Biotech Daily

Thursday December 13, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CLINUVEL UP 10%; AIRXPANDERS DOWN 7%**

*** CYNATA: 'NHMRC $2m FOR OSTEOARTHRITIS STEM CELL STUDY'**

*** BARD1 RAISES $1.2m; $3.3m EXPECTED**

*** PHARMAXIS RESUMES US SALES OF ARIDOL, $2m POTENTIAL**

*** GENEODX TO DISTRIBUTE ANTEO MOLECULAR GLUE IN CHINA**

*** PERTH'S ONCORES WINS BRITISH ROYAL 'ENTREPRENEUR' GONG**

*** MESOBLAST, FDA AGREE GvHD REGULATORY PATHWAY**

*** ADHERIUM LOSES US CEO ARIK ANDERSON, CFO DAVID ALLINSON**

*** PARADIGM CEO PAUL RENNIE INCREASES, DILUTED TO 16.7%**

*** REGAL REDUCES TO 6.5% IN PRESCIENT**

*** RACE CHAIR DR BILL GARNER REDUCES TO 15%**

MARKET REPORT

The Australian stock market was up 0.14 percent on Thursday December 13, 2018, with the ASX200 up 8.1 points to 5,661.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and three were untraded.

Clinuvel was the best, up $1.57 or 9.6 percent to $17.98, with 40,938 shares traded.

Volpara climbed 7.5 percent; Impedimed improved 6.5 percent; Prescient was up 5.7 percent; Uscom was up 4.2 percent; Cynata and Mesoblast improved more than three percent; Actinogen and Nanosonics rose more than two percent; with Cochlear, Paradigm, Pro Medicus and Resmed up by less than one percent.

Airxpanders led the falls, down 0.2 cents or 7.1 percent to 2.6 cents, with 1.1 million shares traded.

Imugene and Osprey fell more than four percent; Dimerix lost 3.2 percent; Avita, Immutep, LBT, Medical Developments, Prana and Universal Biosensors shed more than two percent; Pharmaxis, Proteomics, Starpharma and Telix were down more than one percent; with CSL, Neuren and Polynovo down by less than one percent.

CYNATA THERAPEUTICS

Cynata says the National Health and Medical Research Council has approved a $1,982,802 grant for a phase II trial of its Cymerus stem cells for osteoarthritis.

Cynata said the 448-patient, placebo-controlled trial would study the effects of its Cymerus mesenchymal stem cells (MSCs) on “clinical outcomes” and knee structure in the treatment of knee osteoarthritis over a two-year period.

The company said the trial would begin by the end of 2019 with costs substantially funded by the NHMRC, with no cash contribution form Cynata.

Cynata head of product development Dr Kilian Kelly told Biotech Daily that apart from the grant from the NHMRC, the in-kind contribution from the participating hospitals in running the trial and covering staff costs was “significant”.

The company said it was also conducting a phase II trial of its stem cells for graft versus host disease and was planning a critical limb ischemia trial (BD: Aug 30, 2018).

Cynata said it would retain full commercial rights to the use of Cymerus mesenchymal stem cells in osteoarthritis, representing a market opportunity “forecast to be worth $US11.6 billion ($A16.1 billion) globally by 2025”.

The company said the study would be led by University of Sydney’s Prof David Hunter and be conducted in Sydney and Tasmania.

Cynata said that Prof Hunter was the University of Sydney’s chair of rheumatology, chair of the Institute of Bone and Joint Research and professor of Medicine.

The company said that Prof Hunter has been chief investigator of numerous clinical trials in osteoarthritis, with more than 450 publications in journals including the New England Journal of Medicine, Journal of the American Medical Association and British Medical Journal.

Dr Kelly said “this clinical trial in patients with osteoarthritis is a very significant milestone for the Cymerus platform, as it will be the largest clinical trial to date with Cymerus MSCs”.

“The trial will provide Cynata with an enormous amount of clinical data in a very large commercial opportunity…in fact, it will be among the largest clinical trials ever conducted with MSCs from any source,” Dr Kelly said.

“With an enormous need for disease-modifying agents in osteoarthritis, we are excited to explore the potential role of Cymerus MSCs in improving the quality of these patients’ lives,” Dr Kelly said.

Cynata was up 3.5 cents or 3.6 percent to $1.015.

BARD1 LIFE SCIENCES

Bard 1 says it has received applications for up to $1,184,484 million in shares in its non-renounceable $3.3 million one-for-five entitlement issue at two cents a share.

Last month, the company said the funds would be used to develop its auto-antibody tests for the detection of breast, ovarian and lung cancers, research and general working capital (BD: Nov 11, 2018).

Today, Bard 1 said that Merchant Corporate Advisory had agreed to place or purchase all of the shortfall shares from the offer.

Bard1 chief executive officer Dr Leearne Hinch told Biotech Daily the company’s vision was “to develop blood tests to detect cancer early and save lives”.

“These funds will assist the company to advance its innovative diagnostics pipeline towards clinical development and commercialization to benefit patients, the healthcare system and our shareholders,” Dr Hinch said.

Bard1 was unchanged at 1.9 cents with 12.3 million shares traded.

PHARMAXIS

Pharmaxis says it has had its first US sales of its asthma diagnostic Aridol, or the mannitol bronchial challenge test, following the relaunch of the product.

Pharmaxis said that Aridol was sold in the US by distribution partner the Brantford, Ontario-based Methapharm Inc.

The company said that in August 2018 the US Food and Drug Administration approved its Sydney manufacturing facility to produce Aridol for the US market.

In August, Pharmaxis said Aridol had non-US sales of $2 million a year and the addition of the US "offers an opportunity to at least double that revenue".

The company said that Aridol was approved by the FDA to identify bronchial hyperresponsiveness, as part of a physician's assessment of asthma in patients six years of age and over, which was sold in the US until its withdrawal from the market in 2013 as part of "a corporate restructuring" (BD: Oct 6, 2010; Jun 3, 2013).

In 2013, Pharmaxis said the FDA had included Aridol on an Import Alert list, effectively stopping the import of Aridol into the US (BD: Jun 3, 2013).

The company said at that time that it had US sales of about $99,000 for the three months to March 31, 2013, it had not received any direct communication from the FDA in relation to the listing and was seeking to clarify the reasons for the listing.

Pharmaxis said in 2013 that it believed the listing could relate to issues outstanding from a 2012 scheduled FDA audit of a third-party contract packer and the company continued to work with the packer in its response to the audit to have Aridol removed from the Import Alert as soon as possible.

Today, Pharmaxis chief executive officer Gary Phillips said that "Aridol was approved by the FDA in 2011 to identify bronchial hyper-responsiveness and commercialized by Pharmaxis in the US until its withdrawal from the market in 2013 as part of a corporate restructuring when we closed the facility used to manufacture Aridol for the US".

"Two years ago, Pharmaxis partnered with Methapharm to re-enter the US market and commenced the validation work required to have our remaining manufacturing facility approved by the FDA for Aridol," Mr Phillips said.

"Both Methapharm and Pharmaxis believe there remains a strong need in the US for objective tests to aid physicians in diagnosing asthma," Mr Phillips said.

"It's good to be back," Mr Phillips said.

Pharmaxis said it had clinically trialled and developed Aridol which was available as a standardized test kit containing pre-filled mannitol capsules and a hand-held dry powder inhaler.

The company said that in a mannitol challenge test, the subject inhaled increasing doses of mannitol with their lung function measured after each dose to determine the level of bronchial hyper-responsiveness.

Pharmaxis fell half a cent or 1.9 percent to 25.5 cents.

ANTEO DIAGNOSTICS

Anteo says it has appointed Shanghai Geneodx Biotechnology as exclusive distributor of its Anteobind molecular glue for diagnostics in China.

Anteo said that Geneodx would market, sell and distribute a specific range of its Anteobind products.

The company said Geneodx was associated with the China National Pharmaceutical Group (Sinopharm) and was a "well established and successful" distributor of in-vitro diagnostics and with Chinese manufacturers of point-of-care products and diagnostics.

Anteo was up 0.1 cents or 5.6 percent to 1.9 cents with 70.7 million shares traded.

ONCORES MEDICAL

The Perth, Western Australia-based Oncores says it is one of three companies to win a British royal family Entrepreneur of the Year award.

A media officer for Oncores told Biotech Daily the other two winners were the Kampal, Uganda-based Matibabu with a portable diagnostic for malaria and Hanoi's Logivan, developing an 'Uber' for trucks, unifying the fragmented trucking industry in Vietnam.

Oncores said it was developing an imaging tool to improve the outcome of breast cancer surgery and was one of two Australian finalists form a field of 42 entrants.

The company said that it had two minutes to pitch the company to a room of investors, technology entrepreneurs and industry professionals at London's St James's Palace against 22 other start-ups.

Oncores said there was no cash prize but "Pitch@Palace" provided "exposure to an influential global audience and comes with a guarantee that the winners will be actively promoted to the Pitch@Place network".

The company said it hoped to raise $15 million in 2019 to help take its diagnostic to US Food and Drug Administration approval and pivotal clinical trials.

Oncores said that so far it had received $6 million of venture capital investment from the Brandon Capital-managed Medical Research Commercialisation Fund.

The company said its handheld imaging probe and console would provide intra-operative guidance to surgeons by delineating breast cancer tumor from healthy tissue, at a microscopic level.

Oncores said its goal was "to provide surgeons with an image identifying residual cancerous tissue remaining within the breast, so it can be removed during surgery, reducing the need for repeat surgery, which currently happens in 30 percent of cases".

Oncores is a private company.

MESOBLAST

Mesoblast says the US Food and Drug Administration has indicated support for its planned regulatory filing for remestemcel-L for paediatric acute graft versus host disease.

Mesoblast said that in recent meetings it had gained agreement from the FDA on the proposed chemistry and manufacturing for commercialization of its mesenchymal stem cell remestemcel-L, formerly known as MSC-100-IV.

The company said the FDA had provided advice on how to present data from its 55-patient phase III trial and its 241-patient trial under the expanded access program.

Mesoblast said it had been advised to include results from the study in the filing for approval of remestemcel-L as a treatment for children with steroid refractory acute graft versus host disease.

The company said the phase III trial had met the primary endpoint of improved overall response at 28 days and improved responder survival at 180 days (BD: Jun 21, 2018).

Mesoblast said that it planned to begin its submission for regulatory approval with the in early 2019.

Mesoblast said that there were currently no US approved products for the disease.

Mesoblast acquired its mesenchymal stem cells assets from Osiris in 2013 for up to $105.7 million in cash and scrip, including Prochymal which was available at that time under an extended access program for graft versus host disease (BD: Oct 11, 2013).

Mesoblast was up four cents or 3.5 percent to $1.195 with 2.4 million shares traded.

ADHERIUM

Adherium says it will reduce its New Zealand and US staff, starting with US chief executive officer Arik Anderson and US chief financial officer David Allinson.
The company said that head of finance and business and joint company secretary Rob Turnbull had been appointed general manager, based in Auckland, New Zealand.
In August 2015, Adherium said it raised $35 million at 50 cents a share in its initial public offer for its Smartinhaler devices, since rebranded as Hailie, that attach to inhalers to record patient use and compliance (BD: May 27, 2015; Aug 27, 2015).
Earlier this year, Adherium said the US Food and Drug Administration had granted the Hailie device 510(k) clearance (BD: Jul 27, 2018).
In June 2017, the company said Arik Anderson replaced founder Garth Sutherland as chief executive officer and then quietly announced the retirement of Mr Sutherland from the board six months later (BD: Jun 9; Dec 4, 2017).
In September 2017, the company said it had replaced then chief financial officer Rob Turnbull with the US-based Timothy Marcotte and Mr Turnbull would continue as the head of finance and business services (BD: Sep 19, 2017).
In May 2018, the company said it had appointed David Allinson as chief financial officer, replacing Mr Marcotte (BD: May 23, 2018).
Today, the company said the US FDA had granted 501(k) clearance to use its Hailie sensor for Astrazeneca's Bevespi for chronic obstructive pulmonary disease.
The company has previously said that it had received revenue from sales of its Hailie device to Astrazeneca and that its Hailie device had been used in clinical trials by Astrazeneca (BD: May 21, 2018; Oct 31, 2017).
Adherium was up 0.3 cents or 6.1 percent to 5.2 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm chief executive officer Paul Rennie says his substantial holding has increased and been diluted from 22,559,543 shares (18.73%) to 23,379,935 shares (16.68%).
The Adelaide-based Mr Rennie said that between November 26, and December 13, 2018 he purchased 300,000 shares for $345,000 through the employee share plan, 147,059 shares for $100,000 through the company's 2018 placement and $333,333 shares for $100,000 in the 2017 placement, or an average of 69.8 cents a share.
The substantial shareholder notice listed Mr Rennie, the Melbourne-based Kzee Pty Ltd and Ear Investments as registered holders of the shares.
Paradigm was up one cent or 0.8 percent to $1.32.

PRESCIENT

Regal Funds says it has reduced its substantial holding in Prescient from 16,521,910 shares (7.76%) to 14,110,378 shares (6.66%).
The Sydney-based Regal Funds said it sold shares between August 13 and December 10, 2018, with the single largest sale of 1,111,532 shares for $95,035 or 8.55 cents a share on December 10, 2018.
The substantial shareholder notice listed the Basel, Switzerland-based UBS AG, Melbourne's Merrill Lynch Australia and the Zurich-based Credit Suisse Europe as registered holders of the shares.
In August, Regal Funds said it had reduced its substantial holding from 8.78 percent to 7.76 percent (BD: Aug 15, 2018).
Prescient was up 0.4 cents or 5.7 percent to 7.4 cents.

RACE ONCOLOGY

Race chairman Dr William Garner says he has reduced his substantial holding in the company from 12,583,443 shares (16.29%) to 11,398,338 shares (14.76%).

The San Juan, Puerto Rico-based Dr Garner said that on November 23 and December 7, 2018, a total of 1,185,105 shares were transferred off-market to “non-related shareholders” with the financial consideration for the shares listed as “nil”.

The substantial shareholder notice listed Dr Garner, the Lebanon, New Jersey-based Update Pharma and Melbourne’s Citicorp Nominees as registered shareholders with Dr Garner as the holder of the interests.

Race fell 0.1 cents or 1.1 percent to 8.9 cents.