Biotech Daily

Thursday October 25, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PARADIGM UP 9%; IMUGENE DOWN 13%**

*** VICTORIA $1.5m FOR CSIRO BIOLOGICS MANUFACTURING FACILITY**

*** AUSTRALIA-TEXAS MEDICAL CENTER COLLABORATION**

*** PARADIGM RAISES $9m; PPS DEAL TO TREAT RETIRED US ATHLETES**

*** PATRYS RECEIVES $3m PAT-SM6 SETTLEMENT**

*** REDHILL ASSESSES FINAL PHASE III RHB-105 HELIOBACTER PATIENT**

*** ONCOSIL: 'ANALYSIS BACKS BRACHYSIL FOR PANCREATIC CANCER'**

*** AVITA BEGINS RECELL TRIAL FOR PAEDIATRIC BURNS**

*** COMPUMEDICS CHINA JV TALKS 'STALLED'; $1.1m CHINA ORDER**

*** CANN COLLABORATES WITH CSIRO ON MEDICINAL MARIJUANA**

*** CREDIT SUISSE TAKES 5% OF BARD1, AGAIN**

*** AIRXPANDERS EGM 22% OPPOSE CHAIR BARRY CHESKIN SHARES**

*** BLUECHIIP AGM FOR 2.3m CEO 'PERFORMANCE' RIGHTS**

*** ADALTA 375k CEO REPLACEMENT OPTIONS AGM**

MARKET REPORT

The ASX followed the US down 2.83 percent on Thursday October 25, 2018 with the ASX200 down 164.9 points to 5,664.1 points. Six of the Biotech Daily Top 40 stocks were up, 28 fell, five traded unchanged and one was untraded. All three Big Caps fell.

Paradigm was the best of the six, up 6.5 cents or 8.9 percent to 79.5 cents with 196,131 shares traded. Airxpanders climbed three percent; Avita rose 2.15 percent; Ellex and Factor were up more than one percent; with Volpara up 0.4 percent.

Imugene led the falls, down 0.3 cents or 13.0 percent to two cents, with 77.2 million shares traded. Compumedics lost 12.8 percent; Benitec and Optiscan fell more than 11 percent; Prana was down 10.2 percent; Dimerix shed 8.3 percent; Clinuvel and Osprey retreated more than seven percent; Prescient, Pro Medicus, Telix and Uscom were down six percent or more; Impedimed and Mesoblast lost more than five percent; CSL, LBT, Medical Developments, Nanosonics, Orthocell, Starpharma and Universal Biosensors fell more than four percent; Cynata and Neuren were down more than three percent; Actinogen, Bionomics, Cochlear, Immutep, Opthea and Resmed shed more than two percent; with Pharmaxis and Polynovo down more than one percent.

VICTORIA GOVERNMENT
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Victoria Government says it has allocated $1.5 million to the Advanced Biotechnology Manufacturing Platform for biopharmaceutical production.

A media release from Victoria Minister for Trade and Investment Philip Dalidakis said the facility would be built at the Commonwealth Scientific and Industrial Research Organisation's Clayton Biomedical Manufacturing Precinct and would manufacture products such as vaccines, antibodies, growth factors and stem cells for testing in human clinical trials, specifically for the small and medium sized businesses in the biotechnology sector.

CSIRO manufacturing deputy director Dr Paul Savage told Biotech Daily the total cost of the facility would be about $10 million to $20 million and he expected it would be completed and ready for manufacturing by mid-2020.

"This facility will enable CSIRO to help new and existing companies develop and grow their biopharmaceutical manufacturing processes locally, instead of heading overseas," Dr Savage said.

The Victoria Government media release said that Australian biotechnology companies were "currently forced to manufacture their promising biological candidates overseas, and the high cost prevents many smaller companies from taking new therapies beyond the laboratory".

"A local facility will allow innovative Australian biotech companies to retain their [research and development] investment in the local economy while retaining and creating jobs here and boosting the number of companies undertaking clinical trials in Victoria," the media release said.

The Government said that about 1,000 new clinical trials started in Australia every year with more than one third in Victoria.

The media release said that advanced manufacturing, including medical and high-tech products, was "key to the state's economic future, with the Labor Government actively supporting sector development through the Future Industries Fund".

"We're proud to support the development of this new CSIRO facility which will help us meet emerging market demands for medical and pharmaceutical products while creating investment and local jobs," Mr Dalidakis said.

"We're supporting the sector's transition from traditional to advanced manufacturing by attracting the investment that creates new jobs in growth industries," Mr Dalidakis said.

FEDERAL GOVERNMENT

The Federal Government says it has a collaboration with the Texas Medical Center allowing researchers to work on medical breakthroughs and clinical trials.

A media release from Federal Health Minister Greg Hunt said the memorandum of understanding would "enable Australian medical researchers to better develop clinical practice and commercial opportunities in … genomics, rare cancers, brain cancer research and current and emerging clinical trials".

The media release said that Australia was "the first country to form such an agreement with [the Houston-based Texas Medical Center], home to the world's largest children's hospital and the world's largest cancer hospital".

The Government said the agreement would "provide economic opportunities and Australian patients could potentially be given earlier access to breakthrough medical technologies and treatment".

PARADIGM BIOPHARMA

Paradigm says it has commitments for a $9 million placement at 68 cents a share and has an agreement to treat joint pain in retired US athletes.
Paradigm said it received “substantial excess demand” for its $9 million placement to institutional and sophisticated investors in Australia and Asia.
The company said that Bell Potter Securities was the lead manager of the placement.
Paradigm said the funds would be used for a US Food and Drug Administration-approved phase III trial of injectable pentosane polysulfate sodium to treat osteo-arthritis pain, as well as a compassionate use program to treat pain in retired athletes through its agreement with the New York-based Pro Player’s Elite Network.
In a separate announcement, the company said it had signed an agreement with the Network would identify retired US sportspeople, particularly US National Football League players, with existing knee and joint injuries for treatment with Paradigm’s injectable pentosan polysulfate sodium.
Paradigm said the Network would manage publicity associated with the treatment of “high profile US sportspeople” treated with injectable pentosan polysulfate sodium and data gathered through the treatment of US patients through the Network would assist with the FDA regulatory approval for pentosan polysulfate sodium.
Paradigm was up 6.5 cents or 8.9 percent to 79.5 cents.

PATRYS

Patrys says it has negotiated an additional $3 million settlement with insurers for the failed manufacturing runs for PAT-SM6 in 2014 and 2015.
Patrys said the settlement was reached with no admission of liability from the insurers for complications in the manufacturing process, which resulted in insufficient quantities and inadequate quality of its PAT-SM6 (BD: Jun 11, 2015; Nov 7, 2014).
The company said payment would be received within 30 days.
Patrys fell 0.2 cents or 5.7 percent to 3.3 cents with 5.4 million shares traded.

REDHILL BIOPHARMA

Redhill says it has assessed the last of 455 patients in its randomized, double-blind, confirmatory, phase III study of Talicia (RHB-105) for helicobacter pylori.
Redhill said the final patient in the US-based study of RHB-105 had been assessed at the study’s primary endpoint of the eradication of helicobacter pylori infection at least 43 days after treatment and it expected top line results by the end of 2018.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Today, Redhill said the two-arm study compared Talicia against a dual therapy of amoxicillin and omeprazole at equivalent doses.
The company said the study had enrolled non-investigated dyspepsia patients with confirmed helicobacter pylori infections at 55 sites in the US, with patients randomized in a one-to-one ratio to receive four capsules three times a day of either Talicia or the comparator for 14 days.
On the Nasdaq, Redhill was up seven US cents or 0.89 percent to $US7.90 ($A11.17) with 77,637 shares traded.

ONCOSIL MEDICAL

Oncosil says an interim analysis of 42 patients in its study of Brachysil radiation for pancreatic cancer shows 37 patients (88.1%) had local disease control ($p < 0.0001$).

Oncosil said that at week 16 there was “strong evidence of target tumor regression, with statistically significant and in some cases substantial volumetric reduction [of] 29.7 percent mean tumor volume reduction”.

The company said that of the planned 50 patients in the ‘Panco’ trial, and 42 treated so far, nine (21.4%) had undergone surgical resection, or tumor removal, with curative intent.

Oncosil said the analysis had been submitted to the Milton Keynes, England-based British Standards Institute as additional evidence of the clinical performance and safety profile of the device.

Oncosil chief executive officer Daniel Kenny said the results from the Panco study interim analysis were “very encouraging”.

“The analysis shows clinically relevant and statistically significant results in numerous important clinical endpoints,” Mr Kenny said.

“Most notably, the resection data is suggestive of the potential to convert selected patients from an initially inoperable status to a surgically resectable and potentially curative state when Oncosil is used in combination with chemotherapy,” Mr Kenny said.

“This finding provides support for future studies of the … device as part of a neo-adjuvant treatment strategy in resectable and/or borderline pancreatic cancer,” Mr Kenny said.

Oncosil said that the key clinical performance and safety findings from the analysis of the radiation device when used in combination with standard-of-care chemotherapy were “very encouraging”.

The company said that the intention-to-treat population comprised all 50 patients whether they were implanted with the device or not, while the per protocol population comprised the 42 patients enrolled and implanted with the device.

Oncosil said that the maximum target tumor regression was 90 percent, with evidence of significant reduction in CA19-9 tumor marker in the per protocol population from baseline to week-6 ($p = 0.0082$).

The company said that 27 percent of evaluable patients showed a reduction in CA19-9 of more than 90 percent.

Oncosil said there was “evidence of a satisfactory safety profile overall with no convincing evidence of significant safety concerns or unexpected/serious toxicities associated with the investigational device”.

The company said there was no evidence to suggest significant additional risk when the device was used with contemporary systemic chemotherapy regimens.

Oncosil said that the overall safety profile was largely consistent with that expected in a high-risk population receiving chemotherapy.

The company said its device had a favorable risk-benefit profile when used with standard-of-care chemotherapy in a high-risk patient population with unresectable locally advanced pancreatic cancer.

Oncosil said that the British Standards Institute was currently undertaking the detailed review necessary for granting Conformité Européenne (CE) mark.

The company has previously said the multi-centre, randomized, open-label Oncopac global trial would enroll up-to 300 patients with locally advanced unresectable pancreatic cancer in Australia, the US and Europe (BD: Aug 2, 2016; Feb 13, 2017).

Oncosil was unchanged at 17.5 cents with 2.9 million shares traded.

AVITA MEDICAL

Avita says it has begun a 90-patient, randomized, controlled trial of its Recell autologous cell harvesting device to treat burns in children under the age of 18 years.

Avita said that patients with superficial partial and mid-thickness burns would be randomly assigned into one of three groups, to be treated with Recell spray-on skin and Biobrane dressing, the Biobrane dressing alone or the current standard-of-care, a silver impregnated silicone lined dressing.

The company said that the primary endpoint of the trial would be the number of days to re-epithelization, or the regrowth of skin, on the burn injury and that secondary endpoints would include pain, patient satisfaction and scarring.

The company said that the trial was being conducted by the Queensland University of Technology in collaboration with Brisbane's Lady Cilento Children's Hospital.

Avita was up 0.2 cents or three percent to 6.9 cents.

COMPUMEDICS

Compumedics says its Chinese joint venture has "stalled", but it has received a separate $1.1 million order from its China distributor.

Compumedics said its joint venture negotiations with the China-based Meinan Onehealth Healthcare Holdings, also known as Health 100, had stalled on issues that included the scope, control and protection of intellectual property rights.

The company said the issues included commercial conflicts of interest with an unnamed third party that "arose and/or were introduced" into discussions of the joint venture "at a late stage in the negotiation and completion process" (BD: May 31, Aug 13, 2018).

In a separate ASX announcement, Compumedics it had received a $1.1 million of its neuro sleep diagnostic devices from an unnamed but "long-standing" distributor in China.

Compumedics fell five cents or 12.8 percent to 34 cents.

CANN GROUP

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Cann says it has a three-year research and development agreement with the Commonwealth Scientific and Industrial Research Organisation.

Cann said it would will work with multiple CSIRO business units to develop technology for the manufacture and sale of its medicinal cannabis products, and it would own all intellectual property produced through the collaboration with the CSIRO.

Cann chief executive officer Peter Crock said the company's "commitment to building a science-based business will be complemented by the outstanding facilities, skills and experience that CSIRO will contribute to the collaboration".

CSIRO manufacturing deputy director Dr Paul Savage said the Organisation was "looking forward to working on a range of research areas associated with the emerging market demand for novel medicinal cannabis treatments and delivery systems".

"The growing medicinal cannabis sector provides an exciting new frontier for medical research and we are delighted to be involved with Cann Group," Dr Savage said.

"Medicinal cannabis is gaining greater support in various geographies around the world, yet there is still much to be learned from a scientific perspective," DR Savage said.

"With our history and capability in medical research and the support of a local industry leader like Cann Group, we expect to be able to make significant discoveries in this developing sector," Dr Savage said.

Cann fell 29 cents or 11.5 percent to $2.23 cents with 682,077 shares traded.

BARD1 LIFE SCIENCES

Credit Suisse Australia on behalf of Credit Suisse Group AG says it has become a substantial shareholder in Bard1, again, with 42,819,450 shares (5.17%)
The substantial shareholder notice said that Credit Suisse bought and sold shares between June 19 and October 18, 2018 with the single largest purchase of 2,579,447 shares for $33,533 or 1.3 cents a share on October 18 and the single largest sale of 1,470,238 shares for $21,760 or 1.5 cents a share on July 16, 2018.
In September, Credit Suisse said it had reduced below five percent in Bard1, six months after becoming a substantial shareholder (BD: Sep 11; Apr 20, 2018).
Bard1 fell 0.2 cents or 5.1 percent to 3.7 cents with 392.55 million shares traded.

AIRXPANDERS

The Airxpanders extraordinary general meeting passed all resolutions but faced 22.4 percent opposition to chairman Barry Cheskin buying shares in a placement.
Airxpanders proposed that Mr Cheskin be allowed to buy 299,060 US shares at 16.7 US cents each, equivalent to 897,180 Chess depository instruments (CDIs) at 7.66 cents per CDI (BD: Sep 24, 2018).
The company said that 102,456,776 votes (77.28%) supported Mr Cheskin buying the shares, with 29,730,890 (22.42%) opposed.
Airxpanders said that the issue of 28,922,901 options to chief executive officer Frank Grillo “equal to five percent of the fully-diluted capitalization of the company” was passed with 4.39 opposition, with all other resolutions passed overwhelmingly.
Following the May annual general meeting, the company said the strongest opposition was to the grant of options to Mr Cheskin with 30,325,587 votes (42.9%) against, with other resolutions passed easily, except for the re-election of Mr Cheskin who was re-elected with 78.77 percent in favor and 21.23 percent “withheld” (BD: May 22, 2018).
The company’s most recent Appendix 3B new issue announcement said that Airxpanders had the equivalent to 557,552,670 CDIs on issue, meaning the votes against Mr Cheskin’s share purchase amounted to 5.3 percent of the company, sufficient to requisition extraordinary general meetings under the Australian Corporations Act.
Airxpanders is a Delaware US-incorporated company and its certificate of incorporation said that “only the chairman of our board of directors, chief executive officer or a majority of our board of directors may call special meetings of our stockholders”.
Airxpanders was up 0.2 cents or three percent to 6.9 cents.

BLUECHIIP

Bluechiip will vote to issue chief executive officer Andrew McLellan 2,283,105 free ‘performance rights’, pending performance hurdles.
Bluechiip said the rights would vest in three tranches on August 30, 2019, 2020 and 2021, based on the company’s performance relative to the All Ordinaries Accumulation Index.
Last year, the company’s annual general meeting overwhelmingly approved all resolutions including 3,000,000 performance rights for Mr McLellan based on similar hurdles.
Today, Bluechiip said that the annual general meeting would vote on the remuneration report, the re-election of chairman Iain Kirkwood, the ratification of a previous share issue and the approval of the 10 percent placement capacity.
The meeting will be held at Phillips Ormonde Fitzpatrick, Level 16, 333 Collins Street, Melbourne, on November 26, 2018 at 10am (AEDT).
Bluechiip fell 0.1 cents or 1.7 percent to 5.9 cents.

ADALTA

Adalta says shareholders will vote to issue Sam Cobb 375,000 options replacing those approved at last year's annual general meeting (BD: Oct 12, 2018).

Last year, Adalta shareholders approved the issue to Ms Cobb of 1,750,000 options, pending performance hurdles, with 750,000 options exercisable at 25 cents each, 500,000 options exercisable at 50 cents, 250,000 options exercisable at 75 cents and 250,000 options exercisable at $1.00.

Ms Cobb told Biotech Daily that the first tranche of 375,000 options "had the milestone 'Release of AD-114 for human trials' … [and] as we are no longer working on AD-114, the first lot of options at 25 cents are not worth anything".

"The aim … is to replace these options exactly as they were issued with the milestone 'Release of Adalta compound for human trials' with all other terms the same," Ms Cobb said.

In April, Adalta said it had developed an improved form of its AD-114 for idiopathic pulmonary fibrosis treatment drug, re-named AD-214 (BD: Apr 18, 2018).

"It is not the intent of the board to issue options in the money," Ms Cobb said.

"In fact, these options, as well as all others issued to me, are still at risk and require the milestone of getting AD-214 to human trials to be met," Ms Cobb said.

The company said the meeting would vote on the remuneration report, the participation of directors Dr John Chiplin and Dr Robert Peach in the July placement, the prior issue of placement shares, to refresh the placement capacity and re-elect directors Dr James Williams and Liddy McCall.

The meeting will be held at the Collins Street Business Centre, Level 14, 330 Collins Street, Melbourne on November 28, 2018 at 3pm (AEDT).

Adalta was untraded at 28 cents.