Biotech Daily

Tuesday October 23, 2018

Daily news on ASX-listed biotechnology companies

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*** BARD 1: 'BREAST CANCER BLOOD TEST 86% ACCURATE'**

*** TELIX STARTS ZIRCON TLX250 RENAL CANCER IMAGING TRIAL**

*** PHOSPHAGENICS $425m MYLAN CASE 'PROGRESS'**

*** NUHEARA RECEIVES $1.9m FEDERAL R&D TAX INCENTIVE**

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*** INVITROCUE APPOINTS DR GARY PACE DIRECTOR**

*** ANATARA APPOINTS PRODUCT DEVELOPMENT ADVISORY BOARD**

*** NEUROTECH: PROF EMANUELA RUSSO CSO, ADVISORY BOARD**

*** STEMCELL GLENN DAVIES, EE TING NG IN; CHAIR JAMIE KHOO OUT**

MARKET REPORT

The Australian Stock Market fell 1.05 percent on Tuesday October 23, 2018 with the ASX200 down 61.8 points to 5,843.1 points. Ten of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and six were untraded. All three Big Caps fell.

Benitec was the best, up three cents or 17.1 percent to 20.5 cents with 1.3 million shares traded. Prana climbed 13.6 percent; Dimerix was up 9.1 percent; Impedimed improved 6.3 percent; LBT and Orthocell were up more than four percent; Airxpanders rose 2.8 percent; Optiscan and Prescient were up more than one percent; with Pro Medicus up 0.1 percent.

Avita led the falls, down 0.9 cents or 8.6 percent to 9.6 cents, with 6.3 million shares traded. Cynata and Uscom lost more than six percent; Neuren fell 5.8 percent; Cochlear, Pharmaxis and Volpara were down more than three percent; Bionomics, Compumedics, Immutep, Mesoblast, Opthea, Osprey and Starpharma shed more than two percent; with Clinuvel, CSL and Factor down more than one percent.

BARD1 LIFE SCIENCES

Bard1 says its breast cancer test has an overall accuracy of 86 percent with 70 percent sensitivity, 88 percent specificity and can tell malignant cancer from benign lesions.

In September, Bard 1 says its ovarian cancer test combined with the CA125 blood test has shown an average 0.97 “area under the curve” or 97 percent accuracy, with 89 percent sensitivity (true positives) and 97 percent specificity (true negatives) in the detection of ovarian cancer across all cancer stages (BD: Sep 6, 2018).

Today, Bard1 said the breast cancer blood test used the same diagnostic platform as the its ovarian cancer test and it planned to develop both tests in parallel using the same Luminex instrumentation platform.

The company said there was “currently no blood test available for screening or early detection of breast cancer” and the test “could be used to screen average-risk asymptomatic women to detect breast cancer earlier, increase screening uptake, improve survival and reduce healthcare costs”.

Bard1 said the test could be used as a diagnostic aid to assess the risk of malignancy of suspicious lesions detected by mammography to determine if a lesion was benign or malignant, which currently could only be achieved with biopsies followed by histopathology-based diagnosis.

Bard1 chief executive officer Dr Leearne Hinch said the breast cancer test “addresses an unmet need for an accurate, reliable and affordable blood test to detect breast cancer early”.

Dr Hinch said the global breast cancer diagnostics market was the second largest diagnostic segment after lung cancer and valued at $US20.1 billion in 2013.

“Bard1 already has a development program for the game-changing Bard1 ovarian cancer test which has shown excellent diagnostic accuracy for early detection of ovarian cancer”.

“The new Bard1 breast cancer test is a world-first blood test in development for early detection of breast cancer, has demonstrated high diagnostic accuracy to detect breast cancer across common breast cancer types and all stages, and is based on the same Bard1 autoantibody test methodology and Luminex instrumentation enabling fast development and clinical testing in parallel with the Bard1 ovarian cancer test,” Dr Hinch said.

Bard1 said that its breast and ovarian cancer tests could follow BRCA1 and BRCA2 genetic testing and “provide the tool that makes it possible to regularly monitor high-risk women to detect cancer early”.

Bard1 executive director and chief scientific officer Dr Irmgard Irminger-Finger said that women with identified mutations in BRCA1/2 would undergo Bard1 breast and ovarian cancer tests and if cancer was detected they would be directed to further testing including mammography, transvaginal ultrasound and biopsies to determine the best treatment pathway.

“Women identified positively for BRCA1/2 mutations and negative for Bard1 tests should be advised to undergo Bard1 breast [and] ovarian tests in six-monthly intervals to enable early detection of breast or ovarian cancer,” Dr Irmgard Irminger-Finger said.

Bard1 said it planned to conduct additional breast cancer studies to further develop, optimize and evaluate the breast cancer for early detection of breast cancer in larger cohorts comprising different breast cancer types and stages, benign breast lesions, and healthy controls to further improve the diagnostic accuracy of Bard1 BC for early detection of breast cancer.

Bard 1 was up three cents or 214.3 percent to 4.4 cents with 1,084.0 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has been approved to begin recruitment to its 250-patient Zircon phase III imaging trial of TLX250, or 89-zirconium-girentuximab, for clear cell renal cell cancer.
Telix said it had completed Australian Therapeutic Goods Administration clinical trial notification submission for four Australian trial sites, received its first ethics approval and was submitting applications to European regulatory authorities and clinical sites.
Telix chief executive officer Dr Christian Behrenbruch said that "as an Australian … company, it's very pleasing to be able to start to recruit patients in our own backyard while we finalize the regulatory documentation in the various international jurisdictions".
"Our [European Union] submissions are progressing well with several key review milestones in November that should enable us to bring further international sites online before end-year," Dr Behrenbruch said.
Telix said the prospective zirconium imaging in renal cancer oncology, or Zircon, study was a multi-centre, phase III study with at least 15 sites in Europe, Australia and the US, subject to regulatory approval.
The company said the trial of 250 renal cancer patients undergoing kidney surgery would determine the sensitivity and specificity of the TLX250 companion diagnostic positron emission tomography (TLX250-CDx-PET) imaging to detect clear cell renal cell cancer in comparison with histologic "ground truth" determined from surgical resection specimens.
Telix fell half a cent or 0.5 percent to 92.5 cents.

PHOSPHAGENICS

Phosphagenics says the Singapore International Arbitration Centre has progressed its arbitration of the $US300 million ($A424.5 million) Mylan Laboratories case.
In September, Phosphagenics said the Singapore International Arbitration Centre expected a draft decision "shortly" (BD: Sep 4, 10, 2018).
The Centre said in September that on receipt of its tribunal's "draft award … [it would] endeavor to expedite the scrutiny which typically takes at least three weeks".
Last year, Phosphagenics said it had filed its expert reports in the Mylan arbitration, including a $US300 million damages claim over Mylan's licence of its tocopheryl phosphate mixture (TPM) daptomycin for skin infections and staphylococcus aureus bloodstream infections licenced to Strides Arcolab subsidiary, the India-based Agila Specialties, acquired by Mylan in 2013 (BD: Oct 30, 2012; Mar 3, May 29, 2017).
Today, the Centre said: "We note that the Tribunal submitted the draft award to SIAC, and we have now returned the same to the Tribunal today."
"Once the Tribunal has reviewed SIAC's comments and has finalized the award, we will issue it to the parties," the Centre said.
Phosphagenics said that neither the Centre nor the Tribunal had indicated when the parties may receive the final award.
Phosphagenics climbed 0.3 cents or 15.0 percent to 2.3 cents with 4.2 million shares traded.

NUHEARA

Nuheara says it has received $1,940,741 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Nuheara said that the funds related to expenses in the year to June 30, 2018.
Nuheara was up 0.1 cents or 1.3 percent to 7.7 cents with 1.0 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Hong Kong has approved its Penthrox inhaled methoxyflurane analgesic.

Medical Developments said that the registration was issued by the Hong Kong Pharmacy and Poisons Board approving Penthrox for "the emergency relief of pain by self-administration in conscious haemodynamically stable patients with trauma and associated pain, under supervision of personnel trained in its use and the relief of pain in monitored conscious patients who require analgesia for surgical procedures".

Medical Developments chief executive officer John Sharman said Hong Kong was "an important market in Asia and we believe this approval will have a positive influence within the region and on achieving Penthrox's approval in China".

"Importantly, the approval is for both trauma pain and surgical procedures and includes the use of Penthrox for children," Mr Sharman said.

Mr Sharman said a subsidiary of Clinigen Group Plc was its Hong Kong distribution partner with sales to begin in 2019.

Medical Developments chairman David Williams said the Hong Kong registration complemented the distribution agreement with Daiichi Sankyo for China.

Medical Developments fell three cents or 0.6 percent to $4.90.

ORTHOCELL

Orthocell says it has been granted a Japanese patent for its Celgro collagen medical device platform for soft tissue regeneration and repair applications.

Orthocell said the patent titled 'A Medical Procedure Kit and A Related Method' "provides additional important intellectual property to protect the Celgro product platform" and expires on June 5, 2037.

Orthocell managing-director Paul Anderson said the company was "focused on building and maintaining patent protection for our technologies and treatment processes".

"Securing this patent for soft tissue repair in Japan is another milestone in strengthening our [intellectual property] position in key global markets and compliments the progression of our products through the registration processes in key markets," Mr Anderson said.

Orthocell said that Celgro patents had been granted in the US, China, Canada, Singapore, Australia and New Zealand

The company said that Celgro was a customizable collagen medical device with "numerous competitive advantages over existing synthetic and biologic tissue repair devices, particularly in the areas of cell compatibility, tensile strength and the promotion of quality tissue in growth and repair … [and had been shown] to improve tissue in-growth and repair in clinical studies using the collagen medical device to guide bone regeneration within the jaw and [was] currently being assessed for performance in the rotator cuff tendon within the shoulder, to assist in the re-joining of severed, or damaged peripheral nerves and repair of articular cartilage in the hip".

Orthocell was up one cent or 4.4 percent to 23.5 cents.

RESONANCE HEALTH

Resonance has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 86.4 percent from 2.2 cents on October 16 to 4.1 cents today October 23, 2018 and noted a "significant increase" in trading volume.

Resonance was up 0.6 cents or 20.7 percent to 3.5 cents with 64.8 million shares traded.

FISHER & PAYKEL HEALTHCARE CORP, RESMED

Fisher & Paykel says the Munich Regional Court has found the headgear for two of its masks used in the treatment of obstructive sleep apnoea infringed a Resmed patent.
Fisher & Paykel said that the ruling would not impact the sale or supply of the affected masks.
The company said that the Court ruled that Resmed patent EP '368 was infringed by the headgear for Fisher & Paykel Healthcare's Simplus and Eson 2 masks.
Fisher & Paykel said the decision could be appealed to the Munich Higher Regional Court.
The company said it had earlier appealed a decision of the European Patent Office regarding the validity of these patent claims and if successful, the appeal would invalidate the claims that the Munich Regional Court found to be infringed.
Fisher & Paykel said two other patents asserted by Resmed in Germany against the Simplus and Eson 2 masks were stayed pending the outcome of its challenges to their validity in the European Patent Office.
The company said the decision was also separate to patent EP '271 being asserted by Fisher & Paykel Healthcare in relation to Resmed's Airsense 10 and Aircurve 10 range of flow generator products and Lumis series of non-invasive ventilators, which was currently stayed, also pending a validity evaluation by the European Patent Office.
Fisher & Paykel fell 31 cents or 2.4 percent to $12.39 with 468,161 shares traded.
Resmed fell two cents or 0.1 percent to $14.35 with 2.5 million shares traded.

CORRECTION: RESAPP

Last night's edition carried an incorrect headline for the Resapp trading halt request.
The correct headline should have read: "Resapp requests 'Smartcough-C-2 trial' trading halt" and not "Resapp requests 'Sleep Apnoea trial' trading halt".
The mistake was made by the Monday sub-editor who had no problem sleeping on the job and is currently looking for new employment opportunities.
Resapp last traded at 22 cents.

IDT AUSTRALIA

IDT lost its 'second strike' remuneration vote with 32.95 percent opposed but won the consequent spill resolution with 65.94 percent of the vote.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed by more than 50 percent of votes the directors must stand for reelection.
Last year, IDT said it faced 48.8 percent opposition to the remuneration report and today's vote triggered an automatic spill resolution (BD: Oct 24, 2017).
In 2012, IDT faced 27.5 percent against the remuneration report and the subsequent spill resolution failed with 73.6 percent against.
Today, IDT said that 39,166,704 votes supported the spill resolution and the company's 2018 annual report said it had 244,466,732 shares on issue, meaning that the votes for a spill amounted to 16.0 percent, sufficient to requisition extraordinary general meetings.
Resolutions to re-elect directors Alan Fisher and Hugh Burrill were passed but with 28.6 percent and 15.8 percent opposition, respectively.
IDT was up one cent or 6.25 percent to 17 cents.

PATRYS

Patrys says that shareholders will vote to approve the issue of 24,000,000 options to four directors and increase the directors fee pool 60 percent to $400,000 a year.
Patrys said it proposed to grant chief executive officer Dr James Campbell 10,000,000 options, chairman John Read 6,000,000 options and directors Michael Stork and Suzy Jones 4,000,000 options each.
The company said that 6,000,000 options would vest immediately, 9,000,000 options at 12 months if the share price was equal to or greater than a 20-day volume-weighted average price of 5.0 cents, with 9,000,000 options vesting at 24 months with a share price equal to or greater than a 20-day volume-weighted average price of 7.0 cents.
Patrys said the exercise price would be a 30 percent premium to the 5-day volume-weighted average price from board approval, expiring on November 22, 2023.
The company said the meeting would vote on the remuneration report, re-elect director Mr Stork, ratify three prior share issues and approve the 10 percent placement facility.
The meeting will be held at Arnold Bloch Leibler, Level 21, 333 Collins Street, Melbourne on November 22, 2016 at 12pm (AEDT).
Patrys was unchanged at 3.4 cents with 1.5 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm has requested a trading halt “to finalize … a potential capital raise”.
Trading will resume on October 25, 2018 or on an earlier announcement.
Paradigm last traded at 73 cents.

ESENSE-LAB

Esense says it has a two-year supply agreement for the supply of marijuana terpenes to the Romsey, England-based, E-Quits Group trading as Lonjas UK.
Esense said E-Quits would buy its Super Lemon Haze Mix for integration into a variety of products to be marketed in the UK, including terpenes for the food additive market.
The company said that E-Quits had acquiring other “electronic liquid” manufacturers for use with vaporizers, including Lonjas UK and Proof E-liquids, and had established a retail distribution company called Vaping Warehouse.
Esense was up 1.2 cents or 19.05 percent to 7.5 cents with 16.5 million shares traded.

BIOTRON

Biotron says it has appointed World Health Organisation regional reference laboratory for hepatitis B and D director Prof Stephen Locarnini as a director, effective from today.
Biotron said that Prof Locarnini was named on more than 20 granted patents, the author of 289 peer-reviewed articles, 24 invited editorials and 100 book chapters and reviews.
The company said Prof Locarnini previously worked at Melbourne’s Victorian Infectious Diseases Reference Laboratory and oversaw the amalgamation of all the Fairfield laboratories into one service at Melbourne Health.
Biotron said that Prof Locarnini was currently an academic at the University of Melbourne.
The company said that Prof Locarnini held a Bachelor of Science from Melbourne’s Monash University, a Bachelor of Medicine and Bachelor of Surgery form the University of Melbourne and a Doctor of Philosophy from Monash University.
Biotron fell 3.5 cents or 13.7 percent to 22 cents with 40.6 million shares traded.

INVITROCUE

Invitrocue says it has appointed Dr Gary Pace as an independent non-executive director, effective immediately.
Invitrocue said that Dr Pace had more than 40 years of experience in the development and commercialization of life sciences and related technologies and was currently a director of Resmed, Pacira Pharmaceuticals, Simavita and Antisense Therapeutics, as well as private companies.
The company said that Dr Pace held a Bachelor of Science from the University of New South Wales and a Doctor of Philosophy from the Massachusetts Institute of Technology.
Invitrocue was untraded at 9.2 cents.

ANATARA LIFESCIENCES

Anatara says it has appointed a product development advisory board for its non-antibiotic, pineapple stem bromelain-derived gastro-intestinal health programs.
Anatara said the board would be chaired by Prof Peter Gibson and comprise Dr Rebecca Burgell, Dr Jakob Begun, Prof Barry Campbell and Prof Simon Keely and provide advice on issues relating to research priorities, strategies and product development programs
Anatara fell two cents or five percent to 38 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has promoted former head of research Prof Emanuela Russo to chief scientific officer and appointed a scientific advisory board.
Neurotech said that Prof Russo had been the head of research since 2016 and was a cognitive neuroscientist and a clinical psychologist.
The company said that Prof Russo was previously a professor at the University of Rome and holds a Doctor of Philosophy from the University of Rome.
The company said that the scientific advisory board comprised chairman Dr David Cantor; Prof Russo, Dr Tanju Surmeli and Dr Evian Gordon.
Neurotech fell one cent or 10.1 percent to 8.9 cents.

STEMCELL UNITED

Stemcell says it has appointed Glenn Davies and Ee Ting Ng as directors, chair Jamie Khoo will depart the company and chief executive officer Philip Gu will be acting chair.
Stemcell said that Mr Gu would be acting chair while the board looked for a suitable candidate and Ms Khoo would continue as an advisor.
The company said that Mr Davies had 25 years of experience leading private and public organizations, was the founder of marijuana company Cannacubed which had operations in China, Israel, Los Angeles and Africa, and was the director-general of the Asian Federation of Corporate Football, organization governing corporate football in Asia.
Stemcell said that Ms Ng held a Bachelor of Science and had more than 10 years research experience in developmental and evolutionary biology, was a cosmetic chemist with more than eight years formulation experience, held a Diploma in Cosmetic Science, and was currently a director of Invitrocue.
Stemcell fell 0.2 cents or 6.9 percent to 2.7 cents with 8.0 million shares traded.