MS), which was the company's initial focus and still hopes to pursue. Antisense is also seeking a treatment for acromegaly, the enlargement of hands, face and feet usually caused by a non-cancerous tumor.

Cashed up

After a \$5 million capital raising, Antisense is all cashed up with somewhere to go with its RNA-targeted therapeutics. RNA refers to ribonucleic acid, which is present in all cells and carries instructions from DNA to control the development of proteins. (DNA stands for deoxyribonucleic acid, but I'm sure we all knew that.)

The Antisense program is based on two molecules, ATL1102 and ATL1103 - licenced from global antisense technology leader Ionis Pharmaceuticals (formerly ISIS before a certain terrorist group pilfered the name).

ATL1102 targets MS and DMD, while ATL1103 has acromegaly in its sights.

The raising was backed by Australian Ethical, which took a \$500,000 placement. Other participants in the raising were Platinum Asset Management, ASX-listed private-equiteer CVC and Leon Serry (the biotech sector doyen who founded Circadian Technologies).

Mr Diamond says the institutions are squarely focused on the company's upcoming phase II trial for DMD, with the raising made possible after the company won approval for the study.

"That is where we are spending most of the funding," he says.

Making sense of Antisense

As well as being the name of the company, antisense is a platform first identified in the late 1970s.

Typically, most drugs work by directly binding to the target protein to treat a disease.

However these targets are limited to 500 proteins, whereas the human genome (30,000 genes) control thousands of different ones.

Antisense drugs focus on the RNA 'messengers', thus tackling a much wider array of targets.

While the effect is the same - the protein production is inhibited - there are key advantages.

In the company's words: "Antisense drugs don't require the complex and time-consuming analysis of the structure of the target protein that is required for conventional (small molecule) drugs."

Once the company has identified a therapeutic application and corresponding gene target, an antisense inhibitor compound can be designed within hours suitable for use in research and clinical trials.

Antisense drugs are rapidly and effectively absorbed in the blood, but they do have side effects. These are “generally predictable, occur at high doses and are well understood.”

In the clinic

Antisense has completed phase II studies for acromegaly and MS and has ethics approval for a local phase II trial pertaining to DMD.

With ATL1102, Antisense is targeting patients with relapsing remitting MS (ATL1102 is an antisense inhibitor of the VLA-4 protein a recognised MS target).

The MS trial produced evidence that the drug “significantly reduced the number of brain lesions in patients with relapsing-remitting MS”.

The trial met the primary endpoint with a 54.4 percent reduction in the cumulative number of new active brain lesions (compared with placebo).

With DMD, the company received assent in late February for a phase II trial at the Melbourne Royal Children's Hospital neuromuscular centre.

This will enrol 10 wheelchair-bound boys between 10 years and 18 years, weighing 25kg to 60kg.

The trial will assess the safety and tolerability of ATL1102, but also efficacy in terms of the blood and imaging markers of inflammation and muscle damage.

The DMD trial is due to start by June this year, with first results by June next year.

Mr Diamond says the drug tackles inflammation that exacerbates muscle fibre damage. Currently, inflammation is managed by cortico-steroids which, while improving muscle strength, have multiple side effects. Tragically, most boys do not live beyond their 20s.

“If we show good activity in DMD that could be highly supportive of an MS study,” Mr Diamond says.

Acromegaly progress

Acromegaly, meanwhile, is caused by a benign tumor of the pituitary gland that causes an excess growth hormone and insulin-like growth factor 1 (IGF-1).

ATL1103 reduces the expression of these growth hormones in the liver, thus reducing serum (or blood) IGF-1 (sIGF-1).

Antisense’s phase II trial met its efficacy endpoint with a significant reduction in sIGF-1.

ATL-1103 is intended to be as a second-line therapy, when other treatments have failed, but the company hopes that it could be eventually be a first-line therapy.

With acromegaly affecting 85,000 adults in the US and Europe, ATL1103 has been granted orphan drug status in US and Europe.

Antisense has also submitted a request for early access program status with European regulators, with the company preparing enough of the raw material to treat 15 patients.

Dr Boreham's diagnosis:

The road to progress for Antisense has been full of potholes and investors have needed the patience of Job.

"We have had a couple of setbacks along the way but we built up a lot of knowledge and awareness," Mr Diamond says.

In a major setback, Teva pulled out of an exclusive worldwide development and commercialization deal for MS.

Announced in February 2008, the tie-up involved a \$US2 million upfront payment and up to \$US100 million of milestone payments.

But in March 2010 Teva determined the drug no longer suited its "product profile".

Teva was also thought to have been concerned with toxicology issues in an earlier pre-clinical trial.

Multiple sclerosis is a lucrative market worth \$US20 billion and the company is hopeful of grant funding from the US National Institutes of Health and/or the US MS Society.

Dr Bill Goolsbee was chairman of the Nasdaq-listed immunotherapy house Sarepta Therapeutics and is a key part of the Antisense story.

In 2016, Sarepta went from a \$US50 million market cap when it gained FDA approval for its Exondys 51 DMD drug (which has a different mechanism of action from ATL-1102) and is now worth \$US6 billion.

Antisense might be happy with a similar uplift.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort and does not live in Toorak, but has passed through there once in a battered Volkswagen.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says 600 guests marked its 10th Connecting Women lunch, “the biggest celebration of gender diversity in the ... sector”.

Bio-Melbourne chief executive officer Dr Krystal Evans said that since 2009 the annual Connecting Women Lunch had celebrated the accomplishments of women in health industries in Victoria, increasing “the invaluable networks of women”.

The Network said that the event was opened for attendees of all genders and “everyone needs to be part of the conversation”.

The industry organization said that philanthropist Susan Alberti was the keynote with a panel including CSL director Christine O’Reilly, Adalta chief executive officer Sam Cobb, Melbourne Health chief executive Prof Christine Kilpatrick and Johnson & Johnson Innovation senior director Kathy Connell.

The Bio-Melbourne Network said the panel discussed the value of diversity in businesses and the increasing focus on initiatives to boost participation of women at all levels.

“We need more women in leadership positions because we need to see different opinions, diversity of backgrounds and diversity of experiences for the sector to grow and thrive” Ms Cobb said. “I want to see us reach a 50-50 ratio in my lifetime.”

The Network said that CSL continued as the premier sponsor of the Connecting Women Lunch along with major sponsors Novartis, Johnson & Johnson Innovation, Swinburne University of Technology and KPMG.

COMPUMEDICS

Compumedics says it has new three-year distribution agreements worth \$15 million with three of its China distributors for sleep and neuro-diagnostic and monitoring systems.

Compumedics said that along with the \$15 million in minimum sales commitments over the next three years a new \$1.5 million would be shipped by June 30, 2018.

The company said that the distribution agreements followed an earlier announcement that its Germany-based business DWL had a \$2.9 million sales commitment for the next 12 months, from its long-term distributor in China (BD: May 1, 2018).

Compumedics said the deals “underpin ... [its] future growth in China, which has averaged approximately 20 percent per annum over the last five years ... [and] dominant position in China in the areas of sleep diagnostics, brain research and DWL’s trans-cranial doppler”.

The company said that more than 2,000 Compumedics systems had been installed at more than 600 hospitals and more than 333 universities across China, with seven of the top 10 hospitals in China using Compumedics equipment.

Compumedics executive chairman Dr David Burton said the sales commitments “not only generate important new revenue for Compumedics but also confirm the importance of the Chinese market for the company”.

Dr Burton said that Compumedics had more than two decades of experience in China and the investment in sales, marketing, technology and development produced an average 20 percent a year growth over the last five years “and we expect that this growth should continue in the double digits over the foreseeable future”.

“Compumedics has worked with its Chinese partners to build a foundation for future growth in one of the world’s most challenging and highest-growth markets,” Dr Burton said.

“Close to half our new sales commitments are for the supply of neuro diagnostic and monitoring equipment into China,” Dr Burton said.

Compumedics was up six cents or 16.4 percent to 42.5 cents with 1.5 million shares traded.

MEMPHASYS

Memphasys says that horse owner and breeder Bob Peters will invest \$1 million to advance its work in fertility outcomes for both humans and horses.

Memphasys said that through Peters Investments Pty Ltd Mr Peters would be issued 1,000,000,000 shares at 0.1 cents a share, 650,000,000 shares to be issued under the existing placement capacity and the balance subject to shareholder approval.

The company said that following completion of the placement, Peters Investments would hold 18.32 percent of the company.

Memphasys executive chair Alison Coutts said that horses were “well-known to have a high rate of pregnancy failure due to sperm quality issues among stallions, with both natural and assisted reproductive technologies”.

“This lack of equine fertility success causes emotional distress to horses as well as significant economic losses for their owners,” Ms Coutts said.

“We see a significant commercial opportunity that is not only beneficial to Memphasys, but also to owners and veterinarians in their endeavor to achieve pregnancy with horse breeds that allow artificial insemination,” Ms Coutts said.

Memphasys was unchanged at 0.2 cents with 1.5 million shares traded.

MEDIBIO

Medibio says that Jacobs Engineering will adopt its cardiac rhythm for mental health ‘Check-in’ program, generating \$50,000 for the initial four-week program.

Medibio said that the Dallas-Texas-based Jacobs had more than 77,000 employees in the Asia Pacific, Middle East and Europe and the contract would be available to 8,000 of its staff including its European leadership team.

The company said that further work would be billed as services were provided, including the request for consultancy and delivery of ongoing mental health interventions and programs.

Medibio chief executive officer Jack Cosentino said the company was “thrilled to extend our pivotal agreement with Jacobs Engineering, a long-term supporter of Medibio and a leading corporation in driving the way mental health care is delivered to their employee base”.

Medibio was up half a cent or 2.7 percent to 19 cents.

FACTOR THERAPEUTICS

The Factor Therapeutics annual general meeting faced 87,457,158 votes (23.83%) opposition to its remuneration report, narrowly avoiding a ‘first strike’.

Factor’s meeting results notice said that 46,246,824 votes (12.47%) opposed the additional 10 placement capacity, with 324,558,416 votes (87.53%) in favor.

The company said that chair Dr Cherrell Hirst and director Dr Christian Behrenbruch were elected overwhelmingly.

Factor Therapeutics most recent Appendix 3B new issue announcement said the company had 834,335,633 shares on issue, meaning that the votes against the remuneration report amounted to 10.5 percent of the company, sufficient to requisition extraordinary general meetings.

Factor was up 0.1 cents or 2.5 percent to 4.1 cents.

PHOSPHAGENICS

Phosphagenics says its annual general meeting overwhelmingly passed the remuneration report following a first strike at last year's meeting.

Phosphagenics said the report was supported by 393,957,357 votes (83.06%), opposed by 13,972,137 votes (2.95%), with 66,380,822 votes (13.99%) at the proxy's discretion.

Last year, the report was opposed by 27.73 percent of votes (BD: May 31, 2017).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company with a vote of 25 percent or more against the remuneration report in two successive meetings is required to vote on a board spill.

Today, the company meeting results said that 50,131,913 proxy votes were recorded supporting a conditional resolution to hold the spill meeting which was not required, while chairman Dr Greg Collier was re-elected overwhelmingly with 0.88 percent opposition.

According to Phosphagenics most recent Appendix 3B new issue announcement, the company had 1,577,457,420 shares on offer, meaning that the votes in favour a spill meeting amounted to 3.2 percent of the company, not sufficient to requisition extraordinary general meetings.

Phosphagenics rose 0.2 cents or 12.5 percent to 1.8 cents with 27.4 million shares traded.

PATRYS

Patrys director Michael Stork says his Stork Holdings has been diluted from 98,773,814 shares (10.60%) to 9.20 percent.

The Ontario, Canada-based Mr Stork said the dilution was through the company's recent placement at 3.4 cents a share which raised \$4.6 million (BD: May 21, 2018).

Patrys was up 0.2 cents or 5.6 percent to 3.8 cents with 4.3 million shares traded.

GENERA BIOSYSTEMS

Genera chief executive officer Richard Hannebery says he has increased his substantial holding from 10,169,401 shares (9.46%) to 11,827,755 shares (11.01%).

Mr Hannebery said he bought 300,000 shares on-market for \$49,828 or 16.6 cents share between May 9 and 21, 2018 and had an "accelerated relevant interest in [4,358,354] shares to be acquired under put/call and call option deeds where the counterparty has a relevant interest".

Mr Hannebery told Biotech Daily that shares were held by his company EG Capital and his spouse Robyn Gould's Silica Investments, with the option allowing him to buy the shares at 23 cents a share.

Genera was unchanged at 19.5 cents.

QUEENSLAND BAUXITE

Queensland Bauxite has requested a fourth extension to the suspension following a trading halt relating to an acquisition by subsidiary Medical Cannabis.

Queensland Bauxite said the extension request was "due to the finalizing of the significant and price sensitive announcement still requiring finalization and ASX approval" and followed the trading halt, the first suspension request and subsequent suspension extension requests (BD: May 2, 4, 18, 2018).

The company said it expected everything to be finalized with the ASX on or before trading on June 1, 2018.

Queensland Bauxite last traded at 4.9 cents.

PHOSPHAGENICS

Phosphagenics says that non-executive director Peter Lankau retired from the board and chose not to stand for re-election at today's annual general meeting.

Phosphagenics chairman Dr Greg Collier said the board thanked Mr Lankau "for his considerable contribution and commitment to Phosphagenics over the last three years and we wish him well in all of his future endeavours".