



Biotech Daily

Thursday March 28, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: USCOM UP 9%; ONCOSIL DOWN 9%**
- * **MACH7 WINS SENTARA PICTURE ARCHIVE CONTRACT**
- * **VOLPARA WELCOMES FDA BREAST DENSITY CHANGES**
- * **GENETIC TECHNOLOGIES OPENS HONG KONG, CHINA OPERATIONS**
- * **PHARMAUST MONEPANTEL FOR CANCER 'SAFE IN DOGS'**
- * **ANALYTICA RECEIVES \$745k TAX INCENTIVE**
- * **PARADIGM PLEADS SCHULTZ TO ASX 18% QUERY**
- * **JOHN MCBAIN, PICTON, 52nd CELEBRATION TAKE 8% OF RHINOMED**
- * **BLUE SKY CEASES IN ALCIDION**
- * **BIO-MELBOURNE LOSES 5-YEAR CEO DR KRYSTAL EVANS**
- * **INVICTUS APPOINTS DR JORDAN MOON ADVISOR**

MARKET REPORT

The Australian stock market was up 0.65 percent on Thursday March 28, 2019, with the ASX200 up 40.1 points to 6,176.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and two were untraded.

Uscom was the best, up 1.5 cents or 9.1 percent to 18 cents, with 308,363 shares traded. Osprey climbed 8.3 percent; both Compumedics and Optiscan were up 7.1 percent; Neuren was up 5.4 percent; Cynata and Volpara improved more than four percent; Telix was up 3.7 percent; Airxpanders, Antisense, Genetic Signatures, Impedimed, Pharmaxis and Polynovo rose two percent or more; Avita was up 1.8 percent; with Clinuvel, CSL and Resmed up by less than one percent.

Oncosil led the falls for the second day in a row, down 0.4 cents or 9.1 percent to four cents, with 7.4 million shares traded. Patrys lost 7.4 percent; Universal Biosensors was down six percent; Paradigm fell four percent; Orthocell retreated 3.85 percent; Kazia shed 2.2 percent; Cochlear, Opthea, Pro Medicus and Starpharma were down more than one percent; with Mesoblast, Nanosonics and Prescient down by less than one percent.

MACH7 TECHNOLOGIES

Mach7 says the Norfolk, Virginia-based Sentara Healthcare will pay a minimum of \$420,000 a year to modernize its picture archive communication system.

Mach7 said it was selected by Sentara as a "a vendor of choice" last year and the contract including the \$420,000 minimum recurring subscription fee and annual support fees would earn a minimum \$850,000 a year, which would increase where study exceeded the contracted minimums.

Mach7 said it jointly developed an imaging innovations laboratory at Sentara to allow prospective customers to see its software in use and in development.

Mach7 was up half a cent or 2.9 percent to 17.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it welcomes a US Food and Drug Administration proposal to require US mammography facilities to provide information on breast density.

Volpara is commercializing its Volpara Density technology to measure breast density along with its Volpara Enterprize which measures pressure and radiation and use of mammography machines.

The company said that the FDA proposed to amend the Mammography Quality Standards Act to include a requirement that all US screening facilities provide information on breast density to women and their healthcare providers after a mammogram.

Volpara said the Act authorized FDA oversight over mammography facilities, including their accreditation, certification, annual inspections and enforcement of standards to help ensure mammography facilities provide quality care.

The FDA said the proposed changes were a "landmark policy to modernize mammography services and improve their quality".

The FDA said the proposed rule would require breast density reporting and enhance the FDA's ability to enforce mammography facilities' compliance with standards.

The US regulator said the proposal would amend regulations issued under the Act, "which Congress passed to ensure quality mammography for early breast cancer detection".

Volpara said the proposed regulations were open to comment for a three-month period before being finalized.

The company said the FDA was "proposing language that would outline how breast density can influence the accuracy of mammography and recommend that patients with dense breasts talk to their healthcare provider about their breast cancer risk".

Volpara said that the proposed rule would establish four categories for reporting density, with specific language to be included in notification letters.

The company said that criteria for reporting included that "the breasts are almost entirely fatty; there are scattered areas of fibro-glandular density; the breasts are heterogeneously dense, which may obscure small masses; and the breasts are extremely dense, which lowers the sensitivity of mammography".

Volpara chief executive officer Dr Ralph Highnam said the proposed changes were "a major step forward for the women of the United States".

"No matter where they live, they are about to receive information regarding an important part of their breast health for them to monitor and act on with their healthcare professionals," Dr Highnam said.

"This will lead to increased commercial opportunity for the Volpara Density clinical application," Dr Highnam said.

Volpara was up five cents or 4.2 percent to \$1.25.

GENETIC TECHNOLOGIES

Genetic Technologies says it has established Asian operations in Hong Kong and Hainan, China to market its genetic risk assessment tests for breast and other cancers.

Genetic Technologies said the China operation was organized through the Hainan Resort Software Community Free Trade Zone, which would provide tax benefits, subsidies and help in obtaining China Food and Drug Administration approval.

Genetic Technologies executive chairman Dr Paul Kasian said “the establishment of operations in Hainan, China is a significant step to advance the adoption of genetic risk assessment tests in China and in due course other parts of Asia”.

The company said it would access China through its subsidiary, Hainan Aocheng Genetic Technologies and would have office space in a free trade zone and medical precinct.

“This is likely to include partnering with Chinese health and medical distribution companies and [China Food and Drug Administration] accredited genetic testing laboratory operations,” Dr Kasian said. “The [Hainan Resort Software Community] team will help us find appropriate collaboration partners in mainland China.”

“We hope that [our] growing suite of world-leading genetic risk assessment test products will become central to China’s future preventative medicine activities,” Dr Kasian said.

Genetic Technologies was up 0.05 cents or 6.7 percent to 0.8 cents with 13.5 million shares traded.

PHARMAUST

Pharmaust says a nine-dog, phase I escalating single dose study shows that monepantel for cancer is safe in healthy dogs.

Pharmaust said no adverse effects or toxicity was observed in beagles administered two, four, seven or 10 tablets and monitored over three days.

Pharmaust chief scientific officer Dr Richard Mollard told Biotech Daily that although the precise dose per tablet was not disclosed, each tablet was sufficient “to achieve blood levels predicted to be compatible with anti-cancer activity” (BD: Mar 14, 2019).

The company said the lack of adverse effects following up to 10 tablets was evidence of the safety and no apparent taste issues were noted for dogs that were administered 10 tablets in one dose supporting the palatability, compared to the previous liquid formulation.

Pharmaust said it would begin a phase II trial on completion of a pharmaco-kinetic study.

Pharmaust was up 0.1 cents or 2.8 percent to 3.7 cents with 1.8 million shares traded.

ANALYTICA

Analytica says it has received \$745,112 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Analytica said the funds related to research and development expenditure for the year to June 30, 2018.

Analytica was unchanged at 0.4 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm 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 18.4 percent from \$1.605 on March 26 to \$1.90 yesterday, March 27, 2019 and noted a significant increase in trading volume.

Paradigm fell eight cents or four percent to \$1.90 with 630,024 shares traded.

[RHINOMED](#)

Dr John McBain, Picton Cove and Fifty-Second Celebration say they have increased their holding in Rhinomed from 8,397,981 shares (7.13%) to 11,638,566 shares (8.2%).

The Melbourne-based Dr John McBain said that between October 30, 2018 and March 21, 2019, Picton Cove acquired 1,179,251 shares at prices ranging from 14.5 to 25 cents a share; between September 21, 2018 and February 2, 2019, Thirty-Fifth Celebration for the JC McBain Super Fund bought 390,000 shares for 18 cents to 26 cents a share and on November 6, 2018 Fifty-Second Celebration acquired 1,671,334 shares in a placement at 21 cents a share.

Rhinomed was up 1.5 cents or 8.1 percent to 20 cents.

[ALCIDION GROUP](#)

Blue Sky Private Equity (BSPE) Medical Technology says it has sold all 84,864,273 shares and ceased its substantial holding in Alcidion.

The Brisbane-based Blue Sky said that between March 20 and March 27, 2019 it sold all its shares on market for prices ranging from 4.5 to 6.3 cents a share.

In a separate announcement Alcidion said Blue Sky ceased its substantial shareholding "in line with the fund's investment mandate".

Alcidion chairman Ray Blight said the company was "very grateful for the support of Blue Sky" which had supported the company from the early stages of its development.

The company said that Blue Sky director Nick Dignam would remain on the board, having been re-elected for a further two years in October 2018.

Alcidion was up half a cent or 7.9 percent to 6.8 cents with 8.7 million shares traded.

[BIO-MELBOURNE NETWORK](#)

The Bio-Melbourne Network says that chief executive officer Dr Krystal Evans has resigned, effective from today, March 28, 2019.

Dr Evans was appointed to the position in August 2014, having formerly worked as a researcher at the Walter and Eliza Hall Institute of Medical Research (BD: Jul 4, 2014).

The Network thanked Dr Evans "for her commitment and tireless efforts toward developing our organization over the past [five] years".

A replacement chief executive officer has not been named.

[INVICTUS BIOPHARMA](#)

Invictus says it has appointed Dr Jordan Moon to its scientific advisory board.

Invictus said Dr Moon was currently Impedimed's director of research and education and was formerly a program director of sports management and sports and health sciences at American Public University and American Military University.

The company said that Dr Moon was a "sports physiology clinical trials expert", who had conducted more than 45 clinical trials, published more than 140 peer-reviewed scientific articles and held a Doctor of Philosophy from the University of Oklahoma.

Invictus is a public unlisted company.