Biotech Daily

Monday April 15, 2019

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: PROTEOMICS, VOLPARA UP 6% - AVITA DOWN 6%**

*** PARADIGM RAISING $78m ON PPS OSTEOARTHRITIS PAIN RESULTS**

*** STUDY BACKS LBT APAS FOR MRSA (GOLDEN STAPH)**

*** RESAPP FILES FDA APPLICATION FOR RESAPPDX-US**

*** IMMURON CLAIMS 9-MONTH SALES UP 23% TO $1.7m**

*** ADMEDUS VACCINES SALE, 3m CEO OPTIONS, 2nd REM STRIKE AGM**

*** ADMEDUS REQUESTS CORIDON 'IMMUNOTHERAPIES SALE' HALT**

*** PRANA ASX CODE PBT CHANGES TO ALTERITY ATH**

*** KARST PEAK, ADAM LEITZES TAKE PROFIT, REDUCE TO 10.5% IN AVITA**

*** MMJ HANDS EMBARK MARIJUANA INVESTMENTS, DROPS SHARE PLAN**

*** MICRO-X LOSES RICHARD HANNEBERY**

*** HARLEY FRANKFURT REPLACES ANTEO CEO CHRISTOPHER PARKER**

MARKET REPORT

The Australian stock market was flat on Monday April 15, 2019, with the ASX200 up 0.1 points to 6,251.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and four were untraded.

Proteomics and Volpara were the best, up 5.8 percent to 27.5 cents and $1.84, respectively, with 435,086 shares and 715,509 shares traded, respectively. Polynovo climbed 5.5 percent; Mesoblast improved 4.6 percent; Uscom was up 3.3 percent; Prescient and Universal Biosensors rose more than two percent; Actinogen, Cochlear, Genetic Signatures and Neuren were up more than one percent; with Nanosonics, Pro Medicus and Resmed up by less than one percent.

Avita led the falls, down two cents or 5.6 percent to 34 cents, with 8.8 million shares traded. Patrys fell 4.2 percent; Benitec, Ellex and Opthea were down more than three percent; Alterity (Prana), Clinuvel, Compumedics and Starpharma shed two percent or more; with CSL, Kazia, LBT, Medical Developments, Pharmaxis and Telix down by more than one percent.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it expects to raise $77.9 million on the back of positive data from last year's phase IIb trial of pentosan polysulfate sodium for knee osteoarthritis pain.

Paradigm said it expected to raise $51.5 million in a placement to sophisticated and professional investors, with a one-for-eight $26.3 million non-renounceable rights offer.

The company said that following the raising it would have $82 million in cash which would put it "in a strong negotiating position for commercial transactions".

Paradigm said the funds would be used for its osteoarthritis and muco-poly-saccharidosis programs to the end of their pivotal phase III studies, new drug applications, working capital, further preclinical studies and possible further intellectual property acquisitions.

The company said that the record date for the rights offer was April 17, the offer would open on April 24 and close on May 6, 2019.

Paradigm said that Bell Potter was the lead manager to the placement and lead manager and underwriter for the entitlement offer.

Late last year, the company said its 112-patient, phase IIb trial showed that pentosan polysulfate sodium (PPS) significantly reduced knee osteoarthritis pain compared to placebo ($p = 0.031$) (BD: Dec 18, 2018).

Paradigm said at that time that 126 patients with knee osteoarthritis and bone marrow oedema lesions enrolled in the trial, with 112 evaluable after receiving 2mg/kg of pentosan polysulfate sodium (PPS) by subcutaneous injection, twice weekly for six weeks, 42 days

The company said the primary endpoint was the change in knee injury and osteoarthritis outcome score (KOOS) from baseline to day-53, with secondary endpoints including safety, pain, symptom, function, quality of life, bone marrow oedema lesion volume and patient global impression of change

Today, Paradigm said the duration of effect had been shown for six months to day-165.

The company said that the reduction in bone marrow lesion grade, volume and area at day-53 signalled "possible remission of disease, in conjunction with previously demonstrated statistically significant reduction in pain and improvement in function".

Paradigm said that the secondary endpoints included improved knee function, or activities of daily living, to day-165 with a mean change for the PPS group of 39.6 percent compared to 26.6 percent for placebo ($p = 0.0061$).

The company said that the KOOS pain reduction at six months "demonstrated a clinically effective outcome at day-165" with more patients in the PPS group experiencing a greater than 50 percent reduction in pain score ($p = 0.0469$) compared to placebo.

Paradigm said that objective magnetic resonance imaging (MRI) data at day-53 showed a reduction in bone marrow oedema lesion grade showed that the number of subjects receiving PPS treatment had a clinically meaningful reduction in the grade of their lesions compared to placebo ($p = 0.03$), along with a reduction in lesion volume of 34.2 percent compared to placebo 3.6 percent and a reduced bone marrow lesion area by 25.3 percent compared to an 11.9 percent increase in the placebo group.

The company said that compared with bone marrow oedema lesions that stayed the same, enlarging lesions were "strongly associated with increased cartilage loss, pain, joint destruction and increased risk of joint replacement".

Paradigm chief executive officer Paul Rennie said the data showed "an accumulation of positive results of PPS over placebo in every single component of the trial and outstanding results for the NRS 4-6 pain stratum, which in our view shows PPS is safe and effective".

"Obviously, the very positive effect that PPS is having on the [numeric rating score moderate pain] four to six stratum further confirms this group will be our target patient group for our upcoming pivotal phase 3 clinical trial," Mr Rennie said.

Paradigm was in a trading halt and last traded at $1.90.

LBT INNOVATIONS

LBT says that Wisplinghoff Laboratories backs its automated plate assessment system (APAS) for methicillin-resistant staphylococcus aureus, MRSA or “golden staph”.
LBT said the data from the Köln (Cologne) Germany-based Wisplinghoff Laboratories was presented at the European Congress of Clinical Microbiology and Infectious Diseases in Amsterdam on April 13, 2019 and concluded that APAS “was at least comparable to conventional reading, maintaining an average read rate of 200 plates per hour; reliably screens for MRSA and would significantly reduce time to report and would reprioritize technician/microbiologist time; [and artificial intelligence]-based systems may provide a great addition to current practices in cultural microbiology”.
The company said that the poster, titled ‘Introduction of artificial intelligence for high throughput culture-based MRSA screening’ detailed the study’s evaluation of more than 17,000 routine specimens over a six-month period to evaluate the accuracy of the APAS Independence detection of MRSA on chromogenic culture plates when compared to conventional reading by an experienced microbiologist.
LBT said the results “were extremely positive” with a sensitivity of 100 percent and specificity of 98.1 percent.
The company said the study, at a high throughput routine clinical setting, showed the clinical utility of the APAS Independence to reliably screen for MRSA and significantly reduce the time to report allowing for technician and microbiologist time to be reprioritized.
LBT said it would progress to a clinical study to formally validate the performance of the modules before regulatory clearance and the module could be released to market.
The company said it expected the MRSA analysis modules to be available in the EU and Australia by the end of 2019 under a self-certification process and would be available in the US after FDA clearance was obtained.
LBT chief executive officer Brent Barnes said that clinical evaluations were “important milestones in demonstrating the utility of new medical technologies”.
“In this study, the APAS Independence has consistently delivered excellent results, achieving high sensitivity and specificity, whilst operating in a high throughput laboratory environment,” Mr Barnes said.
LBT fell0.1 cents or 1.4 percent to 6.9 cents.

RESAPP HEALTH

Resapp says it has submitted an application to the US Food and Drug Administration for the de-novo classification of its Resappdx-US for paediatric respiratory disease.
Resapp said the device was a mobile telephone software application for the diagnosis of paediatric respiratory disease using cough sounds.
The company said that respiratory disease caused “a major portion of healthcare concerns in children, with cough being the most common illness-related reason for ambulatory visits in the US and [one of] the top two principal reasons for children to visit the emergency department”.
Resapp said its device was “intended to be used by clinicians as an aid in the diagnosis of primary upper respiratory tract disease, lower respiratory tract disease and asthma”.
Resapp chief executive officer Dr Tony Keating said the submission was “the culmination of years of development work and [is] a significant milestone towards commercialization”.
“These respiratory diseases are the most common illnesses seen in healthcare, and once cleared by the FDA, Resappdx-US will deliver substantial clinical benefits by providing actionable information to clinicians sooner,” Dr Keating said.
Resapp was unchanged at 12 cents.

IMMURON

Immuron says sales revenue for the nine months to March 31, 2019 is up 23 percent to $1.7 million.

Immuron said that revenue from its over-the-counter, cow colostrum-derived, Travelan travel diarrhoea product for the three months to March 31, 2019 was up 66 percent to $616,000.

The company said that sales increased in Australia and the US, with the company reporting its first purchase order and plans to expand into Canada

Immuron chief executive officer Dr Gary Jacob said the company's focus was on "expanding sales growth of Travelan within existing markets [and] coupled with our re-entry into Canada puts us in a strong position for continued growth".

"We will continue to work towards expanded sales growth, with particular emphasis on building the market for Travelan in North America," Dr Jacob said.

Last week, Immuron said it planned to file an investigational new drug application to the US Food and Drug Administration for IMM-124E, or Travelan, for travelers' diarrhoea, for registration as a drug

Immuron was up two cents or 9.5 percent to 23 cents.

ADMEDUS

Admedus says investors will vote on the sale of its virus vaccines business to Hong Kong interests and issue 3,188,831 options to chief executive officer Wayne Paterson.

Admedus said that Mr Paterson's options would be exercisable at 5.9 cents each within 10 years.

Admedus said that following last year's 34.25 percent first strike, it had included a board spill resolution should the remuneration report face more than a 25 percent opposition (BD: May 24, 2018).

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 at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.

If the spill vote fails, the trigger is reset to no opposition.

Last year, the company's most recent Appendix 3B new issue announcement said it had 272,462,201 shares on issue, meaning that the votes against the remuneration report amounted to 6.49 percent of the company, sufficient to requisition extraordinary general meetings.

On Friday, Admedus said that shareholders would vote ratify the prior issue of 42,599,866 shares to Hong Kong's Star Bright at 10 cents a share, ratify the further issue of 26,289,636 shares to Star Bright at 13.03 cents a share, and approve the 10 percent placement facility.

The company said that the annual general meeting would vote to approve the sale of its immunotherapies business, formerly known as Coridon, with assets developed by Prof Ian Frazer (BD: Apr 27, 2018).

Admedus said that investors would vote to re-elect chairman John Seaberg as a director, along with the election of Hong Kong directors Lishan Zhang, Dr Yanheng Wu and Dr Wenyi Gu and company secretary Stephen Denaro.

The meeting will be held at Hotel Grand Chancellor, 23 Leichardt Street, Brisbane on May 14, 2019 at 9.30am (AEST).

Admedus was in a trading halt (see below) and last traded at 6.0 cents.

ADMEDUS

Admedus has requested a trading halt “pending an announcement regarding the previously announced Admedus immunotherapies sale transaction”.
Last week, Admedus told the ASX that finalizing the sale of the Prof Ian Frazer developed virus vaccines business, formerly known as Coridon, on March 22, 2019, was not material because it had previously announced the terms of the sale and it was conditional (BD: Apr 27, Jun 27, 2018; Apr 10, 2019).
The ASX said at that time that the company’s share price rose 109.3 percent from 4.3 cents on March 29 to 9.0 cents on April 10, 2019, and noted a “significant increase” in the trading volume.
Trading will resume on April 17, 2019 or on an earlier announcement.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

The company formerly known as Prana, now Alterity, has changed ASX code from PBT to ATH.
Earlier this month, a then Prana extraordinary general meeting voted to change the name to Alterity, along with approving the major investment from the Boston-based Life Bioscience (BD: Apr 5, 2019).
The company’s US Nasdaq code changed to ATHE last week and the ASX code changed from the open of trading this morning.
Alterity fell 0.1 cents or two percent to 4.9 cents.

MMJ GROUP HOLDINGS

MMJ says that related party Embark Ventures will manage its marijuana investments removing the need for a chief executive officer and cancelling a share plan.
MMJ said that Embark Ventures was part of the Embark Group which included Embark Health, a marijuana growing company in which it held an investment of $3.8 million.
The company said that Embark principal Michael Curtis was an MMJ non-executive director and would hold about 20 percent of Embark Ventures and 13.2 percent of Embark Health.
MMJ said the bulk of Embark’s remuneration was linked to increases in its share price and net asset value through the issue of performance rights.
The company said that Embark would receive a base management fee of about $440,000 a year based on the current book value of the investment portfolio, which would “be largely offset by the non-replacement of the … [chief executive officer] and Michael Curtis ceasing to receive a director’s fee remuneration”.
MMJ said the appointment of Embark allowed it to remove the immediate need to appoint a new chief executive officer, with the current chief financial officer and company secretary responsible for operations.
The company said it had a cash balance of $11 million and more than $70 million of its investment portfolio in listed investees and expected Embark Health and Bevcanna to list on the Toronto Stock Exchange Venture Exchange this year.
MMJ said that “the discount of the ... share price to its net asset value has materially increased” with the share price at 24 cents compared to net asset value of 39 cents and it did not consider a capital raising “to be in the best interests of shareholders”.
The company said that the planned share purchase plan had been cancelled.
MMJ last traded at 23.5 cents.

AVITA MEDICAL

Karst Peak Capital and Adam Leitzes say they have further reduced in Avita from 269,797,825 shares (14.47%) to 196,154,563 shares (10.52%).
The Hong Kong and Cayman Islands-based Karst Peak said the shares were sold between April 1 and 8, 2019 at prices ranging from 28.5 cents to 32.75 cents a share.
Last week, Karst Peak and Adam Leitzes reduced from 14.47 percent to 10.52 percent (BD: Apr 8, 2019).
Last year, Karst Peak and associated companies said it had acquired 1,300,000 shares on February 7, 2018 at six cents a share and 155,000,000 shares on June 7, 2018 at five cents a share. (BD: Jun 12, 2018).
Avita fell two cents or 5.6 percent to 34 cents with 8.8 million shares traded.

MICRO-X

Micro-X says corporate development executive director Richard Hannebery, has resigned "in order to concentrate on his other business interests".
Micro-X said Mr Hannebery has helped to build the company since 2013 and was appointed a director in 2014.
Mr Hannebery is Genera Biosystems chief executive officer.
Micro-X was unchanged at 34 cents.

ANTEO DIAGNOSTICS

Anteo says it has appointed Harley Frankfurt as its chief executive officer on $280,000 a year, effective from April 23, 2019.
Anteo said the current chief executive officer Christopher Parker would transition to executive director to focus on its life sciences division.
The company said Mr Frankfurt had experience in the energy sector, in particular in renewables which would assist in expanding its battery division (BD: Apr 21, 2015).
Last year, Anteo said that Mr Parker would replace its then three-month chief executive officer, Dr Stefan Enderling, on a short-term contract (BD: Apr 9, 2018).
Today, the company said the Mr Frankfurt had more than 25 years' experience in the renewable energy, power infrastructure, mining and oil industries.
Anteo said that, most recently, Mr Frankfurt was the Dubai, United Arab Emirates-based Enviromena Power Systems major projects chief operating officer and previously established Siemens' Australian renewable energy business.
The company said that Mr Frankfurt would receive up to 15 percent of his base salary as a short term incentive in cash and shares and would receive 15,000,000 performance-based options vesting in three tranches over four years, with 3,000,000 on the share price reaching 100 percent above its 30-day volume-weighted average price, 6,000,000 on a 200 percent rise and 6,000,000 on a 400 percent increase.
The company said Mr Frankfurt held a Master of Business Administration from the University of Sydney.
Anteo was up 0.2 cents or 12.5 percent to 1.8 cents.