Biotech Daily

Monday November 18, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: IMUGENE UP 18%; OPTISCAN DOWN 9%**

*** FDA OKAYS COCHLEAR OSIA 2 FOR CONDUCTIVE HEARING LOSS**

*** SINGAPORE APPROVES VISIONEERING MULTI-FOCAL LENSES**

*** CORRECTION: PALLA PHARMA**

*** ANTISENSE: 7th PATIENT DATA BACKS ATL1102 FOR DMD**

*** EMA GROUP RECOMMENDS ALTERITY'S PBT434 ORPHAN STATUS**

*** PRESCIENT TO WORK WITH CARINA FOR CAR-T CELLS**

*** OVENTUS SIGNS 2 MORE US O2VENT 'LAB-IN-LAB' SITES**

*** ADHERIUM, 'PATIENTS KNOW BEST' COLLABORATION**

*** IMUGENE EGM BACKS VAXINIA ACQUISITION**

*** US PATENT FOR DORSAVI MOTION ANALYSIS**

*** SUDA RECEIVES $928k FEDERAL R&D TAX INCENTIVE**

*** ANTEOTECH, IMRA DEAL FOR LATERAL FLOW ASSAYS**

*** HERAMED RETRACTS REVENUE FORECAST, AS WELL AS $13b TYPO**

*** FDA CLEARS HERAMED'S HERABEAT FOETAL HEART RATE MONITOR**

*** POLYNOVO 25% OPPOSE CHAIR DAVID WILLIAMS**

*** IDT SURVIVES 22.5% REMUNERATION 1st STRIKE VOTE**

*** RHYTHM RELEASES 38.5m ESCROW SHARES**

*** FOUNDER WAYNE STRINGER DECREASES TO 13% IN PROBIOTEC**

*** AVITA: DAVID MCINTYRE CFO; TIM ROONEY CAO**

*** NATHAN JONG REPLACES TOTAL BRAIN JOINT CO SEC HARVEY BUI**

MARKET REPORT

The Australian stock market fell 0.4 percent on Monday November 18, 2019, with the ASX200 down 26.9 points to 6,766.8 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 14 fell, one traded unchanged and four were untraded.

Imugene was the best, up 0.8 cents or 17.8 percent to 5.3 cents with 480.2 million shares traded. Oncosil climbed 16.7 percent; Next Science was up 14.3 percent; Prescient improved 13.6 percent; Alterity and Uscom were up 12 percent or more; Kazia rose 9.8 percent; Paradigm and Patrys climbed seven percent or more; Genetic Signatures and Pharmaxis were up six percent or more; Volpara was up 5.3 percent; Compumedics and Medical Developments were up more than four percent; Resonance was up 3.85 percent; Actinogen rose 2.3 percent; with Clinuvel, Cyclopharm, Neuren, Opthea, Orthocell and Resmed up by less than one percent.

Optiscan led the falls, down 0.4 cents or 8.7 percent to 4.2 cents, with 20,000 shares traded. Antisense fell six percent; LBT fell 5.7 percent; Immutep and Polynovo were down more than three percent; Osprey shed 2.2 percent; with CSL, Cynata, Mesoblast, Nanosonics, Pro Medicus and Proteomics down one percent or more.

COCHLEAR

Cochlear says the US Food and Drug Administration has cleared its Osia 2 system for conductive hearing loss, mixed hearing loss and single-sided sensori-neural deafness.
Cochlear said the FDA approval covered the use of the Osia 2 system for adults and children aged 12 years and older.
The company said the Osia 2 system was the “world’s first active osseo-integrated steady-state implant, using digital piezo-electric stimulation to bypass damaged areas of the natural hearing system and send sound vibrations directly to the cochlea”.
Cochlear said it would begin the US Osia 2 roll-out by the end of the year.
The company said that availability in other countries would be subject to approvals.
Cochlear fell 64 cents or 0.3 percent to $223.91 with 75,680 shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says Singapore’s Health Sciences Authority has provided medical device registration its Naturalvue multi-focal contact lenses to control myopia progression.
Visioneering said its daily contact lenses addressed presbyopia, or the loss of near vision in people over 40 years, and paediatric myopia, or nearsightedness in children.
The company said that about 80 percent of Singapore’s 18-year-olds were myopic and the country was “a large opportunity for treatments that slow the progression of myopia”.
Visioneering said that data presented in January showed that 141 children wearing Naturalvue lenses had “an average decrease of myopia progression of 90 percent, compared to the rate of progression prior to wearing Naturalvue” (BD: Jan 29, 2019).
The company said that myopia progression inhibition was consistent between children who wore the lens for one year and those who had worn the lenses for up to four years.
Visioneering said its lenses were available in powers up to -12.25 diopters, which exceeded the power availability of other myopia control products.
The company said it was approved in into Hong Kong, Europe, Australia and New Zealand and expected to launch in Canada in early 2020.
Visioneering was up 0.1 cents or 1.45 percent to seven cents.

CORRECTION: PALLA PHARMA

Friday's edition reported that Palla raised $10.1 million in a retail entitlement offer, taking the total raised in its two-for-five entitlement offer at 70 cents a share to $18.5 million.
While that is partly correct, the report did not include the institutional rights offer, which raised $12.2 million at the same time that the placement raised $8.4 million, meaning that the total raised in the fully underwritten $31.1 million capital raising was $30.7 million.
Palla said last week the shortfall shares would be allocated to Morgans Corporate and Shaw and Partners as the offer's underwriters and lead managers (BD: Nov 15, 2019).
A Palla Pharma executive told Biotech Daily that the final $422,000 would be taken up by chief executive officer Jarrod Ritchie, with a loan from the company.
The Friday sub-editor has had add-ups and subtracts re-explained and shall spend the remainder of the year on secondment to Primary Mathematics Monthly, without pay.
Palla fell five cents or 5.9 percent to 80 cents.

ANTISENSE THERAPEUTICS

Antisense says that data from seven of nine patients in its phase II trial of ATL1102 for Duchenne muscular dystrophy show continued safety and potential efficacy signals.
In September, Antisense jumped 100 percent on news that preliminary results from six patients dosed with ATL1102 for Duchenne muscular dystrophy indicated a "positive drug effect" (BD: Sep 18, 2019).
In July, Antisense said that five of the nine patients between 10 and 18 years of age had completed the 24-week dosing phase in the phase II trial at Melbourne's Royal Children's Hospital. (BD: Jul 24, 2019).
Today, the company said the additional preliminary data analyses on the seven patients who had completed 24 weeks of dosing was presented by principal investigator Dr Ian Woodcock at the Action Duchenne International Conference, in Hinkley, UK on November 15, 2019.
Antisense said that the "more detailed safety overview" provided re-confirmation that no serious adverse events had been reported to date and the data safety monitoring board had no safety concerns.
The company said that Dr Woodcock presented data on the functional capacity of the participants as evaluated by the performance of upper limb test (PUL2.0) which assessed upper limb function with the aim of reflecting the proximal (near) to distal (far) progression of muscle weakness typically observed in Duchenne muscular dystrophy.
Antisense said that the majority of participants demonstrated either increases or no change in their PUL2.0 scores from baseline after 24 weeks of dosing with ATL1102 "suggestive of an overall improvement in a key parameter of disease progression".
The company said that muscle strength was also evaluated with the data continuing to show an apparent improvement in muscle strength.
Antisense said that the results "continue to appear highly supportive of the company's clinical development program", with plans for a phase IIb clinical trial of ATL1102 for Duchenne muscular dystrophy being reviewed with European regulatory authorities.
Antisense managing-director Mark Diamond told Biotech Daily that the final data from the trial was expected by the end of this year.
Antisense fell 0.6 cents or six percent to 9.4 cents with three million shares traded.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity says that a European Medicines Agency committee has recommended PBT434 for multiple systems atrophy for orphan drug designation.
Alterity said the Agency's orphan medicinal products committee had provided its opinion to the European commission.
In January, the then Prana said the US Food and Drug Administration had granted orphan drug designation to PBT434, as it had been shown to prevent alpha-synuclein accumulation, preserve neurons, and improve motor function in an animal model of multiple system atrophy (BD: Jan 31, 2019).
Today, Alterity chief executive officer Geoffrey Kempler said that Europe was "a key market for Alterity and it will lay the foundation for the company to expand the use of PBT434 into other markets".
Alterity was up 0.3 cents or 12.5 percent to 2.7 cents with 4.9 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it will collaborate with the Adelaide-based Carina Biotech to develop chimeric antigen receptor-T cell combination therapies for cancer.
Prescient said chimeric antigen receptor-T cell (CAR-T cell) therapy used the patient's own immune system to target and attack cancer.
The company said it would combine its targeted therapies with Carina's cell therapies and share any resulting intellectual property from the collaboration.
Prescient said that the work will be funded from its current budget and would not require additional capital.
The company said that the exact terms of the agreement and collaboration were confidential.
Prescient was up 0.6 cents or 13.6 percent to five cents with four million shares traded.

OVENTUS MEDICAL

Oventus says it has contracts with the California Center for Sleep Disorders and Feeling Great Sleep to distribute its devices for obstructive sleep apnoea.
In September, Oventus said it had US Food and Drug Administration clearance for its O2Vent Optima, which was part of its sleep treatment platform and laboratory inside a laboratory or 'lab in lab' business model, which used "a scanner to measure the patient's mouth size for a custom-fit for the O2vent" (BD: Sep 2, 2019).
Last month, the company said it had launched the first five 'lab-in-lab' sites in the US and Canada to coincide with the launch of its O2Vent optima oral device for obstructive sleep apnoea (BD: Oct 11, 2019).
Today, Oventus said it had signed the San Francisco-based California Center for Sleep Disorders and the Durham, North Carolina-based Feel Great Sleep, which would launch the Oventus 'lab-in-lab' agreement in December 2019 and January 2020, with a minimum monthly quota of 20 devices each.
The company said it had 29 contracted sites, with five sites launched and a further eight sites in the implementation phase.
Oventus fell four cents or 7.5 percent to 49.5 cents.

ADHERIUM

Adherium says it has an agreement to integrate its Hailie sensors for asthma and chronic obstructive pulmonary disease inhalers to the Patients Know Best platform.

Adherium said the Cambridge, UK-based Patients Know Best was an on-line patient portal which allowed patients access their medical records and help them better manage their health and social care.

The company said it expected that integrating the Hailie inhaler to the Patients Know Best platform would help to monitor dose compliance and promote a high level of adherence.

Adherium said it would work with Patients Know Best to promote the economic benefit of the Hailie technology's in the UK's National Health Service economic benefit and develop a reimbursement code.

Adherium fell 0.2 cents or five percent to 3.8 cents.

IMUGENE

Imugene says investors overwhelmingly passed all extraordinary general meeting resolutions relating to the acquisition of Vaxinia for its oncolytic virus CF33.

Imugene said that shareholders approved the allotment and issue of shares to Vaxinia shareholders, the allotment and issue of shares to Imugene and Vaxinia chairman Paul Hopper, and the acquisition of Vaxinia.

In July, the company said that through related company Vaxinia, it would acquire the City of Hope invented CF33 technology, paying Vaxinia $462,500 in cash and $1,619,000 in shares, subject to shareholder approval (BD: Jul 15, 2019).

Today, Imugene chief executive officer Leslie Chong said the company was "delighted to be able to complete the acquisition of Vaxinia and City of Hope licence of such a promising next generation oncolytic virus in a competitive market place where big pharma companies are actively seeking [oncolytic virus] technologies".

"CF33 comes with robust intellectual property and long patent life, compelling pre-clinical efficacy and safety, and is anticipated to enter two phase I clinical trials in 2020," Ms Chong said.

Imugene climbed 0.8 cents or 17.8 percent to 5.3 cents with 480.2 million shares traded.

DORSAVI

Dorsavi says the US Patent and Trademark Office has granted a patent covering its wearable motion analysis technology for the assessment of injury risk and cause.

Sienna said that the patent, titled 'Apparatus and method for measuring reaction forces' would provide intellectual property protection until July 24, 2033.

The company said the patent would protect its sensor and algorithm technologies which determined the reaction force of the limb contacting the ground or surface upon which a person was walking or running.

Dorsavi said the patent had previously been granted in Australia and China.

Dorsavi fell 0.4 cents or 11.8 percent to three cents.

SUDA PHARMACEUTICALS

Suda says it has received $927,970 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Suda said the rebate related to expenditure for the year to June 30, 2019.

Suda fell 0.1 cents or 1.9 percent to 5.1 cents.

ANTEOTECH (FORMERLY ANTEO DIAGNOSTICS)

Anteotech says it has an agreement with IMRA America to produce and market Anteobind-coated IMRA 40 nanometer colloid gold particles.
Anteotech said the Ann Arbor, Michigan-based IMRA America colloid gold particles would be used in lateral flow assays in the point-of-care diagnostic market.
The company said the product would be marketed as an IMRA particle “powered by Anteobind” and would be distributed through IMRA’s network.
The company said that initial sales exposure into the IMRA network would “provide Anteo with a potential compounding effect for additional partnerships”.
Anteotech was up 0.2 cents or 11.1 percent to two cents with 20.6 million shares traded.

HERAMED

Heramed says it has formally retracted revenue forecasts made in a paid article on the Next Tech Stock website that falsely valued the company at $13 billion.
Last week, Heramed told the ASX that a typographical error in the article valued the company at $13 billion which may have pushed its price up as much as 51.7 percent from 14.5 cents to 22 cents between November 13 and 14, 2019 (BD: Nov 14, 2019).
Biotech Daily calculated that at the close of market on November 14, 2019, Heramed had a market capitalization of $18.8 million.
Today, the company said that “there was no reasonable basis for making the forecasts” and following consultation with the ASX it had retracted, without any admission of liability, the forecasts made in the article, and confirmed that Next Tech Stock had overwritten the article and removed the incorrect information.
Heramed was up 5.5 cents or 25.6 percent to 27 cents with 39.5 million shares traded.

HERAMED

Heramed says it has US Food and Drug Administration 510(k) clearance for its Herabeat foetal ultrasonic heart rate monitor.
Heramed said Herabeat was a hand-held, battery powered audio device integrated used to detect and display the foetal heart rate, which connected to a smartphone application which controlled the device, displayed heartrate data, played heartrate sounds and logged the data history.
The company said that it would begin US commercialization “as quickly as possible”.

POLYNOVO

All resolutions to the Polynovo annual general meeting were passed but with significant dissent against the re-election of chair David Williams.
The resolution to re-elect Mr Williams was opposed by 58,193,802 votes (24.54%), with 178,897,678 votes (75.46%) in favor.
The company’s most recent Appendix 3B new issue announcement said Polynovo had 661,088,044 shares on issue, meaning that the votes against Mr Williams amounted to 8.80 percent of the company, sufficient to requisition extraordinary general meetings.
The remuneration report passed overwhelmingly, with 191,156,593 votes (95.27%) for and 9,488,883 votes (4.73%) against.
All other resolutions, including the re-election of director Leon Hoare, the non-executive directors’ fees, and the employee share plan passed easily.
Polynovo fell seven cents or 3.2 percent to $2.14 with 4.1 million shares traded.

IDT AUSTRALIA

IDT has avoided a remuneration report first strike with the annual general meeting voting 21,919,808 votes (22.49%) against the report and 75,563,866 votes (77.51%) in favor.
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, directors must stand for re-election at a meeting within 90 days.
IDT said the re-election of director Mary Sontrop and the approval of the employee share plan faced similar dissent.
In May, the company said it had 236,359,103 shares on issue, meaning that the 28,216,909 votes against the share plan placement amounted to 11.9 percent of the company, sufficient to requisition extraordinary general meetings.
Last year, 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 (BD: Oct 23, 2018).
IDT fell half a cent or 3.2 percent to 15 cents.

RHYTHM BIOSCIENCES

Rhythm says that 38,500,000 shares will be released from ASX escrow on December 7, 2019, as well as 2,000,000 options exercisable at 30 cents by December 7, 2020.
According to Rhythm's most recent Appendix 3B, after the release of the escrow shares there would be 100,750,000 shares available for trading with no further shares in escrow.
Rhythm said there were a further 1,000,000 options in escrow, exercisable at 20 cents, by May 21, 2021.
Rhythm was up half a cent or three percent to 17 cents.

PROBIOTEC

Probiotec founder and former executive director Charles Wayne Stringer says his holding has decreased from 9,998,405 shares (16.4%) to 9,744,868 shares (13.03%).
The substantial shareholder notice said that the shares were held by the Melbourne-based Mr Stringer and Jane Stringer, as well as Mr Stringer's Inston Pty Ltd.
Mr Stringer said that between July 15 and 24, 2019 he made seven on market trades, with the single largest trade of 113,806 shares for $188,918 or $1.66 a share.
Mr Stringer said his holding was diluted on October 1 through the issue of 6,000,000 shares in the placement that raised $10.56 million and on October 24 through the issue of 8,750,000 executive option plan shares (BD: Sep 25, 2019).
Probiotec was up two cents or one percent to $2.06.

AVITA MEDICAL

Avita says it has appointed David McIntyre as chief financial officer effective from today, with interim chief financial officer Tim Rooney to continue as chief administrative officer.
Avita said Mr McIntyre had more than 20 years' experience including with venture capital fund Apple Tree Partners, as Braeburn Inc chief financial officer, Heartware chief financial officer and chief operating officer and as a lawyer at Baker and McKenzie, and KPMG.
The company said Mr McIntyre held a Bachelor of Economics from the University of Sydney, a Bachelor of Law from the University of Technology Sydney and a Master of Business Administration from the Durham, North Carolina-based Duke University.
Avita fell half a cent or 0.85 percent to 58 cents with 14.6 million shares traded.

TOTAL BRAIN

Total Brain says that Nathan Jong will replace Harvey Bui as joint company secretary, effective from November 18, 2019.

Total Brain said that both Mr Bui Mr Jong was employed by the Melbourne-based CFO Solution.

Total Brain was up 3.7 cents or 47.4 percent to 11.5 cents with 56.1 million shares traded.