



# Biotech Daily

Friday June 10, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH EVEN: PRANA UP 13%; ORTHOCELL DOWN 5%**
- \* **INNATE PLACEMENT RAISES \$2.4m, RIGHTS OFFER FOR \$3m MORE**
- \* **RHINOMED COPS 2<sup>nd</sup> ASIC \$33k NON-DISCLOSURE FINE**
- \* **MESOBLAST EXTENDS 'CORPORATE DEVELOPMENTS' SUSPENSION**
- \* **RHINOMED SLEEP APNOEA TRIAL 'NON-SIGNIFICANT'**
- \* **MEDTRONIC BELOW 5% IN REVA**
- \* **LBT CEO LUSIA GUTHRIE APPOINTED CLEVER CULTURE CHAIR**
- \* **MICHAEL CORRY TO REPLACE OPTISCAN CFO CO SEC BRUCE ANDREW**

## MARKET REPORT

The Australian stock market fell 0.92 percent on Friday June 10, 2016 with the ASX200 down 49.3 points to 5,312.6 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and three were untraded.

Prana was the best, up 1.1 cents or 12.8 percent to 9.7 cents with 1.6 million shares traded, followed by Cellmid up 12.0 percent to 2.8 cents with 1.7 million shares traded and Viralytics up 11.05 percent to \$1.055 with 1.3 million shares traded.

Universal Biosensors climbed 7.4 percent; Factor Therapeutics was up 5.9 percent; Impedimed improved four percent; Ellex was up 3.65 percent; Admedus and Starpharma rose more than two percent; Acrux, IDT, Polynovo and Pro Medicus were up more than one percent; with Cochlear and Resmed up by less than one percent.

Orthocell led the falls, down two cents or 5.4 percent to 35 cents with 465,632 shares traded, followed by Genetic Technologies down five percent to 1.9 cents with 1.3 million shares traded.

Biotron and Living Cell fell more than four percent; Actinogen was down 3.45 percent; Opthea, Osprey, Prima and Uscom shed more than two percent; CSL, Medical Developments and Reva were down more than one percent; with Nanosonics and Sirtex down by less than one percent.

## INNATE IMMUNOTHERAPEUTICS

Innate says it has raised \$US1,801,635 (\$A2,429,628) in a private placement and will offer a rights issue to raise up to \$3,025,000.

Innate said that the funds would be used to complete the phase IIb randomized, double-blind, placebo-controlled trial of the efficacy and safety of MIS416 for the treatment of secondary progressive multiple sclerosis, advance the development of an industrial scale manufacturing method for the production of MIS416, seek approval from the US Food and Drug Administration for an investigational new drug program, continue the preclinical evaluation of a possible oral formulation of MIS416 and for working capital.

The company said that the placement was at 18 US cents a share about 25 Australian cents, the issue price of the one-for-nine non-renounceable pro-rata entitlement offer. Innate said the rights issue record date would be June 16, the offer would open on June 21 and close on July 5, 2016.

The company said that non-executive directors Chris Collins and Dr Robert Peach participated in the placement, pending shareholder approval.

Innate was down one cent or 3.45 percent to 28 cents.

## RHINOMED

Rhinomed says the Australian Securities and Investments Commission has fined it \$33,000 for failing to disclose the loss of its Resmed distribution contract.

In May 2015, Rhinomed said Resmed would sell its Mute nasal plugs for snoring reduction in the UK and in August 2015, said that Boots UK pharmacies would be the exclusive retailer for its Mute snoring and sleep technology in the UK (BD May 15, Aug 21, 2015).

"The exclusive distribution deal supersedes previous UK distribution deals for Mute," Rhinomed said in the August announcement, without mentioning Resmed by name.

Today, ASIC said that following discussions and email exchanges between Rhinomed and Resmed regarding the May 15 announcement, on June 9, 2015 Rhinomed was informed by Resmed that the distribution arrangement had been terminated.

ASIC said that "by failing to inform the ASX on June 9, 2015 of the termination of the distribution arrangement with Resmed regarding the Mute product, Rhinomed was in breach of its continuous disclosure obligations between June 9 and August 21, 2015".

In June 2015, Rhinomed paid a \$33,000 ASIC penalty for disclosing on July 9, 2014 that it would partner with the Fitness First health clubs to promote its Turbine technology throughout July and described the deal as an "outstanding commercial opportunity" and "a real coup" for the company (BD: Jun 10, 2015).

ASIC said that Rhinomed and Fitness First entered into the agreement on June 6, 2014 and by failing to inform the ASX of the agreement on that day, Rhinomed was in breach of its continuous disclosure obligations.

ASIC said it issued the company with an infringement notice and Rhinomed complied with the infringement notice and paid the penalty on June 9, 2015.

Today, Rhinomed said that payment of the penalty was "not an admission of liability and cannot be regarded as a finding that Rhinomed contravened the Corporations Act".

The company said it had undergone "change at board level and ... reviewed and improved its corporate governance and disclosure policies".

Rhinomed said that it had offered and ASIC had accepted an enforceable undertaking that will result in further improvements to its continuous disclosure processes, including the appointment of an expert external advisor to develop a framework to ensure the company meets all requirements in the future.

Rhinomed was down 0.1 cents or 3.85 percent to 2.5 cents with 5.2 million shares traded.

## MESOBLAST

Mesoblast has extended its voluntary suspension “regarding material corporate developments with respect to certain assets of the company” to June 14, 2016.

Mesoblast first asked for a trading halt on June 1, followed by the first suspension request on June 3, 2016 (BD: Jun 1, 3, 2016).

There has been intense speculation whether the announcement will be good news or bad news for the company.

The speculation ranges from a licencing deal from Mesoblast for its stem cell therapy for back pain, to an in-licencing deal or acquisition, along with the possibility of one of the company’s existing partners ending a relationship, with a number of people concerned that Israel’s Teva Pharmaceuticals could be handing back the cardiac program.

Biotech Daily does not normally report speculation and does not believe that any of the above options have any more merit than any other possibility, including others not canvassed at this time.

Mesoblast last traded at \$1.92.

## RHINOMED

Rhinomed says its 19-patient phase I trial of its nasal plugs for sleep apnoea saw non-significant improvements in 12 patients.

Rhinomed said the results supported the continued development of its intra-nasal positive expiratory air pressure (Inpeap) technology for moderate obstructive sleep apnoea.

The company said the Monash Health trial was led by Prof Darren Mansfield and consisted of an in-clinic study using poly-somnography and a 14-day home tolerance trial.

Rhinomed said that seven patients met the primary end point with a 50 percent or more reduction in their apnoea-hypopnea index levels using the Rhinomed Inpeap device, five subjects were partial responders, obtaining an index reduction of 30 to 50 percent and seven did not see an improvement or had a deterioration in their scores.

The company said four of the seven who did not improve or deteriorated were mouth-breathing, leading to inefficient intranasal pressures making it difficult to assess.

Rhinomed said that mouth breathing was not identified in any of the positive responders.

The company said that the apnoea-hypopnea index (AHI) measured the number of apnoeas, or complete cessation of airflow, plus hypopneas, or a 50 percent reduction in airflow associated with oxygen desaturation and/or arousal from sleep, divided by number of hours of recorded sleep and an AHI score of five or more indicated obstructive sleep apnoea and a score greater than 30 was severe obstructive sleep apnoea.

The company said that the 19 healthy subjects had moderately severe obstructive sleep apnoea with index scores ranging from 15 to 29.

Rhinomed said that four subjects were unable to tolerate the device for the 14 days of the trial, with comfort cited as the most common reason for poor tolerance.

The company said that assessments of snoring and sleep by partners showed a modest reduction in snoring severity and an increase in sleep from 6.14 hours to 6.38 hours.

Rhinomed said the mean AHI reduced non-significantly from 19.2/hr to 16.5/hr, with similar non-significant reductions demonstrated in supine sleep, or patients lying on their backs, from 35.2/hr to 30.9/hr and in rapid eye movement sleep for 22.0/hr to 17.5/hr, but in lateral sleeping AHI increased from 7.7/hr to 11.2/hr.

Prof Mansfield said the preliminary results “show this device assists some patients with moderate obstructive sleep apnoea with mouth breathing being a limitation for others”.

“Evaluation of efficacy in more severe subsets of [obstructive sleep apnoea] will be of interest,” Prof Mansfield said.

## REVA MEDICAL

Medtronic says it has ceased its substantial shareholding in Reva.

In February, Reva said that Medtronic held 2,635,479 US shares, equivalent to 26,354,790 Chess depository instruments (CDIs) or 6.2 percent of the company.

Medtronic said that it sold shares between February 26 and June 2, 2016 with the single largest disposal 200,000 US shares equivalent to 2,000,000 CDIs for \$2,136,000 or \$1.068 a share on May 11 and 12, 2016.

Today, Reva said that Medtronic held 13,526,095 CDIs equivalent to 1,352,609 shares of common stock and 379,651 shares of common stock equivalent to 3,796,510 CDIs or 4.06 percent of the company.

Reva said the selling was part of a Medtronic corporate portfolio balancing effort and not related to Reva's recently released clinical results, that sales had ceased and that there were no current plans to resume selling.

Reva fell 1.5 cents or 1.4 percent to \$1.05.

## LBT INNOVATIONS

LBT says that co-founder and chief executive officer Lusia Guthrie has been appointed chair of joint venture Clever Culture Systems effective from June 1, 2016.

LBT said that Ms Guthrie would retire from LBT in August with Brent Barnes taking up the role of LBT chief executive officer.

The company said that Ms Guthrie would replace Clever Culture chair Klaus-Gunter Eberle, who continued as a director.

LBT said that the Zurich, Switzerland-based Clever Culture was a 50-50 joint venture with laboratory instrument maker Hettich AG Switzerland to commercialize LBT's automated plate assessment system (APAS).

The company said it was "working closely with Hettich's engineers to develop and bring to market laboratory equipment integrated with APAS", with the first instrument the APAS Independence automated culture plate reader, expected to be on sale in early 2017.

LBT said it met with the US Food and Drug Administration in May 2016 to clarify its APAS 510(k) de novo submission and was continuing discussions with potential licencing partners.

LBT was up one cent or 6.25 percent to 17 cents.

## OPTISCAN

Optiscan says that Michael Corry will replace Bruce Andrew as chief financial officer and company secretary, effective from June 13, 2016.

Optiscan said that Mr Andrew would remain with the company for the remainder of June to effect a handover.

The company said it thanked Mr Andrew "for his valuable contribution to the company over many years and [wished] him all the best for future endeavours".

Optiscan said that Mr Corry was a Fellow of the Institute of Chartered Accountants in Australia and New Zealand, a qualified company secretary and a Fellow of the Governance Institute of Australia.

Optiscan was in a suspension at two cents.