



Biotech Daily

Wednesday October 31, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PRESCIENT UP 8%; BIONOMICS DOWN 12.5%**
- * **RESAPP 'VERY PLEASED' WITH RESULTS; 'BEATS STETHOSCOPE'**
- * **RESONANCE: 'UNNAMED US PHARMA \$1m TRIAL CONTRACT'**
- * **OPTHEA RECEIVES \$12m FEDERAL R&D TAX INCENTIVE**
- * **BIOTECH DAILY AGM REPORTING POLICY**
- * **MESOBLAST AGM FOR 990k DIRECTOR OPTIONS**
- * **STEMCELL AGM FOR 18.6m DIRECTOR OPTIONS**
- * **CORRECTION: RECCE**
- * **OPTISCAN REQUESTS 'REGULATORY APPROVAL' TRADING HALT**
- * **RHINOMED REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **FOUNDER YACOV GEVA LENDS G MEDICAL \$9.9m MORE; RAISES \$4.5m**
- * **INVITROCUE HAS LESS THAN TWO QUARTERS CASH; FUND RAISING**
- * **STEMCELL HAS LESS THAN ONE QUARTER CASH**
- * **MEDICAL DEVELOPMENTS TO LOSE 12-YEAR DIRECTOR DR HARRY OXER**
- * **BIOSCIENCE MANAGERS APPOINTS DR KATE ROWLEY**

MARKET REPORT

The Australian Stock Market was up 0.43 percent on Wednesday October 31, 2018 with the ASX200 up 25.2 points to 5,830.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and five were untraded. All three Big Caps were up.

Prescient was the best, up 0.7 cents or 8.2 percent to 9.2 cents with 5,000 shares traded. Opthea, Osprey and Volpara climbed more than six percent; Orthocell and Reva improved more than four percent; Clinuvel and Mesoblast were up more than three percent; Oncosil rose 2.6 percent; Cochlear was up 1.5 percent; with CSL, Ellex, Medical Developments, Nanosonics, Polynovo and Resmed up by less than one percent.

Bionomics led the falls, down two cents or 12.5 percent to 14 cents, with 1.98 million shares traded. LBT lost 9.1 percent; Paradigm was down 6.6 percent; Dimerix fell 4.55 percent; Benitec, Telix and Universal Biosensors shed more than two percent; Airxpanders and Starpharma were down more than one percent; with Cynata and Pro Medicus down by less than one percent.

[RESAPP HEALTH](#)

Resapp says it is “very pleased” with the mixed results of its Smartcough-C-2 trial and its Resappdx agreed with the final diagnosis more often than the first two adjudicators. In a prepared statement for a teleconference, Resapp chief executive officer Dr Tony Keating said the company was “very pleased with these positive results as they allow us to submit to the [US Food and Drug Administration] for approval for at least three indications, lower respiratory tract disease, upper respiratory tract disease and asthma/reactive airway disease”.

“We will very likely add croup to this list for approval as well, considering our previous results for croup,” Dr Keating said.

Yesterday, Resapp emerged from a suspension to report that it missed its first primary endpoint for pneumonia, with accuracy rates ranging from 73 percent to 86 percent for three diseases, and lower rates for other respiratory diseases (BD: Oct 30, 2018).

Today, Dr Keating said the company would make submissions to the Australian Therapeutic Goods Administration and for Conformité Européenne (CE) mark for six indications, lower respiratory tract disease, upper respiratory tract disease, asthma/reactive airway disease, croup, bronchiolitis and pneumonia, “based on our very strong Australian study results”.

“This is an exciting time for Resapp,” Dr Keating said.

Dr Keating said the trial had two adjudicators review a patient’s complete medical record and independently make a diagnosis, and if they did not agree, then a third independent adjudicator is used.

He said the adjudication process gave “us insight into the accuracy of clinicians and we found that in one-third of cases ... the first two adjudicators did not agree on the diagnosis and a third was required to form a consensus, that is, only in 66 percent of cases did the first two adjudicators agree with each other”.

“This gives us a very large dataset of clinician accuracy, which will also form part of our FDA submission, allowing us to directly show how Resappdx performance compares to clinician performance,” Dr Keating said.

Dr Keating said that he was not concerned that the Resappdx showed accuracy readings in the 70 percent range rather than the 80 percent range.

“Our algorithms agreed with the final consensus more often than either of the first two adjudicators, which is excellent,” Dr Keating said.

Dr Keating said that health professionals using stethoscope for auscultation to hear chest sounds was “very subjective”.

“Our algorithms are objective and their results are repeatable,” Dr Keating said.

“They can be used in hospitals, clinics, [general practitioner] offices and especially in telehealth, where no stethoscope is available,” Dr Keating said.

“Resapp was founded on a single algorithm designed to diagnose pneumonia in children in the developing world,” Dr Keating said. “It is the developing world where pneumonia has a high prevalence, while in the US it is a low prevalence disease.”

“Pneumonia patients were a small single digit percentage in our study, compared to over 50 percent of patients having upper respiratory tract disease, 30 percent of patients having lower respiratory tract disease and 15 percent of patients having asthma,” Dr Keating said.

“The most important and the most commercially significant tool is our ability to differentiate between upper and lower respiratory tract disease,” Dr Keating said. “The results from our studies prove that Resappdx is a valuable tool for clinicians worldwide and will have myriad commercial applications, especially in telehealth.”

Resapp rebounded 1.5 cents or 15 percent to 11.5 cents with 27.1 million shares traded.

RESONANCE HEALTH

Resonance says it has a \$US747,550 (\$A1,055,457) contract with an unnamed US pharmaceutical company to use its Ferriscan services in a clinical trial.

Resonance said the 70-month trial was expected to begin in January 2019 and it would receive monthly payments for fixed costs as well as variable costs for the use of products and services, with provision "for ad hoc consulting services".

Resonance said the order brought the total amount of clinical trial work so far this year to \$US2,426,008 for eight clinical trials.

Resonance was up 0.4 cents or 14.8 percent to 3.1 cents with 2.8 million shares traded.

OPTHEA

Opthea says it has received \$12,017,248 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Opthea said the rebate related to Australian and eligible overseas expenditure on the development of OPT-302 for the year to June 30, 2018.

Opthea was up four cents or 6.8 percent to 63 cents.

BIOTECH DAILY AGM REPORTING POLICY

Biotech Daily reports all annual general meetings that are likely to be significant to shareholders or potentially cause dissent.

Issues that Biotech Daily judges as reportable range from remuneration report second strikes leading to a spill resolution, to company name changes or a change of operations.

One highly controversial issue for shareholders is the giving away of free 'performance shares', ordinary shares and options to directors and senior management, especially when the company is small and struggling and not yet paying dividends to shareholders.

Some companies think it is a good idea to give away options that are "in the money" while others seek to reward already well-remunerated executives with excessive "incentives" that dilute shareholders.

Options are a reward for future good performance, not past. Low-premium options to board members are controversial, because directors need to be thinking about maximizing long-term shareholder value, not a near-term strike price.

This can lead to investor dissent with resolutions lost.

Options with a reasonable premium to the current price can be warranted, especially if the recipient is on a relatively low pay rate relative to the risk.

If a company is performing very well and returning dividends to shareholders as well as increasing in share price, that ameliorates the issue of stock.

But even the biggest biotech, CSL, has seen dissent over its provision of performance shares to senior management.

When companies say the stock is "in lieu" of cash to conserve money, we judge that as a positive and don't report the meeting.

Biotech Daily reports meetings that appear to be controversial and are likely to raise investor opposition.

We note that although 25 percent dissent at the meeting is required for a remuneration strike, just five percent of the company is all that is required to call extraordinary general meetings, which can be very disruptive to operations.

We report results where the voting dissent is significant or above five percent of the shares on issue.

David Langsam, Editor

MESOBLAST

Mesoblast says its annual meeting will vote to grant seven directors 990,000 options. Mesoblast said that it proposed to issue 200,000 options each to Joseph Swedish and Shawn Tomasello, with 150,000 options for chairman Brian Jamieson, 120,000 options each to directors William Burns and Dr Eric Rose, with 100,000 options each to Michael Spooner and Donal O'Dwyer.

The company said that the options for Mr Swedish and Ms Tomasello would be exercisable at \$1.52 and \$1.56 each, respectively; with the other director options exercisable at the 5-day volume-weighted average price to the date of the annual general meeting; vesting in three equal tranches, with vesting dates on the first, second and third anniversaries of the grant date, expiring in seven years from the grant date.

Mesoblast said shareholders would vote on the 20 percent increase in the directors' fees pool from \$1,250,000 a year to \$1,500,000 a year, as well as the remuneration report, the prior issue of 8,474,576 shares to Novaquest Capital and 14,464,259 shares to Tasly Pharmaceutical Group, the proportional takeover provisions, a new constitution and the election of directors Mr Swedish, Ms Tomasello, Mr Jamieson and Mr Spooner.

The meeting will be held at Minter Ellison, Level 23, Rialto Towers, 525 Collins Street, Melbourne on November 30, 2018 at 3pm (AEDT).

Mesoblast was up six cents or 3.1 percent to \$1.99 with 1.8 million shares traded.

STEMCELL UNITED

Stemcell says its annual general meeting will vote to issue 18,600,000 options to four directors, all exercisable at one cent each within 10 years of issue.

Stemcell said the meeting would vote to issue chairperson Gu Huan Qing (Philip Gu) 9,500,000 options, Jamie Khoo Gee Choo 4,500,000 options, Chow Yee Koh 4,000,000 options, Savio Cheung Ka Lung 600,000 options,

Stemcell said that it would ask shareholders to approve the remuneration report, approve the 10 percent placement capacity, ratify the prior issue of 3,600,000 shares and elect directors Mr Cheung, Mr Koh, Glenn Davies and Ee Ting Ng.

The meeting will be held at HLB Mann Judd, Level 19, 207 Kent Street Sydney, on November 30, 2018 at 11am (AEDT).

Stemcell fell 0.1 cents or 4.2 percent to 2.3 cents with 1.5 million shares traded.

CORRECTION: RECCE PHARMACEUTICAL

Last night's edition described executive director James Graham as the company's chairman.

Dr Graham Melrose is Recce's executive chairman.

The mistake was made by the annual general meeting sub-editor who was confused by two executive Grahams and has been returned to the typing pool until further notice.

Biotech Daily apologizes unreservedly for the error.

Recce was up half a cent or 2.9 percent to 18 cents.

OPTISCAN IMAGING

Optiscan has requested a trading halt "pending an announcement ... in relation to a regulatory approval".

Trading will resume on November 2, 2018 or on an earlier announcement.

Optiscan last traded at 5.5 cents.

RHINOMED

Rhinomed has requested a trading halt “pending an announcement in relation to a proposed capital raising”.

Trading will resume on November 2, 2018 or on an earlier announcement.

Rhinomed last traded at 25 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says founder and major shareholder Dr Yacov Geva has increased his loan to the company from \$US3 million to \$US10 million (\$14.1 million) (BD: May 18, 2018).

Last year, G Medical chief executive officer Dr Geva said his 193,469,154 shareholding had been diluted to 57.51 percent (BD: Nov 22, 2018).

Today, G Medical said that the extended loan was “further short-term funding ... to fund the company’s inventory, medical devices and working capital requirements”.

The company said the loan had an interest rate of 10 percent a year, was currently unsecured, it had the option to fully repay the loan at its own discretion and the board was “of the view that the current terms on which Yacov Geva has agreed to provide the facilities are substantially better than those available to the company from commercial lenders and that the agreement is otherwise on arms’ length terms”.

In a separate announcement G Medical said it had raised \$US3,250,000 (\$A4,500,000) of its proposed multi-closings round of \$US5,000,000 through the issue of 3,250,000 convertible securities to New York’s MEF I LP fund, which would be granted 3,737,100 options exercisable at 39.1 cents each, a 15 percent premium to the closing price on the ASX on the day prior to the execution date, within five years.

The company said its cash burn for the three months to September 30, 2018 was \$US3,401,000, with cash and cash equivalents of \$US2,397,000.

G Medical said it had received \$US671,000 in receipts from customers for the three months to September 30, with an expected cash burn to December 31, 2018 of \$4,250,000.

G Medical was up 3.5 cents or 10.3 percent to 37.5 cents with 4.2 million shares traded.

INVITROCUE

Invitrocue says its net operating cash burn for the three months to September 30, 2018 was \$924,000 with cash at the end of the quarter of \$1,583,000.

Invitrocue said it had \$101,000 in receipts from customers for the three months to September 30 with an expected cash burn for the three months to December 31, 2018 of \$1,000,000.

Invitrocue head of operations Martin Bach told Biotech Daily that the company was currently raising funds.

Invitrocue fell 0.2 cents or 2.2 percent to nine cents.

STEMCELL UNITED

Stemcell says its net operating cash burn for the three months to September 30, 2018 was \$385,000 with cash at the end of the quarter of \$705,000.

Stemcell said the expected cash burn for the three months to December 31, 2018 was \$1,210,000 including \$760,000 for the acquisition of the Yunnan Huafang Industrial Hemp Co, with revenue for the three months to September 30 of \$264,000.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says 12-year non-executive director Dr Harry Oxer intends to step down after the December board meeting.

Medical Developments said that Dr Oxer had been a director since 2006 and “feels it is timely to make way for a new director that can bring new insights and experiences to the board”.

Medical Developments chairman David Williams said that Dr Oxer’s contribution to the board and support to management “has been enormous and invaluable”.

“He often acted for the company talking with foreign drug regulators and others using his deep knowledge of the history and practice of analgesia and Pentrox in particular,” Mr Williams said.

“He has also been a tremendous support for management in better understanding Pentrox and its many applications across medicine,” Mr Williams said.

Medical Developments was up two cents or 0.4 percent to \$4.83.

BIOSCIENCE MANAGERS

Melbourne’s Bioscience Managers says it has appointed Dr Kate Rowley as its London-based investment director.

Bioscience Managers said that Dr Rowley would “review and evaluate healthcare investment opportunities and manage investment deals from across the globe, in particular from the UK and Europe”.

The healthcare investment company said that Dr Rowley was previously a director with the London-based IP Group PLC, responsible for sourcing investment opportunities, due diligence and management of investment deals for the Group’s healthcare portfolio.

Bioscience Managers said that previously Dr Rowley was employed by Quotient Clinical, now Quotient Sciences, and the West of Scotland Bioscience Network, Nexxus.

The company said that Dr Rowley held a Bachelor of Science from the University of Sunderland, a Doctor of Philosophy from the University of Reading and a Master in Business Administration from the University of Glasgow.