Biotech Daily

Thursday September 6, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMMUTEP UP 9%; REVA DOWN 11%**

*** FEDERAL GOVERNMENT, MOVEMBER $12m FOR PROSTATE CANCER**

*** BARD1 OVARIAN CANCER TEST '97% ACCURATE'**

*** MEDIBIO CLAIMS HEART RHYTHM DEPRESSION TEST '70% ACCURATE'**

*** EYEPOINT (PSIVIDA) C-CODE REIMBURSEMENT FOR DEXYCU**

*** REGENEUS RECEIVES $2.4m FEDERAL R&D TAX INCENTIVE**

*** NUHEARA RECEIVES $145k EXPORT GRANTS**

*** FACTOR: LEG ULCER TRIAL RESULTS IN NOVEMBER**

*** MGC: AM MANGION EUROPE, MID EAST, NTH AFRICA DISTRIBUTOR**

*** BLUECHIIP REQUESTS CAPITAL RAISING TRADING HALT**

*** VIVO TAKES 19.9% OF AIRXPANDERS**

*** NOVITA APPOINTS SUE MACLEMAN CHAIR**

*** AUTOMIC'S LEE TAMPLIN REPLACES CELLMID CO SEC RAYMOND TING**

*** SUDA APPOINTS PROF STEPHEN WATSON ANAGRELIDE ADVISOR**

MARKET REPORT

The Australian stock market fell 1.12 percent on Thursday September 6, 2018 with the ASX200 down 70.0 points to 6,160.4 points. Seven of the Biotech Daily Top 40 stocks were up, 20 fell, 11 traded unchanged and two were untraded. All three Big Caps fell.

Immutep was the best, up 0.3 cents or 8.8 percent to 3.7 cents with 20.15 million shares traded. Prescient climbed 7.1 percent; Avita and Genetic Signatures improved five percent or more; Clinuvel was up four percent; Starpharma rose 2.7 percent; with Sirtex up 1.4 percent.

Yesterday's 12.5 percent best, Reva, led the falls, down three cents or 11.1 percent to 24 cents, with 6,003 shares traded. Neuren lost 9.7 percent; Impedimed fell 8.9 percent; Cochlear shed 6.1 percent; Polynovo was down 5.3 percent; Airxpanders, CSL, Imugene, LBT and Pharmaxis fell more than four percent; Ellex, Nanosonics and Optiscan were down more than three percent; Benitec, Medical Developments, Pro Medicus and Universal Biosensors shed two percent or more; Actinogen, Cynata, Opthea, Resmed and Telix were down more than one percent; with Mesoblast down 0.3 percent.

FEDERAL GOVERNMENT

The Federal Government says that with the Movember Foundation it will provide $12 million for prostate cancer research.

A media release from Federal Health Minister Greg Hunt said that prostate cancer was "Australia's second most deadly cancer, claiming the lives of around 3,500 men in 2018" and 17,000 Australian men were diagnosed with prostate cancer each year.

The Government said that prostate cancer was a complex disease that caused a range of health problems including bladder or bowel incontinence, sexual dysfunction and psychological trauma.

The media release said that the funding would establish the Prostate Cancer Research Alliance, comprising research teams focused on prostate cancer research to prevent prostate cancer progressing to advanced, more deadly stages and improve treatments and life expectancy for men with advanced prostate cancer.

The Government said that similar collaborations such as the UK's Centres of Excellence for prostate cancer research, established by the Movember Foundation, had "delivered new medications and treatments that have extended or improved the quality of life of thousands of patients".

Mr Hunt said that the Government was "committed to improving men's health".

"Men experience worse longer-term health than women and die on average six years earlier," Mr Hunt said.

The Government media release said it would provide $6 million over three years for the Prostate Cancer Research Alliance, matched by the Movember Foundation.

The media release said that submissions to establish the research teams would open "in the coming months" and cancer research teams were encouraged to apply.

BARD1 LIFE SCIENCES

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.

Bard1 said the 261-patient study compared blood plasma samples from 134 healthy controls with 127 women who had family histories of breast or ovarian cancers or genetic mutations that predisposed to breast or ovarian cancer.

The company said its test demonstrated 89 percent sensitivity (true positives) and 97 percent specificity (true negatives) in the detection of ovarian cancer across all cancer stages, but did not provide "p" probability values.

Bard1 said the results "demonstrated the high diagnostic accuracy of the improved BARD1-Ovarian test for detection of ovarian cancer in high-risk women across all cancer stages" with an average "area under the curve" of 0.99 in training sets, and an average area under the curve of 0.97 in the cross-validation test sets.

Bard1 said the sensitivity of the test for detection of ovarian cancer was highest in women with BRCA1/BARD1 mutations, showing 100 percent sensitivity at fixed 90 percent specificity, and was independent of cancer stage, which was expected as BARD1 formed a complex and acted with BRCA1 in healthy people to suppress cancer.

Bard1 chief scientific officer Dr Irmgard Irminger-Finger said that "as people have become aware of their genetic make-up and predisposition to disease, they want to take action to protect their health".

"Bard1-ovarian [cancer test] has demonstrated high accuracy to detect ovarian cancer at early stages and these latest research findings underline how significant the test can be in routine screening of high-risk women," Dr Irminger-Finger said.

Bard1 fell 0.1 cents or 7.7 percent to 1.2 cents with 28.1 million shares traded.

MEDIBIO

Medibio says its cardiac rhythm diagnostic algorithm has shown 70 percent sensitivity and 71 percent specificity in diagnosing a major depressive episode.
Medibio said 82 of 230 patients completed the full-course monitoring for the study consisting of four scans over two weeks.
The company said that for patients who completed the full-course of the study, sensitivity (accurate positives) in identifying a major depressive episode was 70 percent (p = 0.098) and specificity (accurate negatives) was 71 percent (p = .073).
Medibio said that for the patients who completed between one and three scans, sensitivity was 60 to 69 percent and specificity was 63 to 64 percent and the results indicated its algorithm was a “20 to 40 percent improvement from [the] current diagnostic standard”.
Medibio said the primary endpoint of the study was assessing the specificity and sensitivity of the algorithm and the secondary efficacy endpoint was the repeatability of the algorithm in accurately identifying a major depressive episode.
The company said the trial was pivotal in the filing of a de novo application for its cardiac rhythm diagnostic with the US Food and Drug Administration (BD: Jul 16, 2018).
Medibio fell three cents or 21.4 percent to 11 cents with 2.1 million shares traded.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA)

Eyepoint says the US Centres for Medicare and Medicaid Services (CMS) has approved “transitional pass-through status” and reimbursement for its Dexycu therapy.
Eyepoint said that CMS approved a “C-code”, for Dexycu, or 9.0 percent dexamethasone intraocular suspension, for post-operative inflammation, administered as a single intraocular dose at the end of ocular surgery.
Eyepoint said the code, C9034, would be effective from October 1, 2018.
The CMS website said that C-codes were “unique temporary pricing codes established by CMS for the prospective payment system … only valid for Medicare on claims for hospital outpatient department services and procedures”.
Eyepoint said that about 40 percent of cataract surgery patients were covered by Medicare Part B and drugs administered as part of the cataract surgery procedure could be covered under a CMS transitional-pass-through payment, a system established by the US Government to help foster innovative drug development.
The company said the pass-through status was temporary for three years.
Eyepoint chief executive officer Nancy Lurker said the pass-through status and the assignment of a C-code from CMS “marks another important step forward in our commercialization preparation for Dexycu”.
“Our team continues to make progress on our commercialization strategy, hiring and scale-up initiatives in support of our planned commercial launch expected in the first half of 2019,” Ms Lurker said. “We believe Dexycu has the potential to address the unmet need and limitations of steroid drops, the current standard of care available for patients to treat inflammation following eye surgery, by providing Dexycu as a convenient and long-acting single injection alternative therapy.”
In March, the then Psivida said it would raise $US65 million, take a loan of $US20 million, buy the Newark, California-based Icon Bioscience for Dexycu, which was the first long-acting intra-ocular product approved by the US Food and Drug Administration for the treatment of post-operative inflammation in the eye, rebrand as Eyepoint Pharmaceuticals and delist from the ASX (BD: Mar 29, 2018).
On the Nasdaq, Eyepoint fell nine US cents or 4.07 percent to $US2.12 ($A2.95) with 174,036 shares traded.

REGENEUS

Regeneus says it has received $2,356,937 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Regeneus said the rebate related to research and development expenditure for the year to June 30, 2018.
The company said it would use the funds “to progress its regenerative medicine product pipeline”.
Regeneus was unchanged at 17.5 cents.

NUHEARA

Nuheara says it has received $145,599 in Federal Government export marketing development grants for export expenses beginning in 2016.
The company said the Federal Government’s export marketing development grants reimbursed up to 50 percent of eligible export promotion expenses above $5,000 and provided up to eight grants to each eligible applicant.
The company said that following a successful appeal it had received $73,440 for the 2016 financial year and $72,159 for the 2017 financial year from the Federal Government under the export marketing development grants program.
Nuheara fell 0.7 cents or 7.4 percent to 8.8 cents with 4.4 million shares traded.

FACTOR THERAPEUTICS

Factor says it expects the last patient in its phase II trial of VF-001 for venous leg ulcers will receive their final treatment in the first week of October.
Factor chief executive officer Dr Ros Wilson said completing the treatment stage of the study was “a key milestone for the study as it then triggers a final round of data cleaning and quality checks before top-line results can be analyzed in November”.
In 2016, Factor said it had treated the first of up-to 168 patients at the Florida, Miami Dade Medical Research Institute and in July the company said it had recruited the last of 156 patients (BD: Dec 20, 2016; Jul 16, 2018).
Today, the company said that it expected to release top line results in November.
Factor was unchanged at five cents.

MGC PHARMACEUTICALS

MGC says it has signed a three-year exclusive marijuana product distribution agreement with Malta’s AM Mangion.
MGC said AM Mangion would distribute its products in Malta, Italy, France, Spain, Portugal, the Middle East, North Africa and the UK.
MGC was unchanged at 5.4 cents with nine million shares traded.

BLUECHIIP

Bluechiip says it has requested a trading halt “in connection with a proposed capital raising”.
The announcement said the capital raising would be “via a placement of ordinary shares to sophisticated and professional investors”.
Trading will resume on October 10, 2018 or on an earlier announcement.
Bluechiip last traded at seven cents.

AIRXPANDERS

Vivo Ventures says it has increased its holding in Airxpanders from 50,526,477 Chess depositary instrument equivalents (CDIs) (17.6%) to 110,952,84 CDIs (19.9%).
Last week, Airxpanders said it had raised $20.3 million in a placement and underwritten rights offer at 7.5 cents a share (BD: Aug 27, 2018).
Today, the Palo Alto, California-based Vivo said it bought 20,142,123 shares, equivalent to 60,426,369 CDIs in the rights issue for $US3,367,579 ($A4,674,873) or 5.57 US cents for each CDI.
One Airxpanders US share is equivalent to three CDIs.
Airxpanders fell half a cent or 4.55 percent to 10.5 cents.

NOVITA HEALTH

Novita says it has appointed Sue MacLeman to its board as chair, effective from September 6, 2018.
Novita said Ms MacLeman was currently chair of Anatara, a director of MTP Connect and a director at Oventus (Aug 29, 2018).
Ms MacLeman held “graduate qualifications in pharmacy and post graduate qualifications in commercial law, corporate governance, business administration and marketing”.
Novita was up 0.2 cents or 5.9 percent to 3.6 cents.

CELLMID

Cellmid says Lee Tamplin has been appointed company secretary, replacing Raymond Ting, effective immediately.
Cellmid said that Mr Tamplin worked for corporate law firm Whittens & McKeough.
Mr Tamplin said told Biotech Daily that Whittens & McKeough had merged with share registry company Automic to form the Automic Group which provided professional services to small to mid-capitalization companies.
Cellmid was unchanged as 38 cents.

SUDA PHARMACEUTICALS

Suda says it has appointed Prof Stephen Watson to the scientific advisory board for its Anagrelide project for cancer.
In July, Suda said it was developing a soluble version of Anagrelide that could be administered as an oral spray (BD Jul 12, 2018).
The company said Prof Watson was a professor in cardiovascular sciences and cellular pharmacology at the UK’s University of Birmingham and was head of the Birmingham Platelet Group.
Suda said Prof Watson would join Dr Richard Franklin and Prof Nailin Li on the scientific advisory board for Anagrelide (BD: May 15, 2018).
Suda was unchanged at half a cent with two million shares traded.