Biotech Daily

Monday October 23, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 8%; ACRUX, NEUREN DOWN 8%**

*** TAIWAN APPROVES VOLPARA BREAST DENSITY, DOSE DIAGNOSTICS**

*** CHINA APPROVES TBG HLA GENOTYPING KITS**

*** ONCOSIL: 'EARLY PANCREATIC CANCER DATA, TUMOR SHRINKAGE'**

*** RECCE PLAN RAISES $947k OF HOPED FOR $1m**

*** ESENSE, $766k SINGAPORE MARIJUANA TERPENE DEAL**

*** VISIONEERING: 'STUDY BACKS NATURALVIEW FOR SLOWING MYOPIA'**

*** IMPEDIMED SHIPS L-DEX SOZO; LYMPHOEDEMA STUDY PUBLISHED**

*** CORRECTION: RHINOMED**

*** BENITEC TO ASX: 'PATENT NOT MATERIAL, FDA TICK PUSHED PRICE'**

*** BRAIN REQUESTS CAPITAL RAISING TRADING HALT**

*** GENETIC TECHNOLOGIES 14m CEO EUTILLIO BUCCILLI OPTIONS AGM**

*** CELLMID 20-TO-1 CONSOLIDATION AGM**

*** ONE FUNDS TAKES 10% OF AVITA**

*** DR CHRIS BISHOP REPLACES MEDIGARD CHAIRMAN DON CHANNER**

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday October 23, 2017 with the ASX200 down 13.0 points to 5,894.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and three were untraded.

Prana was the best for the second trading day in a row, up half a cent or 7.7 percent to seven cents with 263,889 shares traded. Benitec climbed 5.9 percent; Cellmid rose 4.35 percent; Cyclopharm, ITL, Opthea and Sirtex were up more than two percent; Impedimed, Nanosonics and Pharmaxis were up more than one percent; with Pro Medicus, Resmed and Viralytics up by less than one percent.

Both Acrux and Neuren led the falls, down 8.3 percent to 16.5 cents and 11 cents, respectively, with 218,038 shares and 5.7 million shares traded, respectively. Airxpanders, Living Cell, Oncosil and Prima lost six percent or more; Bionomics fell 4.55 percent; Ellex, Orthocell, Universal Biosensors and Uscom were down three percent or more; Mesoblast shed 2.3 percent; Avita, Factor Therapeutics, Osprey, Polynovo and Starpharma were down more than one percent; with Clinuvel, Cochlear, CSL, Medical Developments and Volpara down by less than one percent.

VOLPARA HEALTH TECHNOLOGIES

Volpara says the Taiwan Food and Drug Administration has cleared its Volpara Density and Volpara Dose systems as a class II medical device.
Volpara said that the Enterprise breast clinic management software was “not classified as a medical device in Taiwan and does not require regulatory approval”.
The company said that Taiwan had a target screening population of more than 670,000 women and about 300 digital mammography machines, making it “one of world’s largest users of computer-aided detection in mammography outside … the US, in line with its status as a leading adopter of computer technology”.
Volpara said breast cancer was increasing in Taiwan, with the number of cases almost doubling in the 20 years and forecast to approach Western levels over the next 15 years.
The company said breast cancer screening and compliance was a Taiwan Government, focus, with women encouraged to undergo a breast screen every two years.
Volpara said it would launch the products through its Taiwan distributor Best Biomedical Supply, supported by its Asia Pacific sales team.
The company said the Changhua Christian Hospital was evaluating the Volpara Enterprise and was expected to be the first customer in Asia, while the Tri-Service General Hospital in Taipei had been using Volpara Density in clinical research since 2014.
Volpara chief executive officer Dr Ralph Highnam said Taiwan was an important market both for its track record as an early adopter of new technologies “and the increased focus on improvement of breast screening, in light of the growing rate of breast cancer”.
“We also know it has a higher population of women with dense breasts compared to the West,” Dr Highnam said, with breast density a risk factor for cancer and making it more difficult to detect.
“A study conducted at the Changhua Christian Hospital on nearly 100,000 women with Volpara Density, showed 82.1 percent of their population had dense breasts, compared to a more typical 40 to 50 percent in the West,” Dr Highnam said.
Volpara fell half a cent or 0.7 percent to 69 cents.

TBG BIOTECHNOLOGY CORP (FORMERLY PROGEN)

TBG says the China Food and Drug Administration has approved its portfolio of high resolution human leukocyte antigen (HLA) genotyping kits.
TBG said the kits were used widely in haematopoietic cell transplantation in the treatment of leukaemia, lymphoma, aplastic anaemia and myelodysplastic syndromes.
The company said that by law in China, once an approved product was available, all clinical laboratories should use approved products for clinical testing.
TBG said its HLAssure SE SBT kits would be the only marketed products that could fulfil the requirement for high resolution HLA genotyping, with the approval covering the primary genetic targets used for assessing donor-recipient compatibility.
Other applications included autoimmune diseases and drug hypersensitivity prediction.
TBG Xiamen president Ifan Chiu said that China had “one of the fastest growing allogeneic HCT markets … [and TBG was] determined to be the first to provide a CFDA approved high resolution typing solution for the HLA typing laboratories in China”.
TBG said the growth in transplantations was partly due to the increasing availability of compatible donors and all donors required HLA typing and it was in discussion with distributors and service providers.
TBG chief operations officer Eugene Cheng said the company had focused on China as one of its key markets.
TBG was untraded at 8.8 cents.

ONCOSIL MEDICAL

Oncosil says that 14-patient results from its 300 patient pivotal Brachysil for pancreatic cancer trial has shown 100 percent disease control at eight weeks.

Oncosil said the trial, which incorporates its 20-patient Conformité Européenne (CE) mark application study showed up to 73 percent volumetric reduction at four weeks post implant, with median volumetric reduction of 34.5 percent.

The company said that it had recorded no serious adverse events attributed to the device or implantation procedure, which was delivered through endoscopic ultrasound.

Oncosil said that data from the first group of patients who completed computed tomography imaging in the eight, 16 and 24-week study follow-up periods was presented by chief medical officer Dr Ashish Soman at the European Association of Nuclear Medicine meeting in Vienna on October 21, 2017.

Oncosil chief executive officer Daniel Kenny said “the results demonstrate excellent local disease control in subjects at week-8, [and] evidence the down-staging potential of the Oncosil device”.

“The early and substantial volumetric reductions seen in patients four weeks post implant were particularly pleasing to see,” Mr Kenny said.

“We are satisfied that the Oncosil device is clinically de-risked on the basis of these early emerging data,” Mr Kenny said.

Melbourne’s Monash Medical Health principal investigator Dr Marion Harris said her group was “encouraged by the positive early data from the first group of patients completing the week eight and 16 follow-up periods”.

“The Oncosil device has a reassuring safety profile with no serious adverse events attributed to the device or implantation procedure,” Dr Harris said

Monash surgeon Dr Dan Croagh said “we have been able to successfully implant Oncosil on eight occasions with no obvious complications related to the implantation procedure”.

Oncosil fell one cent or 6.1 percent to 15.5 cents with 7.8 million shares traded.

RECCE

Recce says its share purchase plan at 17 cents a share raised $946,500 of a hoped-for $1 million, from 171 shareholders applying for a total of 5,408,487 shares.

Last month, Recce said the funds would be used for its investigational new drug application to the US Food and Drug Administration for its Recce 327 antibiotic and for working capital (BD: Sep 27, 2017).

Recce was unchanged at 18.5 cents.

ESENSE-LAB

Esense says it has a binding distribution agreement with Singapore’s Advanced Technology Management Pte Ltd for its synthetic marijuana terpene products.

Esense said that Advanced Technology specialized in cross-border business development, advising setting-up and managing business centres in Asia.

The company said Advanced Technology agreed to purchase a minimum quantity of its products within the first 12 months valuing the one-year agreement between $US540,000 and $US600,000 ($A689,511 to $766,123) depending on the type of products purchased.

Esense chief executive officer Haim Cohen said he was “very pleased that Esense has executed another significant commercial order for its unique medical cannabis terpene profiles”.

Esense was up one cent or 4.1 percent to 25.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says a retrospective analysis shows its Naturalvue multifocal contact lenses slow the progression of myopia, or near-sightedness in children.

Visioneering said the Naturalvue MF contact lenses with its Neurofocus optics technology used an extended depth-of-focus design to address known optical risk factors associated with the progression of myopia.

The company said the retrospective case-study analysis reviewed the patients records of 32 children aged six to 19 years, from 10 US practices.

Visioneering said at initial presentation, the children wore a mix of glasses, spherical soft contact lenses correcting near-sighted vision, other brands of soft multifocal contact lenses, or orthokeratology lenses, which were hard contact lenses worn overnight while the child sleeps.

The company said that all participants had some degree of myopia and their vision products were replaced with its Naturalvue MF contact lenses.

Visioneering said myopia progression was measured over the following six to 25 months and annualized for direct comparison to each child's historical annualized myopic progression, which served as the control.

The company said the study, entitled 'Case Series Analysis of Myopic Progression Control with a Unique Extended Depth of Focus Multifocal Contact Lens', was co-authored by chief medical officer Sally Dillehay and published in the journal Eye and Contact Lens, with an abstract at: https://www.ncbi.nlm.nih.gov/pubmed/29053555.

The company said that study documented an approximately 96 percent reduction, averaging both eyes, of annualized myopic progression, with 98.4 percent of the children showing a decrease in the rate of worsening of their myopia.

Visioneering said the most frequent amount of the reduction in the myopic progression was 100 percent, meaning that complete halting of myopia progression was the most common result in the children.

The company said that 81.25 percent, or 26 children, had complete halting of myopic progression during the time period of the study, including 6.25 percent, or two children, demonstrating some reversal of their myopia.

Visioneering said slowing the myopia progression was achieved while providing the children with vision equivalent to that of glasses, with high levels of comfort, with children as young as six years old trained to insert and remove contact lenses.

The company said the findings were "particularly significant in that myopia has reached near global epidemic proportions" and the rate of myopia in the US has doubled since the 1970s and reached 80percent or more of children in a number of Asian countries.

Visioneering said that in Australia, which historically had low rates of myopia, the rate in 12-year-old children of European Caucasian descent doubled from 2005 to 2011 and in addition to the increasing prevalence, myopia's magnitude had increased.

The company said that myopia had been identified as the sixth leading cause of vision loss and had been shown to be associated with increased risks of myopic macular degeneration, retinal detachment, glaucoma and cataracts.

The study's lead author, State University of New York College of Optometry Prof Jeffrey Cooper said that "nearly five billion people are predicted to be affected by myopia by 2050, the majority of them children".

Visioneering chief executive officer Dr Stephen Snowdy said that combined with the enormous medical and economic costs of treating the serious eye diseases that come with myopia, myopia deserves the respect of a global epidemic".

Visioneering fell half a cent or 1.3 percent to 39 cents.

IMPEDIMED

Impedimed says it has begun initial shipments of its Sozo bio-impedance body mass assessment systems with its L-Dex technology for lymphoedema to US customers.
Impedimed said the platform allowed “more effective and efficient patient care” and gave large institutions the option of placing devices in multiple locations and integrating the data into a single patient record.
The company said the system was being sold to hospitals and clinicians with an annual licencing contract for the ongoing use of Sozo, with existing customers the initial target for the first phase of the US launch.
Impedimed chief executive officer Richard Carreon said that the initial Sozo feedback was “very positive”.
“In addition to these early shipments, we have received feedback from many existing customers that are looking to add more Sozo units than U400s and they have started including Sozo purchases in their current budgets,” Mr Carreon said.
The U400 was the company’s previous L-Dex device platform
“A number of our largest customers will be expanding their programs from testing only high-risk breast cancers patients to all cancer survivors who are at risk of developing unilateral lymphoedema in their upper or lower extremities,” Mr Carreon said.
Separately, Impedimed said the largest study to date on the effectiveness of the L-Dex for screening, intervention and prevention of disease progression to irreversible stages had been published in The Breast Journal.
In May, Impedimed said the independent, six-year, 596-patient, Nashville study followed breast cancer patients at risk for the development of lymphoedema and showed its L-Dex lymphoedema test could reduce the rates of incidence to three percent from the generally reported seven to 36 percent rate (BD: May 18, 2017).
Today the company said that at the last follow-up, 18 patients (3.0%) had unresolved clinically significant breast cancer-related lymphoedema requiring complete decongestive physiotherapy, a surrogate for the development of clinically significant, chronic breast cancer-related lymphoedema.
Mr Carreon said the published journal article “adds to the mounting peer-reviewed evidence supporting the positive clinical impact of prospective surveillance using L-Dex in limiting this extremely debilitating and lifelong morbidity”.
Study lead author and breast surgical oncologist Dr Pat Whitworth said that lymphoedema was a major concern for women with breast cancer.
“Our patients' relief is palpable when we explain that we can now detect fluid accumulation and intervene with four weeks of simple compression sleeve prior to any swelling, preventing clinical lymphoedema in all but a few cases,” Dr Whitworth said.
“That is a huge advance from prescribing tape measures and restrictions that don't really help,” Dr Whitworth said.
Impedimed was up one cent or 1.35 percent to 75 cents with 3.2 million shares traded.

RHINOMED

Friday’s edition implied that a 100-shop “test and learn” trial of its Mute anti-snoring nasal dilators might have been through the New York-based Duane Reade drug store chain.
Rhinomed said the trial was in 100 shops of an unnamed American pharmacy chain.
Biotech Daily apologizes unreservedly for the implication.
Rhinomed was up one cent or 5.6 percent to 19 cents.

BENITEC BIOPHARMA

Benitec has told the ASX that last week's patent news was not material, despite being marked so, and a 20 percent price jump might relate to a US gene therapy approval.
The ASX said the company's share price increased from 15 cents on October 17, by three cents or 20 percent to 18 cents prior to the release of the announcement on October 18 and a further increase to a high of 19.0 cents following the announcement and noted a significant increase in the share trading volume.
Benitec said it did "not consider approval of this patent to be material price sensitive information" because it already held two related patents and patent was for its hepatitis B program which it said it would not continue without a partner.
The company said that about October 13, 2017, a US Food and Drug Administration committee unanimously approved of Spark Therapeutics AAV based gene therapy.
Benitec said the Nasdaq share price for gene therapy stocks increased in recent weeks "which may be a reason for or contributing factor to the increase in the … share price".
Benitec was up one cent or 5.9 percent to 18 cents.

BRAIN RESOURCE

Brain has requested a trading halt "pending a material announcement to the market concerning a capital raising".
Trading will resume on October 25, 2017 or on an earlier announcement.
In March, Brain raised $1,000,000 at eight cents a share (BD: Mar 30, 2017).
Brain last traded at 6.2 cents.

GENETIC TECHNOLOGICS

Genetic Technologies annual general meeting will vote to grant chief executive officer Eutillio Buccilli 14,250,000 options.
The Genetic Technologies notice said the options would vest in three tranches on issue and at one year and two years, exercisable at the lower of one cent or the 5-day volume-weighted average price to the date of the meeting.
The company said that shareholders would vote to approve the increased placement capacity, renew that employee option plan, re-elect director Dr Paul Kasian Buccilli and adopt the remuneration report.
In 2015, Genetic Technologies voted overwhelmingly to grant Mr Buccilli 14,236,111 options exercisable at two cents each within five years from issue.
The meeting will be held at Treetops, Melbourne Museum, 11 Nicholson Street, Carlton on November 23, 2017 at 10.30am (AEDT).
Genetic Technologies was unchanged at 0.8 cents.

CELLMID

Cellmid says its annual general meeting will vote on a 20-to-one stock consolidation.
Cellmid said that shareholders would vote on the remuneration report, the appointment of Grant Thornton as its auditor replacing BDO East Coast Partnership, the ratification of the prior issue of 99,000,000 placement shares at 0.3 cents a share and the elect of directors Dr Martin Cross and Dr Edward Fintan Walton.
The meeting will be held at BDO, Level 11, 1 Margaret Street, Sydney, on November 23, 2017, at 9.30am (AEDT).
Cellmid was up 0.1 cents or 4.35 percent to 2.4 cents.

AVITA MEDICAL

One Funds Management says it has increased its holding in Avita from 56,125,447 shares (8.34%) to 78,347,669 shares (10.12%).
The Sydney-based One Funds Asia-Pacific Healthcare Fund II said it acquired 22,222,222 shares for $1,000,000 or 4.5 cents a share in a placement that raised $4.5 million, with a rights issue underway for a further $12.4 million (BD: Oct 11, 2017).
The Melbourne-based Bioscience Managers (formerly IB Managers) website said that the Asia Pacific Healthcare Fund II was a 10-year Australian unit trust equity style fund of $55 million, with One Funds a Bioscience Managers trustee.
Avita fell 0.1 cents or 1.85 percent to 5.3 cents.

MEDIGARD

Medigard says that Dr Chris Bishop has replaced Don Channer as chairman effective from the board meeting on October 20, 2017.
Medigard said Mr Channer was its chairman since incorporation and he “considers that now is an appropriate time to retire as Medigard moves towards its next phase” continuing as a non-executive director.
The company said that Dr Bishop had been a non-executive director since 2008 and had experience in the development and commercialization of a range of technologies.
Medigard was untraded at 1.5 cents.