Biotech Daily

Thursday November 3, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CELLMID UP 14%, BENITEC DOWN 9%**

*** 'MARKET CONDITIONS' (TRUMP?) HALTS REDHILL $13m RAISING**

*** VOLPARA: 'FDA MAMMOGRAPHY RULES BACK OUR ENTERPRISE'**

*** ACRUX CHALLENGES KAKEN ONYCHOMYCOSIS PATENT**

*** PRANA PRIORITIZES EUROPE ON US FDA DATA REQUEST**

*** CELLMID US LAUNCH OF ÉVOLIS HAIR-LOSS PRODUCTS NEXT WEEK**

*** MAYNE US LAUNCH OF EXTENDED-RELEASE MORPHINE SULPHATE**

*** MMJ GETS BETTER SUBSIDIARY OFFER FROM HARVEST ONE**

*** RESAPP 26% REMUNERATION 1st STRIKE, 27% DIRECTOR OPTIONS**

*** BARD1 APPOINTS DR LEEARNE HINCH CEO**

*** CRYOSITE APPOINTS NICOLA SWIFT DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Thursday November 3, 2016 with the ASX200 down 3.4 points to 5,225.6 points. Nine of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and one was untraded.

Cellmid was the best, up 0.4 cents or 13.8 percent to 3.3 cents with 6.5 million shares traded. Uscom climbed eight percent; Actinogen and Oncosil were up five percent or more; Anteo and Avita rose two percent or more; Admedus, Impedimed and Pro Medicus were up one percent or more; with CSL and Resmed up by less than one percent.

Benitec led the falls, down one cent or 9.1 percent to 10 cents with 221,273 shares traded. Polynovo lost 6.45 percent; IDT and Opthea fell more than four percent; Factor Therapeutics was down 3.1 percent; Bionomics, Clinuvel, Neuren and Orthocell shed more than two percent; Compumedics, Mesoblast, Prana and Psivida were down more than one percent; with Airxpanders, Cochlear, Cyclopharm, Ellex, Genetic Signatures, Medical Developments, Nanosonics, Reva, Sirtex and Viralytics down more than one percent.

REDHILL BIOPHARMA

Redhill says it has withdrawn its $US10 million ($13.1 million) underwritten American depositary share offer at $US11 a share “due to market conditions” (BD: Nov 2, 2016).
Redhill said it was “not in the best interest of its stockholders to raise the equity capital in the current market environment”.
It is being widely reported that the current fall in global stock markets is related to the increasing possibility that Republican candidate Donald Trump could be elected President of the United States of America.
Redhill said it held about $US40.5 million at September 30, 2016.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
On the Nasdaq, Redhill climbed 30 US cents or 2.57 percent to $US11.99 ($A15.67) with 217,017 shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says the US Food and Drug Administration enhancing quality using the inspection program (Equip) will benefit its Volpara Enterprise system.
In September, Volpara chief executive officer Dr Ralph Highnam told Biotech Daily that FDA medical officer Dr David Lerner told the FDA National Mammography Quality Assurance Advisory Committee that the “FDA intends to propose amendments to [the Mammography Quality Standards Act] regulations … to require reporting of breast density in reports to [professionals] and lay summaries to patients” (BD: Sep 21, 2016).
Today, Volpara said that the Equip program was launched on October 27, 2016 and was designed to emphasise “the need for on-going facility review of clinical image quality”.
The company said that from January 1, 2017, the 8,744 accredited US breast screening providers would have three new questions to ensure annual quality assurance compliance including procedures to ensure that clinical images comply with quality standards, including positioning, reviews of images from each technologist and each interpreting physician; the use of corrective procedures for poor quality images; and procedures for oversight of quality assurance and quality control records,including the frequency of performance of all required tests and appropriate adoption of corrective actions when needed to amend images of poor quality.
Dr Highnam said the new requirements were highly relevant to Volpara’s business, and the recently launched Volpara Enterprise internet “cloud-based” product.
“These new requirements are placing a greater onus on the lead interpreting physician to ensure they have procedures in place to constantly assess image quality and take appropriate corrective actions,” Dr Highnam said.
“They also reflect the growing body of evidence demonstrating that factors such as positioning and compression of the breast impact the quality of the image, and could impair a radiologist’s ability to detect breast cancer in a screening mammogram,” Dr Highnam said.
“The wide array of quality control features and data we provide enhance quality and productivity, and ensure facilities are compliant with the new Equip initiative,” Dr Highnam said.
“Our dialogue with our existing and prospective customers is now very much focused on how our suite of solutions can assist in the early detection of breast cancer not only through assessment of image quality, but also the measurement of breast density and comfort factors such as compression pressure,” Dr Highnam.
Volpara was up one cent or 1.4 percent to 74 cents.

ACRUX

Acrux says it has filed a petition to institute an inter partes review of US patent number 7,214,506, owned by Kaken Pharmaceutical Co.
Acrux said that the patent, entitled 'Method for treating onychomycosis' was believed to be licensed by Valeant Pharmaceuticals International Inc.
The company said that the alleged invention covered the use of various anti-fungal compounds, including efinaconazole, for the treatment of onychomycosis.
Yesterday, Acrux said it filed a patent application entitled 'Topical Antifungal composition and Method for treatment of Fungal Infections' covering ACR-065 which it said was an improved formulation of Jublia, containing the anti-fungal agent efinaconazole for fungal infection of the nail bed in toes and fingers, or onychomycosis (BD: Nov 2, 2016).
Today, Acrux said that an inter partes review was a procedure for challenging the validity of a granted US patent before the US Patent and Trademark Office.
The company said that if the review was instituted, the process provided a relatively cost effective and short duration option to invalidate a granted patent in the US.
Acrux said that lodging the petition was an "important step in Acrux' patent strategy to enter the onychomycosis space".
Acrux was unchanged at 33.5 cents.

PRANA BIOTECHNOLOGY

Prana says the US Food and Drug Administration requires more non-clinical studies to remove the partial clinical hold on PBT2, which limits trial doses of PBT2 in US trials.
Prana said that as part of its "global clinical development strategy, the company has now prioritized clinical development of PBT2 in Europe".
The company said it would meet with the UK Medical and Healthcare Regulatory Agency in London and the Medical Products Agency in Stockholm this month "to receive formal scientific advice on how to best proceed to a phase III trial in Huntington's disease".
Prana said that there was increasing non-clinical evidence that PBT2 protected brain cells from decay and death and PBT2 had been shown to improve aspects of cognitive function in two clinical trials, one in Alzheimer's disease and one in Huntington's disease.
The company said that the data supported the grant of orphan drug designation for PBT2 in Europe for the treatment of Huntington's disease.
Prana said that US consultancy Defined Health conducted research in Europe on its behalf and reported that cognitive decline in Huntington's disease was "a significant unmet medical need, with no approved treatments".
The company said that while pursuing the significant commercial opportunity to develop PBT2 for Huntington's disease in Europe, it was undertaking a review of all available options to improve shareholder value.
Prana said it was reviewing other potentially suitable opportunities that might be attractive with the ability to add shareholder value and it had cash reserves of about $30 million.
Prana fell 0.1 cents or 1.6 percent to 6.3 cents.

CELLMID

Cellmid says its wholly-owned subsidiary Advangen has launched its Évolis hair loss products in the US with pre-beginning on November 7, 2016.
Cellmid said orders could be placed on the Évolis website www.evolisprofessional.com with product to be shipped to US customers from December 5, 2016.
Cellmid was up 0.4 cents or 13.8 percent to 3.3 cents with 6.5 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it has launched morphine sulfate extended-release tablets in 15mg, 30mg, 60mg and 100mg doses in the US.
Mayne said the US Food and Drug Administration approved its abbreviated new drug application for its generic version of MS Contin opioid for moderate to severe pain.
The company said that US brand and generic sales of morphine sulfate extended-release tablets amounted to about $US280 million for the year to August 31, 2016.
Mayne was up 12.5 cents or 7.9 percent to $1.705 with 7.6 million shares traded

MMJ PHYTOTECH

MMJ says it has a better offer from Harvest One Capital for its subsidiaries United Greeneries and Satipharm than from Top Strike Resources.
In September, MMJ said it would spin-out the subsidiaries through a back-door listing into Top Strike Resources for $C40 million ($A39.4 million) (BD: Sep 28, 2016).
MMJ said at that time that Top Strike was listed on the Calgary, Alberta-based Toronto Stock Exchange Venture Exchange and would pay $C2.5 million in cash and the balance in scrip to become “a large-scale cannabis producer targeting … the Canadian medical and recreational market” estimated to be $C8 billion by 2024.
Today, the company said that the Harvest One proposal included total consideration of $C42 million, of which $C2 million would be in cash and the balance in scrip, in comparison to $C40 million from Top Strike deal, with pro forma ownership of the TSX-V listed entity at 70 percent compared to 69 percent with the Top Strike deal.
MMJ said that Harvest One’s principals were experienced in the Canadian cannabis sector and provided access to extensive institutional and retail investor networks.
The company said that the Harvest One proposal was subject to shareholder approval.
MMJ fell half a cent or 2.2 percent to 22 cents with 1.2 million shares traded.

RESAPP HEALTH

Resapp has a remuneration report first strike with the annual general meeting voting 42,246,469 votes (26.4%) against the report and 117,895,328 votes (73.6%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 a company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings must vote on a board spill.
Resapp said the issue of 3,600,000 options each to chairman Dr Roger Aston and director Chris Ntoumenopoulos was opposed by 42,856,162 votes (26.6%) with 118,203,135 votes (73.4%) in favour, with similar opposition to the employee incentive plan and the issue of options to employees, but resolutions to issue options to director Brian Leedman and chief executive officer Dr Tony Keating were passed overwhelmingly, as were all other resolutions, with Mr Ntoumenopoulos and Mr Leedman re-elected unopposed.
Resapp’s most recent Appendix 3B new issue announcement said that the company had 594,164,603 shares on issue, meaning that the votes against Dr Aston and Mr Ntoumenopoulos options amounted to 7.2 percent of the company, sufficient to requisition extraordinary general meetings.
Resapp has seen a significant share price and market capitalization increase since emerging from Narhex Life Sciences with its cough sound mobile telephone application to differentiate respiratory illnesses and for the year to October 30, 2016, Resapp’s market capitalization climbed 654.1 percent from $37 million to $279 million.
Resapp was up one cent or 2.25 percent to 45.5 cents with 1.5 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says it has appointed Dr Leearne Hinch as chief executive officer, commencing on November 7, 2016.

Bard1 said that Dr Leearne Hinch had more than 20 years' experience in the life sciences industry including management, strategy, fundraising, business development and technology commercialisation.

The company said that Dr Hinch was currently Ingeneus Solutions director of commercialisation advisory and previously was chief executive officer of Immuron and an executive with Eustralis Pharmaceuticals, OBJ, Holista Colltech and Virbac (Australia) Pty Ltd.

Bard1 said that Dr Hinch had strategic, operational and technical experience leading and managing the development and commercialization of multiple drug, device and animal health products.

The company said that Dr Hinch held Bachelor of Science and Bachelor of Veterinary Medicine and Surgery degrees from Murdoch University and a Master of Business Administration from Curtin University.

Bard1 was unchanged at 3.4 cents.

CRYOSITE

Cryosite says that Nicola Swift has been appointed a director effective from today November 3, 2016.

Cryosite said that Ms Swift had more than 15 years experience in investment management as an analyst and portfolio manager, including at AMP in Sydney, Alliance Capital in London and as international research director for the Boston based, Independence Investment Associates.

The company said that Ms Swift was an independent non-executive director of Dyesol until August 2016 and was a director of Ascham School and Ascham Foundation.

Cryosite said that Ms Swift held a Bachelor of Laws and Master of Arts from Trinity College Dublin.

The company said that Graeme Moore ceased as an executive and a director effective from October 6, 2016 and the current board was chaired by Stephen Roberts with directors Andrew Kroger and Ms Swift.

Cryosite was untraded at 19 cents.