Biotech Daily

Monday January 30, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: AVITA UP 9.5%, BENITEC DOWN 8%**

*** BENITEC, NANT SEAL BB-401, BB-501 HEAD, NECK CANCER DEAL**

*** ZOETIS PAYS ANATARA SECOND DETACH OPTION FEE**

*** DUTCH STUDY BACKS VOLPARA BREAST DENSITY TEST**

*** NEUREN COMPLETES PAEDIATRIC RETT TRIAL, MARCH RESULTS**

*** ANTEO'S DIASOURCE REVENUE UP 15.5% TO $23m**

*** HARVEST ONE RAISES $25m FOR MMJ CANNABIS SUBSIDIARIES**

*** MEDIBIO NEGOTIATES $3.3m PATENTS CONVERTIBLE NOTE**

*** PHARMAUST RECEIVES $406k FEDERAL R&D TAX INCENTIVE**

*** IQ3 HAS LESS THAN ONE QUARTER CASH**

*** INVITROCUE HAS LESS THAN TWO QUARTERS CASH**

*** BRAIN LESS THAN 2 QUARTERS CASH, EXPECTS R&D TAX, REVENUE**

*** PHYLOGICA PLEADS SCHULTZ TO ASX 41% QUERY**

MARKET REPORT

The Australian stock market fell 0.92 percent on Monday January 30, 2017 with the ASX200 down 52.5 points to 5,661.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

Avita was the best, up one cent or 9.5 percent to 11.5 cents with 204,272 shares traded. Osprey climbed 7.1 percent; Pharmaxis was up 5.45 percent; Cyclopharm and Neuren improved more than four percent; Clinuvel was up 3.7 percent; Admedus, Airxpanders and Anteo rose two percent or more; Atcor, Ellex, Medical Developments, Opthea and Prana were up more than one percent; with Mesoblast up 0.6 percent.

Benitec led the falls, down one cent or eight percent to 11.5 cents with 1.4 million shares traded. Cellmid and Orthocell lost more than six percent; IDT fell 5.3 percent; Bionomics fell 4.1 percent; Sirtex was down 3.7 percent; Compumedics, Impedimed, Nanosonics and Pro Medicus shed more than two percent; with Cochlear, CSL, Polynovo, Resmed, Starpharma and Viralytics down by more than one percent.

BENITEC BIOPHARMA

Benitec says it has begun work on two oncology pipeline programs having executed its research development agreement with Nant Capital LLC.

Benitec said the alliance with the Los Angeles, California-based Nant Capital was to develop and fund the gene-silencing head and neck cancer squamous cell carcinoma programs (BD: Oct 24, Nov 23, Dec 23, 2016).

Benitec chief executive officer Greg West said the company had “hit the ground running in launching into the development of these two oncology programs”.

“The closing of this transaction solidifies the relationship with a well-respected, strategic investor,” Mr West said.

“The clinical stage asset acquired by Benitec, now termed BB-401, performed well in early stage clinical testing and we look forward to progressing it into mid stage clinical trials,” Mr West said.

Mr West said that Benitec could access capital markets with Nant as a cornerstone investor, to progress the Nant oncology programs and its other programs.

Benitec said it had taken control of the clinical development of BB-401, a recombinant DNA construct that produced an antisense RNA with specificity against epidermal growth factor receptor (EGFR).

The company said that the “clinically validated molecular target [was] overexpressed in up to 90 percent of all [head and neck cancer squamous cell carcinomas]”.

Benitec said that about 64,000 new patients were diagnosed annually in the US with head and neck cancer squamous cell carcinoma and 50 percent were expected to develop recurrent or metastatic disease, with about 13,000 deaths each year.

The company said it planned to meet with the US Food and Drug Administration and other regulatory agencies and hoped to start a mid-stage human clinical study of BB-401 “early in 2018”.

Benitec said it had begun a discovery stage program using its ddRNAi platform to develop follow-on anti-EGFR strategies and data from the BB-401 program would be used to inform the development pathway of BB-501, the ddRNAi DNA construct.

The company said that it was thought the efficiency of target knockdown would be significantly greater with RNA interference as opposed to the post transcriptional gene silencing mechanism of BB-401.

Nant chief investment officer and Benitec director Dr Jerel Banks said that “the unique biological and clinical attributes of these compounds may provide new therapeutic approaches for treating head and neck cancer”.

Benitec fell one cent or eight percent to 11.5 cents with 1.4 million shares traded.

ANATARA LIFESCIENCES

Anatara says it has received a second undisclosed payment under its evaluation and licence option agreement with Zoetis Inc for Detach for pig diarrhoea.

Last year, Anatara said it received a milestone payment for shipping its pineapple stem bromelain-based Detach non-antibiotic treatment for diarrhoea in farm animals to the Florham Park, New Jersey-based Zoetis (BD: Jan 27, Apr 1, 2016).

Today, the company said that Zoetis had exclusive rights to evaluate the potential applications of Detach for veterinary use in food production animals.

Anatara said that Zoetis had an option to licence Detach for development and commercialization in markets worldwide, while it retained the rights to Australia and New Zealand.

Anatara climbed 11 cents or 9.2 percent to $1.30.

VOLPARA HEALTH TECHNOLOGIES

Volpara says that a Dutch study into breast density using its software shows that increased breast density has a direct impact on mammography performance.

Volpara said that the research found that breast density had an impact on measures such as sensitivity and the rates of recall, false positives and interval cancers.

The study, entitled 'Volumetric breast density affects performance of digital screening mammography' was published in the journal Breast Cancer Research and Treatment and is available at http://link.springer.com/article/10.1007/s10549-016-4090-7.

The article concluded that "volumetric mammographic density, automatically measured on digital mammograms, impacts screening performance measures along the same patterns as established with [American College of Radiology] breast density categories".

"Since measuring breast density fully automatically has much higher reproducibility than visual assessment, this automatic method could help with implementing density-based supplemental screening," the article concluded.

Volpara said that the study involved more than 110,000 mammograms from the Dutch Breast Screening Program and found "a strong linear relationship between decreased screening performance and volumetric breast density".

Research leader Dr Carla van Gils said that while there were several studies that demonstrated the impact of breast density on the sensitivity of mammography but "this is the first large-scale study to also demonstrate a strong relationship between volumetric density and other screening performance measures like recall rate, false positives or interval cancers".

"With the high reproducibility of the automatic Volparadensity software, this could help with evaluating risk and better inform clinical decisions about adjunctive screening options based on women's specific density and other risk factors," Dr van Gils said.

Volpara said that the study included 667 screen-detected and 234 interval cancers and of all the tumors, 84.3 percent were invasive cancers.

The company said that the study showed that a woman was nearly seven times more likely to have an interval cancer if her breasts were extremely dense compared to very fatty and about twice as likely to have a false positive if they were extremely dense compared to very fatty.

Dr van Gils said the study found a relationship between cancer type, in-situ or invasive, breast density and detection mode, screen-detected or interval.

Dr van Gils said that when only invasive breast cancer was taken into account, the difference in sensitivity between the density categories was even more pronounced.

"This indicates that the detection of invasive breast cancers in screening is hampered to a larger extent than the detection of in-situ breast cancers," Dr van Gils said.

"A possible explanation for this is that the visibility of micro-calcifications is not hampered as much in dense tissue as the visibility of invasive breast cancers," Dr van Gils said.

"Studying this relationship further could be very important as we further develop our understanding of the effectiveness of screening," Dr van Gils said

Volpara chief executive officer Dr Ralph Highnam said the inclusion of Volparadensity in another large scale study further validated the company's core technology and added to the growing amount of data linking breast density with cancer and the need for improved screening.

Volpara climbed 1.5 cents or 2.4 percent to 63.5 cents.

NEUREN PHARMACEUTICALS

Neuren says the last of 82 patients has completed its phase II trial of trofinetide for paediatric Rett syndrome, with results expected by the end of March 2017.
Neuren said that soon after receiving the results in would “engage potential commercial partners regarding the remaining development and commercialization of trofinetide”.
Neuren executive chairman Dr Richard Treagus said the company was “grateful for the strong support of the Rett syndrome community, which has helped us to complete the expanded paediatric trial on schedule”.
The company said the randomized, double-blind, placebo-controlled phase II trial for girls aged five to 15 years with Rett syndrome was conducted at 12 US sites, led by clinicians experienced in the diagnosis and treatment of Rett syndrome and Rettsyndrome.org contributed towards the cost of the trial.
Neuren said that 82 patients began the trial, one girl withdrew prior to completion, with 62 girls randomized into four treatment groups receiving 50mg/kg, 100mg/kg, 200mg/kg, or placebo; and a further 20 girls were randomized into groups of 200mg/kg or placebo.
The company said that the primary endpoint was the safety and tolerability of trofinetide compared with placebo, with outcome measures included in the study to provide insights into the efficacy of trofinetide in younger subjects.
Neuren said that the efficacy analysis would prioritize five syndrome-specific measures, the first three of which were used in its phase II trial in patients aged 16 to 45 years with Rett syndrome (BD: Nov 12, 2014).
The company said that the five measures were the motor behavior assessment; the caregiver top three concerns visual analog scale; the clinical global impression of improvement; the domain specific concerns visual analog scale; and the Rett syndrome behavior questionnaire.
Neuren said that the analysis would examine the mean changes for each treatment group, as well as the proportion of subjects in each group that showed improvements.
The company said that results from two non-clinical chronic toxicity studies of trofinetide would be required prior to extended dosing in a phase III trial and submitting new drug applications.
Neuren said that the first toxicity study was nearing completion and the second was expected to begin in mid-2017, concluding by July 2018, with plans to enable manufacturing to begin by the end of 2017 for a pivotal phase III trial.
Neuren was up 0.3 cents or 4.4 percent to 7.1 cents with 3.85 million shares traded.

ANTEO DIAGNOSTICS

Anteo says that Diasource Immunoassays SA has increased sales revenue for the 12 months to December 31, 2016 by 15.5 percent to EUR16.347 million ($A23.16 million.
Anteo said the Belgian subsidiary was acquired last year and had completed its first year as part of Anteo with record results and growth strongest in the vitamin D diagnostics.
Anteo was up 0.1 cents or 2.6 percent to four cents with 3.6 million shares traded.

MMJ PHYTOTECH

MMJ says that Canada’s Harvest One Capital has raised $C25 million ($A25.2 million) in a placement to acquire subsidiaries United Greeneries Holdings and Satipharm AG.
Earlier this month, MMJ said that Harvest One had launched a $C15 million placement to acquire the subsidiaries (BD: Jan 22, 2017).
MMJ was up 1.5 cents or 7.5 percent to 21.5 cents with 7.65 million shares traded.

MEDIBIO

Medibio says it has negotiated the early repayment of a $US2.5 million ($3.3 million) convertible note at 31 cents a share.
Medibio said that the note was consideration for the April 2015 acquisition of patents covering the use of 24-hour heart rate data for the diagnosis of depression and other mental health disorders and covered the use of the technology to determine treatment effectiveness.
Medibio was unchanged at 38 cents.

PHARMAUST

Pharmaust says it has received $406,237 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Pharmaust said the rebate related to research and development activities for the year to June 30, 2016 by wholly-owned subsidiaries Epichem and Pitney Pharmaceuticals.
Pharmaust fell 0.1 cents or 1.9 percent to 5.1 cents with 1.4 million shares traded.

IQ3

IQ3 says its net operating cash burn for the three months to December 31, 2016 was $427,000 with cash at the end of the quarter of $375,000.
IQ3 did not provide further details.
IQ3 was untraded at 30 cents.

INVITROCUE

Invitrocue says its net operating cash burn for the three months to December 31, 2016 was $556,000 with cash at the end of the quarter of $911,000.
Invitrocue did not provide further details.
Invitrocue was untraded at 9.3 cents.

BRAIN RESOURCE

Brain says its net operating cash burn for the three months to December 31, 2016 was $506,000 with cash at the end of the quarter of $983,675.
Brain said that it expected increased revenue from its three largest clients as well as about $400,000 under the Federal Government's R&D Tax Incentive program.
Brain was up one cent or 10.5 percent to 10.5 cents.

PHYLOGICA

Phylogica 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 40.6 percent from 3.2 cents on January 23 to 4.5 cents today, January 30, 2017 and noted an increase in trading volume.
Phylogica closed up 0.4 cents or 11.4 percent to 3.9 cents with 1.1 million shares traded.