



Biotech Daily

Friday March 31, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.53 percent on Friday March 31, 2017, with the ASX200 down 31.3 points to 5,864.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and three were untraded. All three Big Caps fell.

Prana was the best on yesterday's PBT434 for Parkinson's disease news, up 1.9 cents or 36.5 percent to 7.1 cents with 3.65 million shares traded. Living Cell climbed 13.0 percent; Pharmaxis improved 9.4 percent; Cellmid, Dimerix and Viralytics were up more than eight percent; IDT and Polynovo were up more than three percent; Avita, Bionomics and Reva rose more than two percent; Acrux, Mesoblast and Pro Medicus were up more than one percent; with Clinuvel up 0.7 percent.

Genetic Signatures led the falls, down three cents or 6.5 percent to 43 cents with 41,548 shares traded. Universal Biosensors and Uscom fell more than four percent; Actinogen and Nanosonics lost more than three percent; Neuren, Oncosil and Orthocell shed more than two percent; Admedus, Atcor, Medical Developments, Osprey, Resmed, Sirtex and Starpharma were down one percent or more; with Airxpanders, Cochlear and CSL down less than one percent.

DR BOREHAM'S CRUCIBLE: INNATE IMMUNOTHERAPEUTICS

ASX code: IIL

Market cap: \$175 million; **Share price:** 76.5 cents; **Shares on issue:** 224 million

Chief executive officer: Simon Wilkinson

Board: Michael Quinn (chairman), Andrew Sneddon, Elizabeth Hopkins, Chris Collins, Dr Robert Peach, Simon Wilkinson

Financials (December quarter 2016): revenue nil, cash burn \$1.78 million, cash balance \$6,016,000* (down 22%), estimated current quarter cash outflows \$2.15 million

* Ahead of March placement that netted \$2 million

Shareholders: Chris Collins 17%, Australian Ethical 4.8%, Caitlin and Cameron Collins 2.34% each (4.7%), founders (combined, 3.6%), National Multiple Sclerosis Society of the US (1.6%)

Most Australian biotechs yearn for recognition on the global stage and in the real corridors of power.

But for the secondary progressive multiple sclerosis (SPMS) drug developer, it's a case of a cabal of influential US Republicans loving the stock a little too much for comfort.

At the risk of repeating the wide reportage on the matter, Innate's biggest shareholder (and a director) Chris Collins is a New York congressman who sits on the health subcommittee of the House Energy and Commerce committee.

He is also President Donald Trump's congressional liaison and one of the first to endorse Mr Trump for the presidency, which was a lonely position within the GOP at the time.

Dr Tom Price, Mr Trump's pick as Health Secretary, also owns shares acquired when he was a member of the House ways and means sub-committee.

This transaction reportedly was being probed by Preet Bharara, the US attorney for the southern district sacked by Mr Trump.

Along with several other Republicans of note, Dr Price's chief of staff Michael Hook and fellow former NY congressman Bill Paxon (not to be confused with deceased actor Bill Paxton) also took a shine to Innate shares.

Rightly or wrongly, the implication is that Innate might enjoy some sort of a free ride when it comes to its yet-to-be-approved SPMS compound, MIS416.

Mr Wilkinson and Mr Quinn say they do not even know most of the gentleman concerned, a key exception being board member Mr Collins.

Mr Wilkinson also told the New York Post the company had no interest in gaining the ear of Washington's heavy hitters, because its primary goal was to strike a partnership with a big pharma partner.

"It won't be up to us to seek approval for the drug."

On a related front, the Takeovers Panel last month rejected a claim that Mr Collins in effect controlled Innate because he was associated with family members and other shareholders.

Citing a lack of evidence, the panel accepted that Collins children Caitlin and Cameron -- who hold just under 5% in their own name -- won't be told what to do by their old man.

As a father of two teenagers, Dr Boreham knows the feeling.

Er, where were we?

Coming back to MIS416, the compound is a micro-particle that targets both the regulatory and defensive functions of the immune system.

The company derives its name from innate immune systems, the first line of defence against external pathogens and internal disorders such as cancer.

From late 2014, 93 patients were enrolled in a placebo-controlled, randomized phase IIb trial targeting safety and efficacy. The last 16 patients are due to complete the study in one month, with top line results due in April ahead of a full clinical report in August or September.

While there are more than a dozen multiple sclerosis drugs of varying efficacy, there is currently no approved treatment for SPMS. About 30 percent of multiple sclerosis patients develop to the SPMS stage, presenting an unmet \$US7 billion a year market.

Management is supremely confident of positive results, citing "strong evidence of safety and likely efficacy" from prior trials (phase I and IIa), as well as the use of the drug in a New Zealand compassionate use program for the past seven years.

So far in the phase IIb trial, 90 percent of patients have applied for on-going access to the drug.

The company also boldly states it "expects" a corporate transaction later this year, following the release of the results.

Prospects:

Innate shares have fared more erratically than Trump's policy positioning, having attracted an ASX query after zooming from 83 cents a share pre-Christmas to a January 25 high of \$1.83.

The company posited that media coverage here and in the US "may also have generated increased in the company's prospects".

Who was it who said any publicity is good publicity?

The shares have tanked since, although put in context the stock traded at 20c a year ago.

Dr Boreham's diagnosis:

We will assume Innate-gate is more a US domestic issue about the probity of these heavy-hitters holding Innate shares, rather than a controversy likely to embroil the company itself.

Thus, Innate's fortunes will prosper or founder on the strength of the upcoming trial results.

In a company-commissioned report, Gordon Capital values Innate at \$1.81 to \$3.63 a share.

This assumes MIS416 achieves a 20 to 40 percent market share by year three, with an earnings before interest taxation and amortization (Ebitda) margin of 30 percent.

But the outcome is binary: MIS416 must work and the company is not presenting a plan B.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Nor does he have White House contacts but he does know someone who met the Donald at a party in the 1980s and there was no pussy grabbing at all.

MESOBLAST

Mesoblast says the independent data monitoring committee for its phase III chronic heart failure trial has begun the interim futility analysis on 270 patients.

Mesoblast said that the pre-specified interim analysis data set had been locked and would be analyzed and reviewed by the trial's independent statisticians, with the company remaining blinded to individual treatment allocation as well as grouped safety and efficacy data.

The company said that the data set for the interim analysis included fatal and non-fatal cardiac events from the first 270 of the expected 600 patients in the trial.

Mesoblast said that the committee would review the interim analysis and provide recommendations "shortly".

The company said the trial's efficacy endpoint was a comparison of recurrent heart failure-related major adverse cardiac events in moderate to advanced congestive heart failure patients receiving either MPC-150-IM mesenchymal precursor cells by catheter injection into the damaged left ventricular heart muscle or sham control.

Mesoblast said that enrolment in the randomized trial was on-going in the US and Canada (BD: Jun 14, 2016).

Mesoblast was up three cents or 1.3 percent to \$2.28 with 1.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says that the Munich, Germany-based Apceth GmbH & Co has dropped cancer but retains an option on its Cymerus mesenchymal stem cells for other indications.

Cynata said its Cymerus cells “demonstrated characteristics appropriate for Apceth’s technology, an outcome both parties considered successful”.

Last year, Cynata said it had a licence option agreement with the Apceth to use its stem cell technology with genetic modification for new indications including cancer and the agreement included an undisclosed up-front payment and milestones, worth potentially more than \$40 million as well as royalties on sales (BD: May 9, 2016).

In its Appendix 4C quarterly report for the three months to June 30, 2016, Cynata said it received an option fee of \$125,000.

Today, Cynata said that Apceth had undertaken a strategic review and shifted its focus to non-malignant indications and the licencing rights in oncology had been returned.

The company said it was undertaking research in genetically modified mesenchymal stem cells in cancer with Massachusetts General Hospital and Harvard Medical School.

Cynata said that Apceth retained an option to non-exclusive rights to several other disease target areas.

Apceth chief executive officer Dr Christine Günther said that “Cynata's cells demonstrated the necessary characteristics required for use with our technology”.

“We are pleased with the results of the evaluation and continue to work with Cynata to determine the next steps in regard to our collaboration,” Dr Günther said. “Its Cymerus platform has huge potential in the area of stem cell product development and its ability to create uniform cells using just one donation from one donor is truly revolutionary.”

Cynata chief executive officer Dr Ross Macdonald said the evaluation had “proven the ability of our platform technology to successfully integrate with other technologies, giving us an even broader market application for our Cymerus [mesenchymal stem cells]”.

Cynata fell nine cents or 15.8 percent to 48 cents with 1.3 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has launched and commenced first sales of its Easyscreen sexually transmitted infection (STI) genital pathogen detection kit.

Genetic Signatures said that the Easyscreen STI launch followed a successful clinical trial and validation that demonstrated its “superior capability over traditional methods to simultaneously and more effectively detect 12 of the world’s most commonly encountered STIs including chlamydia, gonorrhoea and syphilis” (BD: Oct 18, 2016).

The company said there were more than one million sexually transmitted infections contracted daily and they had a profound impact on sexual and reproductive health, particularly as many offer no, or few, clear symptoms that may be recognised as a sexually transmitted infection.

Genetic Signatures said its test used its 3Base platform, which reduced genetic information complexity and delivered “more accurate results in hours versus days when using conventional methods”.

The company said that Sydney’s of St Vincent’s Hospital pathology laboratory Sydpath would be the first customer to use the Easyscreen STI kit on an on-going basis.

Sydpath scientist Dr Damien Stark said the Easyscreen STI “allows my team to simultaneously detect more STIs than our current molecular methodology whilst easily integrating into our consolidated Easyscreen testing workflow, helping us to more readily and rapidly address a serious growing health problem”.

Genetic Signatures fell three cents or 6.5 percent to 43 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it will charge patients directly \$US349 per test compared to \$US2,795 to insurance companies for its Brevagenplus breast cancer risk assessment. Genetic Technologies said that effective from April 1, 2017, it would move from reimbursement through insurers to a direct patient self-pay program.

The company said that gaining adequate payment had become increasingly difficult using a traditional payment model and payment was “an acknowledged issue for ... companies selling molecular diagnostics and seeking reimbursement from insurers through a current procedural terminology miscellaneous code”.

Genetic Technologies said that the current system left patients with little, if any, definition on how much they would have to pay out-of-pocket for the test, the lack of transparency demotivated patients and physicians and made revenue collection more difficult.

The company said that direct payment would add certainty and eliminate low levels of reimbursement, prolonged payment time, patient confusion around eligibility and financial responsibility, poor coverage and the need for multiple laboratory locations.

Genetic Technologies chief executive officer Eutillio Buccilli said the company had been monitoring the payment issue and observed how other companies approached the issue and which ones were successful in transitioning to a different collection methodology.

The company said the price discrepancy appeared large, but insurers generally paid much lower than list price and patients, confronted with the balance, up to nine months after the test, could become upset which was typically directed at their physician.

Genetic Technologies said that the revised price was in line with what the company currently received on a per test basis.

The company said the billing model could also apply to the colorectal cancer risk test it was developing.

Genetic Technologies was unchanged at one cent.

BOTANIX

Botanix has requested a trading halt pending “an announcement regarding a capital raising”.

Trading will resume on April 4, 2017 or on an earlier announcement.

Botanix last traded at 6.8 cents.

PHARMAXIS

Australian Ethical Investment says it has increased its substantial shareholding in Pharmaxis from 24,311,470 shares (7.62%) to 28,424,427 shares (8.91%).

Australian Ethical said that it bought the 4,112,957 shares between March 27 and 29, 2017 for \$1,091,052 or 26.5 cents a share.

Pharmaxis was up 2.5 cents or 9.4 percent to 29 cents with 21.3 million shares traded.

PATRY'S

Dr Dax Marcus Calder has increased his substantial shareholding in Patrys from 51,300,000 shares (7.9%) to 70,521,428 shares (9.46%).

The substantial shareholder notice said that the West Perth, Western Australia-based Dr Calder acquired 13,746,699 shares between April 29, 2016 and March 1, 2017 for \$92,736 or an average price of 0.067 cents a share.

Patrys was unchanged at 0.7 cents.

CRESO PHARMA

Creso says its \$9 million capital raising could have an effect on its share price but it has complied with the ASX Listing Rules.

Following a 32.9 percent share price jump, from 70 cents to 93 cents, the ASX asked Creso when it became aware of a potential capital raising announced on March 27.

The ASX said that Creso closed at 70 cents on March 17, 2017 and requested a trading halt on March 20 "pending a sales and distribution update".

Creso said on March 22 that it had appointed Brazilian distributor Sin Solutions to expand its cannabinoid food additives into Latin American and closed up 17.9 percent to 82.5 cents having traded as high as 93 cents (BD: Mar 20, 22, 2017).

The ASX said that Creso requested a trading halt for a capital raising, before the market opened on March 23 and on March 27 said it had secured an \$8 million placement to institutional and professional investors and would offer a \$1 million share purchase plan at 69 cents a share (BD: Mar 23, 27, 2017).

Today, Creso told the ASX that following the March 22 close of trading, the directors "received an offer in respect of a potential sophisticated and institutional capital raising". "Following receipt of the offer, the board of directors began discussions as to the acceptance of the offer and whether the terms were acceptable to the company," Creso said.

The company said it had not previously made any announcement regarding the capital raising. went into a trading halt before the open on March 23 and made the relevant announcement regarding the capital raising on March 27 and ended the trading halt. Creso said that "the board had conducted discussions with parties in the investment community over the previous months regarding raising additional funding ... however no firm capital raising offer received had been acceptable".

The company said that the Latin American announcement was the catalyst for the offer on terms acceptable to the company and requested the trading halt.

"The Board did not consider and does not consider that it was in a position to be able to announce to the ASX accurate terms of the capital raising prior to the market opening on March 24, 2017, and therefore the only option available to the company to ensure compliance with its obligations was to request the ASX place the company into [a] trading halt until such time as an announcement regarding the capital raising could be made," Creso said.

Creso said it was in compliance with the Listing Rules.

Creso fell two cents or 2.55 percent to 76.5 cents with 1.4 million shares traded.

PROTEOMICS

Proteomics says its second anniversary on ASX is April 16, 2017 when it will release 29,251,563 shares, 3,110,000 options and 175 performance rights from escrow.

Proteomics said that more than at that time, more than 49 percent of shares on issue will be released from ASX mandatory escrow.

The company said that its directors, collectively held 39 percent of shares on issue and had committed to holding 22,967,970 shares in voluntary escrow for further 12-months, subject to the granting of Australian Securities and Investments Commission relief.

Proteomics was unchanged at 20 cents.