



Biotech Daily

Monday November 4, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMPEDIMED UP 12%; ORTHOCELL DOWN 5.5%**
- * **PRO MEDICUS: OHIO STATE UNI \$9m VISAGE 7 DEAL**
- * **PHYLOGICA RAISES \$14.3m, \$12.5m TO GO**
- * **NEXT SCIENCE FALLS ON WRONG MOTLEY FOOL 4C REPORT**
- * **BIONOMICS: FDA FAST TRACK STATUS FOR BNC210 FOR PTSD**
- * **OPTISCAN: FDA CONFOCAL MICROSCOPE ORAL CANCER MEETING**
- * **RHYTHM: CHINA PATENT FOR COLOSTAT**
- * **IMUGENE RECEIVES \$4m FEDERAL R&D TAX INCENTIVE**
- * **NUHEARA RECEIVES \$1.7m FEDERAL R&D TAX INCENTIVE**
- * **IMMURON RECEIVES \$532k FEDERAL R&D TAX INCENTIVE**
- * **MICRO-X REQUESTS 'CAPITAL MANAGEMENT, RAISING' TRADING HALT**
- * **INVION LOSES 6-YEAR DIRECTOR GREG COLLIER**
- * **ELIXINOL APPOINTS TERESA CLEARY CO SEC**
- * **CHRIS MEWS REPLACES AUSCANN DIRECTOR DR PAUL MACLEMAN**
- * **STEMCELL LOSES DIRECTOR SAVIO KA LUNG CHEUNG**

MARKET REPORT

The Australian stock market was up 0.27 percent on Monday November 4, 2019, with the ASX200 up 17.8 points to 6,686.9 points. Twenty of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and three were untraded.

Impedimed was the best, up 1.5 cents or 11.5 percent to 14.5 cents with 358,728 shares traded. Actinogen, LBT and Proteomics climbed more than six percent; Neuren was up 5.8 percent; Alterity, Osprey and Prescient improved four percent or more; Avita, Nanosonics, Polynovo and Volpara were up more than three percent; Compumedics, Medical Developments and Next Science rose more than two percent; Clinuvel, Mesoblast and Pro Medicus were up more than one percent; with CSL, Paradigm and Telix up by less than one percent.

Orthocell led the falls, down 3.5 cents or 5.5 percent to 60 cents, with 2.9 million shares traded. Both Amplia and Pharmaxis lost five percent; Dimerix and Genetic Signatures fell four percent or more; Oncosil was down 3.6 percent; Kazia shed 2.4 percent; Opthea lost 1.2 percent; with Cochlear, Cynata, Resmed and Starpharma down by less than one percent.

PRO MEDICUS

Pro Medicus says it has a \$9 million, five-year deal with the Columbus-based Ohio State University Wexler Medical Center for its Visage 7 Enterprise Imaging system.

Pro Medicus said the contract, was through wholly-owned subsidiary Visage Imaging, would integrate its Visage 7 medical imaging platform across all of the centre's radiology departments and its electronic health records system.

The company said that the Wexler Medical Center had radiology departments in seven hospitals and outpatient clinics.

Pro Medicus said it would begin implementing Visage 7 in the centre by January 1, 2020 and expected to be completed in "mid-2020".

Pro Medicus was up 41 cents or 1.7 percent to \$25.05 with 769,479 shares traded.

PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica says it has raised \$14.3 million in an institution entitlement offer at 5.5 cents with "excess applications," and expects to raise \$12.5 more in a retail offer.

Last week, Phylogica said it expected to raise up to \$26.8 million in a one-for-five, non-renounceable institutional and retail entitlement offer, fully underwritten by Australian Land and controlled by non-executive chairman Alan Tribe (BD: Oct 31, 2019).

Today, the company said that \$6.2 million of the funds raised came from existing major investors, with a shortfall placement of \$8.1 million.

Phylogica chief executive officer Dr Rohan Hockings said the company "now has the funding required to take [the lead drug program for patients living with retinitis pigmentosa] through clinical development".

Phylogica fell 0.6 cents or 9.7 percent to 5.6 cents with 3.7 million shares traded.

NEXT SCIENCE

Next Science says that "an erroneous article ... has been posted by Motley Fool on the Yahoo Finance website".

Next Science said that "the article significantly overstates the net cash used in operating activities for the year to date".

The company said that its Appendix 4C published on October 30, 2019 did not contain any errors and the net cash used in operating activities for the nine months of the year to date was correct.

Last week, the Next Science Appendix 4C quarterly report said it had customer receipts for the three months to September 30 to \$US927,000 (\$A1,340,600) and \$US2,864,000 for the nine months to September 30, 2019.

The company said its cash burn for the three months was \$US2,001,000, it had \$US in cash and cash equivalents \$US20,264,000 at September 30, with an expected cash burn of \$US5,074,000 for the three months to December 31, 2019.

Next Science confirms that it is in compliance with the ASX Listing Rules, in particular, Listing Rule 3.1 and that it will continue to keep shareholders fully informed in accordance with its continuous disclosure obligations.

According to Commsec data, Next Science fell 4.15 percent to \$2.54 on October 30, a further 3.54 to \$2.45 on October 31 and 12.24 percent to \$2.15 on November 1, 2019.

Today, Next Science was up five cents or 2.3 percent to \$2.20.

BIONOMICS

Bionomics says the US Food and Drug Administration has granted fast track status for BNC210 for post-traumatic stress disorder and other trauma-related disorders.

Last year, Bionomics said its 193-patient, phase II, post-traumatic stress disorder (PTSD) trial “did not meet [the] primary endpoint”, but this year said it would change the formulation to raise BNC210 blood levels (BD: Oct 2, 2018; Jun 26, 2019).

In September, the company said that a pharmaco-kinetic study of its solid dose BNC210 showed an exposure-response relationship with a clinician-administered PTSD scale, the primary endpoint measure used in PTSD trials (BD: Sep 26, 2019).

Today, the company said it was preparing for a BNC210 solid dose formulation phase IIb trial in PTSD patients.

Bionomics executive chairman Dr Errol De Souza said the FDA fast track designation was “an important recognition of the high unmet medical need in PTSD and potential benefits of BNC210 with a novel mechanism of action in the treatment of this disorder”.

Dr De Souza said BNC210 was “back on track” following pharmaco-metric analysis and two pharmacokinetic studies showing that the target blood levels predictive of efficacy in the treatment of PTSD could be achieved with the solid dose formulation.

Bionomics said that fast track status meant the program would be eligible for accelerated approval, priority review and a rolling review, enabling the submission of sections of the application, as well as more frequent meetings with the FDA.

Bionomics was up 2.1 cents or 22.3 percent to 11.5 cents with 9.7 million shares traded.

OPTISCAN IMAGING

Optiscan says it has requested a meeting with the US Food and Drug Administration for its confocal microscope for oral cancer 510(K) submission.

Optiscan said the meeting request included an application to develop “in-vivo confocal laser scanning images of the internal microstructure of tissue within the oral cavity, including the oropharynx”.

In August, the company said its microscope had been approved for an oral cancer trial at New York’s Sloan Kettering Cancer Centre, and it would seek approvals for its use in cervical cancer and oesophageal cancer trials (BD: Aug 21, 2019).

In September, Optiscan said its microscope would begin a second trial for early diagnosis of cancerous changes in oral mucosa, led by the University of Melbourne’s Dental School with collaborators including the Royal Melbourne Hospital, Sloan Kettering, Melbourne’s Peter MacCallum Cancer Centre and Perth’s Australian Centre for Oral Oncology Research & Education (BD: Sep 23, 2019).

Today, the company said its microscope could improve health care outcomes for the more than 50,000 patients diagnosed in the US with oral or oropharyngeal cancer this year.

Optiscan was unchanged at 4.1 cents with one million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has a divisional patent from the People’s Republic of China for its Colostat test kit for colorectal cancer, supporting a previously approved parent patent.

Rhythm said the patent, titled ‘Diagnostic for colorectal cancer’ would provide intellectual property protection until 2031.

The company said it had been granted patents for the diagnosis of colorectal cancer in Australia, China, Europe and Japan, with applications pending in the US, Brazil and India.

Rhythm was unchanged at 16.5 cents.

IMUGENE

Imugene says it has received \$4,126,678 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imugene said the rebate related to research and development expenditure for the year to June 30, 2019.

Imugene was unchanged at 2.8 cents with 13.4 million shares traded.

NUHEARA

Nuheara says it has received \$1,673,964 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nuheara said the rebate related to research and development expenditure for the year to June 30, 2019.

Nuheara was up 0.1 cents or 2.6 percent to four cents with 1.3 million shares traded.

IMMURON

Immuron says it has received \$531,828 from the Australian Tax Office under the Federal Government Research and Development Tax Concession Incentive program.

Immuron said the rebate related to research and development expenditure for the year to June 30, 2019.

Immuron was up half a cent or four percent to 13 cents.

MICRO-X

Micro-X has requested a trading halt "to allow the board to conduct a review of [its] current capital management and a potential capital raising".

Trading will resume on November 6, 2019 or on an earlier announcement.

Micro-X last traded at 25 cents.

INVION

Invion chairman Thian Chew said in his annual general meeting address that former executive chairman Dr Greg Collier had resigned effective from today.

In July, Invion said Craig Newton would replace Dr Collier as chief executive officer from November 1, 2019, with Dr Collier to continue as a director (BD: Jul 22, 2019).

Today, Mr Chew said Dr Collier had been with the company for more than six years as chief executive officer and managing director and said his efforts had built "a strong foundation for our initiatives going forward".

Invion fell 0.2 cents or 15.4 percent to 1.1 cents with 5.9 million shares traded.

ELIXINOL GLOBAL

Elixinol says it has appointed Teresa Cleary as general counsel and company secretary, replacing joint company secretaries Ron Dufficy and Kim Bradley-Ware.

Elixinol said Mr Dufficy would continue as the company's chief financial officer.

The company said Ms Cleary was a lawyer and had previously been the general counsel and company secretary of the Australian Institute of Company Directors and the supervising counsel at Telstra Corp.

Elixinol was up half a cent or 0.3 percent to \$1.50.

AUSCANN GROUP HOLDINGS

Auscann says that Merchant Funds Management chief financial officer Christopher Mews will replace Dr Paul MacLeman as director effective from December 1, 2019.

Auscann said that Dr MacLeman, who was appointed chief executive officer in 2018, would retire effective from today.

The company said that the Perth-based Merchant Funds was its largest shareholder.

In October, Merchant Funds said it became a substantial holder in Auscann with 36,237,639 shares (11.43%), acquired from Canopy Growth Corp, buying the shares off-market at 15 cents a share, when the company was trading at 31 cents a share; and last week increased its holding to 13.43 percent (BD: Oct 14; Nov 1, 2019).

Today, Auscann said Mr Mews had more than 20 years' experience in the financial services sector and was Merchant Funds company secretary, VPCL company secretary and non-executive director, and was previously Polynovo chief financial officer and company secretary.

The company said Mr Mews held a Bachelor of Business from Perth's Edith Cowan University.

Auscann was up 1.5 cents or 5.6 percent to 28.5 cents with 1.1 million shares traded.

STEMCELL UNITED

Stemcell says that director Savio Ka Lung Cheung has resigned as non-executive director.

Stemcell was untraded at 1.5 cents.