Biotech Daily

Tuesday June 3, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TISSUE THERAPIES UP 9%, ATCOR DOWN 9%**

*** BIOTA SACKS MORE STAFF, TO CLOSE AUSTRALIAN OPERATIONS**

*** BIOTECH DAILY COMMENT**

*** NSW $19m FOR 3 CANCER RESEARCH TRANSLATION CENTRES**

*** VIRALYTICS: '19 OF 51 MELANOMA PATIENTS REACH 6-MONTH PFS'**

*** BLUECHIIP RAISES $500k**

*** RESONANCE TO BUY SCOTLAND'S VUEKLAR FOR MRI PRODUCTS**

*** QRX BOARD SPILL EGM**

*** AMP REDUCES TO 6% IN ACRUX**

*** AUSTRALIAN ETHICAL BELOW 5% IN UNIVERSAL BIOSENSORS**

*** HUNTER HALL TAKES PROFIT, REDUCES TO 16% OF SIRTEX**

*** HUNTER HALL TAKES 8% OF ALCHEMIA**

MARKET REPORT

The Australian stock market fell 0.7 percent on Tuesday June 3, 2014 with the S&P ASX 200 down 38.8 points to 5,479.7 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Tissue Therapies was the best, up 2.5 cents or 8.8 percent to 31 cents with 100,000 shares traded. Analytica climbed 6.5 percent; Medical Developments was up four percent; Alchemia, Anteo, Psivida and Universal Biosensors rose more than two percent; Pharmaxis was up 1.6 percent; with Nanosonics up 0.7 percent.

Atcor led the falls, down one cent or 8.7 percent to 10.5 cents with 772,760 shares traded, followed by Prima down 8.3 percent to 4.4 cents with 18.3 million shares traded. Antisense lost 6.45 percent; Mesoblast and Osprey shed five percent or more; Avita, Benitec, Oncosil and Prana fell more than four percent; Cellmid, Phosphagenics and Viralytics were down more than three percent; Acrux, Bionomics, Clinuvel, Cochlear, Impedimed, Living Cell and Neuren shed two percent or more; Resmed and Sirtex lost more than one percent; with CSL and GI Dynamics down less than one percent.

BIOTA PHARMACEUTICALS

Biota says that following the termination of its $US231 million US Government contract it will again sack staff and close its Australian operations.

Biota was originally awarded the Biomedical Advanced Research and Development Authority (BARDA) contract in 2011, to develop its long-acting neuraminidase inhibitor laninamivir octanoate, and then merged with Nabi Pharmaceuticals to access its $US54 million in cash, eventually settling for $US27 million in cash; and purportedly to be closer to the Washington DC BARDA and FDA offices (BD: Apr 1, 2011; Apr 23, Oct 30, 2012).

The company then relocated 500 miles away to Georgia (BD: Apr 17, 2013).

In April 2014, BARDA halted work on the contract and last month terminated it and refuted Biota's claims that the company had not been given reasons either for the stop-work order or the termination (BD: Apr 30, May 1, 9, 2014).

Today, Biota said there would be "a re-alignment of the company's operations and resources".

The company said it planned "to reduce its workforce by approximately two-thirds over the next six to nine months and close its Melbourne, Australia facility by June 30, 2015".

Biota said it expected an estimated total charge of up to $US5.5 million in association with this restructuring plan.

The company said that on completion of the plan by July 2015, it expected its annual, ongoing research and development and general and administrative overhead costs will be reduced by about $US8.0 million to $US10.0 million from current annualized levels.

Biota said it would focus on its late-stage clinical assets, namely laninamivir octanoate (Lani) and vapendavir, as well as preclinical compounds being developed for the treatment of respiratory syncytial infections.

The company said that data informing the possible next steps in the development of each of these respective programs would be available by October 2014 and it "anticipates exploring alternative business development and/or financing arrangements that could facilitate the continued development of Lani in later-stage clinical trials".

Biota chief executive officer Russell Plumb said the operational changes "while very unfortunate and difficult to make, will more closely align our ongoing fixed costs with our expected revenues going forward and allow us to continue to support our later-stage clinical and preclinical programs".

Last year, Biota sacked 30 percent of its workforce and closed its pre-clinical antibiotic programs (BD: Apr 17, Nov 22, 2014).

On the Nasdaq, Biota fell a further 13 US cents or 4.83 percent to $US2.56 ($A2.77) equivalent to 34.6 cents prior to the Nabi merger, when it was trading around $A1.00.

Biotech Daily Editorial

The failure of Biota's board and management to capitalize on a $US231 million contract is a breath-taking debacle.

The claims by the company that it would acquire $US54 million at a better rate than otherwise available, by merging with Nabi, proved false and it settled for $US27 million.

The claim by the company that it would be more effective closer to the funding and regulatory authorities was proved false when it relocated 500 miles away in Georgia.

The claims by the company that it had no idea why BARDA issued a stop-work order and terminated the contract, were refuted by BARDA director Dr Robin Robinson.

The closure of the Australian operation undertaking the fundamental research that brought the world Relenza and the ongoing programs is a disgrace.

The board and senior management should resign and repay their salaries to shareholders.

Biotech Daily editor David Langsam holds Biota shares

NEW SOUTH WALES GOVERNMENT

New South Wales says it will invest $19.3 million over five years for three new cancer research centres to translate cancer research into patient care.

In a media release, New South Wales Health and Medical Research Minister Jillian Skinner said the three new research hubs were Hunter Cancer Research Alliance, the Centre for Oncology Education and Research Translation and the Northern Translational Cancer Research Centre.

The media release said that the Hunter Cancer Research Alliance was a collaboration between the University of Newcastle, Hunter New England Local Health District and Hunter Medical Research Institute and would receive $6.5 million.

The State Government said the Centre for Oncology Education and Research Translation was a collaboration between South Western Sydney Local Health District, Illawarra Shoalhaven Local Health District and Australian Capital Territory Health and also receive $6.5 million.

Ms Skinner's media release said that the Northern Translational Cancer Research Centre would combine researchers from the Kolling Institute of Medical Research, Royal North Shore Hospital, Mater Hospital, Macquarie University and Sydney University and receive $6.3 million.

The State Government said the three new centres would join four centres operating through the Cancer Institute New South Wales Translational Cancer Research Program.

Ms Skinner said the funds for the centres would ensure New South Wales "continues to lead the way in improving outcomes for people diagnosed with cancer".

"It is vital we ensure benchtop research meets the bedside needs of people affected by cancer in NSW," Ms Skinner said.

"NSW's translational cancer research program facilitates cutting-edge discoveries that will see the rapid translation of research into real outcomes for people with cancer," Ms Skinner said.

The media release said that Hunter region researchers had conducted clinical trials of a new method of genome sequencing called next generation sequencing (NGS) which confirmed that NGS had the power to more rapidly and effectively screen women for BRCA1 and BRCA2 gene mutations, which caused breast cancer.

The media release said that the researchers had engaged a number of cancer genetics services and surgical oncology units to offer NGS testing at family clinics in the region and the number of women referred to the services had increased more than three-fold.

The State Government said that in south western Sydney, translational cancer researchers designed an integrated magnetic resonance imaging-linear accelerator with which a cancer could be imaged when the patient moved during treatment and thethe patient's treatment could be adapted in real-time so that the radiation was always targeting the tumor rather than healthy tissue and organs.

The media release said the using the technology for lung cancer radiotherapy overall survival could be increased by 25 percent and toxic side effects reduced by 25 percent.

New South Wales chief cancer officer and Cancer Institute NSW chief executive Prof David Currow said that "by uniting researchers through this translational cancer research program, we are giving NSW the best chance to understand how different cancers work and develop targeted new treatments".

"More importantly, outcomes can be translated rapidly from bench to bedside, improving outcomes for the close to 40,000 people in NSW diagnosed with cancer each year," Prof Currow said.

The State Government said it invested more than $200 million a year in medical research.

VIRALYTICS

Viralytics says 19 of 51 evaluable patients have achieved the six month immune-related progression-free survival endpoint in its trial of intra-tumoral Cavatak for melanoma

Viralytics said that the lead investigator in its phase II Cavatak for late-stage melanoma (Calm) clinical trial Utah's Huntsman Cancer Institute's Dr Robert Andtbacka presented the additional data at the American Society of Clinical Oncology conference in Chicago.

The company said that Dr Andtbacka's presentation entitled 'CALM study: A phase II study of an intratumorally delivered oncolytic immunotherapeutic agent, Coxsackievirus A21, in patients with stage IIIc and stage IV malignant melanoma' added to the previously reported primary endpoint of 10 or more patients from a total of 54 evaluable patients reporting immune-related progression-free survival at six months after the first dose of Cavatak, achieved in September 2013.

Viralytics said that Cavatak continued to demonstrate anti-cancer activity in both injected tumors and non-injected tumors, at local and distant lymph nodes, lungs and distant sites.

The company said that investigators had reported overall responses in 15 of 57 (26%) patients and a number of patients were being continually monitored for the development of further overall responses, in addition to those already observed in 15 patients.

Viralytics said that Cavatak continued to be well tolerated in patients and there had been no reports of serious adverse events and grade 3 or 4 adverse events related to the Cavatak treatment in 57 patients on the study.

"Results to date in the CALM trial have been extremely encouraging with ongoing impressive activity in both injected and non-injected metastatic cancer lesions," Dr Andtbacka said. "It is also notable that multiple doses of Cavatak have been well tolerated by patients."

Viralytics said that Dr Andtbacka also presented results from a pre-clinical study assessing Cavatak with a new class of cancer immunotherapy, anti-programmed cell death-1 (anti-PD-1) monoclonal antibodies.

The company said that the pre-clinical study provided evidence of enhanced anti-cancer activity using a combination of Cavatak and an anti-PD-1 monoclonal antibodies compared to the anti-PD-1 monoclonal antibodies or Cavatak treatments alone.

Dr Andtbacka said the pre-clinical results were "quite promising".

"Taken together with the clinical results seen in the Calm study, there is now a strong rationale for a clinical trial co-administering Cavatak and an anti-PD-1 antibody," Dr Andtbacka said. "As a clinician, I would be keen to assess this combination as we try to find better ways to treat patients with metastatic melanoma."

Viralytics chief executive officer Dr Malcolm McColl said the company was "very pleased to report ... the further positive progress achieved in the Calm study".

Viralytics fell one cent or 3.45 percent to 28 cents.

BLUECHIIP

Bluechiip says its share purchase plan at five cents a share has raised $387,000 with an additional $113,000 raised through a placement to professional and institutional investors.

Bluechiip acting chief executive officer Dr Jason Chaffey said the share plan and placement was "a strong vote of confidence in Bluechiip's new business direction and shift in market focus".

The company said that Halcyon Corporate was the lead manager for the placement and the proceeds would provide working capital to support sales and business development activities.

Bluechiip was untraded at 5.6 cents.

RESONANCE HEALTH

Resonance says it has a non-binding heads of agreement to acquire the Dundee, Scotland-based Vueklar Cardiovascular for scrip.
Resonance said the transaction would “provide another pipeline for growth” from Vueklar’s magnetic resonance imaging-related medical devices.
The company said that Resonance director Jason Loveridge was also a director of Vueklar.
Resonance said that Vueklar specialized in the development of a novel technology platform for the magnetic resonance-enhancement of medical devices, which enabled the non-invasive delivery and examination of any medical device in the body.
The company said that Vueklar had focussed initially on developing a magnetic resonance imaging (MRI) visible stent for patients with peripheral arterial disease, which could lead to loss of a limb and was life-threatening.
Resonance said that peripheral arterial disease was a common chronic condition affecting more than 27 million people across Europe and North America and 25 million in China.
The company said that Vueklar was developing a peripheral stenting system that would transform the treatment of peripheral arterial disease in the lower extremities.
Resonance said that stents on the market were typically made of metal which did not allow magnetic resonance imaging, but Vueklar’s technology enabled the non-invasive delivery and examination of the stent by magnetic resonance.
The company said that using magnetic resonance imaging, the inside of the Vueklar stent could be seen, enabling the physician to assess if it was functioning properly over time and allowing normal blood flow.
Resonance said that Vueklar’s technology had applications beyond peripheral vascular disease including cardiovascular implants such as trans-catheter heart valves, occluders and filters.
Resonance said it expected to conclude the deal by the end of July 2014.
Resonance fell half a cent or 9.6 percent to 4.7 cents with 6.6 million shares traded.

QRX PHARMA

QRX says shareholders will vote on four resolutions to replace directors Dr Peter Farrell and Dr Gary Pace with Dr Richard Treagus and Bruce Hancox.
In a teleconference following the third rejection of QRX’s dual opioid Moxduo by the US Food and Drug Administration, Walker Group director Mr Hancox expressed serious concern about previously unknown FDA criticism of the application (BD: Apr 23, 2014).
Last month, the Walker Group which holds 10.0 percent of QRX called for the board spill general meeting (BD: May 15, 2014).
The meeting will be held at the offices of Dibbs Barker Lawyers, Level 8, 123 Pitt Street, Sydney on July 9, 2014 at 10am (AEST).
QRX fell one cent or 9.5 percent to 9.5 cents.

ACRUX

AMP and related bodies have reduced their shareholding in Acrux from 12,254,545 shares (7.36%) to 10,377,476 shares (6.23%).
AMP said that the shares were sold between May 12 and June 2, 2014 in scores of small to medium-sized trades at a range of prices, with the single largest sale 145,877 shares for $126,220 or 86.5 cents a share on May 30, 2014.
Acrux fell two cents or 2.3 percent to 85 cents with 1.5 million shares traded.

UNIVERSAL BIOSENSORS

Australian Ethical Investment has ceased its substantial shareholding in Universal Biosensors reducing from 11,137,347 shares (6.38%) to 8,526,119 shares (4.86%).
Australian Ethical said it primarily bought shares between October 1, 2013 and February 18, 2014, but between May 23 and 28, 2014 it sold 3,477,886 shares for $685,350 or an average price of 19.7 cents a share.
Last October, Australian Ethical bought 2,480,785 shares for $1,866,871 or an average price of 75.25 cents a share (BD: Oct 3, 2013).
Universal Biosensors was up half a cent or 2.6 percent to 20 cents.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex, from 9,332,529 shares (16.63%) to 8,758,488 shares (15.61%).
Hunter Hall bought and sold shares between February 26 and May 30, 2014 with the single largest sale 100,000 shares for $1,717,612 or $17.18 a share.
Hunter Hall has been reducing its holding in Sirtex since May 2013 (BD: May 29, Jun 28, Jul 12, Oct 21, 2013).
Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at $2.35 a share (BD: Mar 5, 2009).
Sirtex fell 27 cents or 1.6 percent to $16.92 with 193,926 shares traded.

ALCHEMIA

Hunter Hall Investment Management has increased its substantial holding in Alchemia from 22,326,686 shares (6.88%) to 25,766,681 shares (7.94%).
Hunter Hall said it acquired the shares between April 29 and May 30, 2014, in a large number of small trades with the single largest purchase on May 21, 2014 of 823,172 shares for $428,756 or an average price of 52.0 cents a share.
Alchemia was up one cent or 2.1 percent to 48.5 cents.