

Biotech Daily

Monday November 19, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: FACTOR UP 50%; AVITA DOWN 7%
- * VOLPARA H1 REVENUE UP 53% TO \$2.5m; LOSS UP 22% TO \$4.8m
- * IMAGION RIGHTS OFFER RAISES FULL \$4.3m
- * CYNATA RECEIVES \$1.3m FEDERAL R&D TAX INCENTIVE
- * ALLAN GRAY SELLS, TAKES LOSS ON ALL 123m FACTOR SHARES
- * DIMERIX STARTS DMX-200 DIABETIC KIDNEY DISEASE TRIAL
- * GENETIC TECHNOLOGIES FILES \$15m KENTGROVE PROSPECTUS
- * CELLMID APPOINTS PHARMACEUTICAL SERVICES NZ DISTRIBUTOR
- * CHINA COPYRIGHTS, TRADEMARKS FOR USCOM 1A, BP+, SPIROSONIC
- * INVION TO RELEASE 2.75b ESCROW SHARES
- * MGC, RMIT, HEBREW UNIVERSITY OF JERUSALEM TO LAUNCH CANNAHUB
- * IMMURON: DR GARY JACOB CEO STARTS ON \$479K; DR KANELLOS COO
- * INVITROCUE APPOINTS DR LINDNER EUROPE CEO, PROF WAUGH ADVISOR
- * SOMNOMED NEIL VERDAL-AUSTIN REPLACES CEO DEREK SMITH ON \$480k
- * ADMEDUS LOSES CFO CATHERINE COSTELLO
- * MEDIBIO APPOINTS MATHEW WATKINS JOINT CO SEC

MARKET REPORT

The Australian stock market fell 0.64 percent on Monday November 19, 2018 with the ASX200 down 36.9 points to 5,693.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and four were untraded.

Last week's 97.3 percent worst, Factor, was today's best, up 0.1 cents or 50 percent to 0.3 cents with 103.25 million shares traded. Uscom climbed 11.1 percent; Airxpanders improved 9.8 percent; Prescient was up 5.3 percent; Dimerix, Osprey and Pro Medicus were up more than three percent; Actinogen and Paradigm rose more than two percent; LBT and Nanosonics were up more than one percent; with Resmed up 0.85 percent.

Avita led the falls, down 0.7 cents or 7.2 percent to nine cents with 2.1 million shares traded. Prana lost 6.8 percent; Immutep, Mesoblast and Pharmaxis fell more than five percent; Imugene and Volpara were down more than four percent; Bionomics and ITL lost more than three percent; Cochlear, Medical Developments, Neuren and Orthocell shed two percent or more; Clinuvel, Cynata, Genetic Signatures, Impedimed, Starpharma and Telix fell more than one percent; with CSL and Polynovo down less than one percent.

VOLPARA HEALTH TECHNOLOGIES

Volpara says revenue for the six months to September 30, 2018 was up 53.4 percent to \$NZ2,662,000 (\$A2,498,200) with net loss after tax up 21.9 percent to \$NZ5,119,000 (\$A4,804,010).

Volpara said that its breast mammography quality assurance equipment sales fell 12.4 percent to \$NZ212,000, but software as a service was up 117.8 percent to \$NZ1,925,000 and software maintenance agreements increased 24.8 percent to \$NZ171,000, with grant income down 25.0 percent to \$NZ354,000.

Volpara chief executive officer Dr Ralph Highnam said the six-month period was "excellent".

"We've seen managed growth in the team, with good progress towards our key financial goals for the year and major new markets opening up, namely in surgery and Asia, and that first sale into a public screening program," Dr Highnam said.

"We're looking forward with great confidence to [the Radiological Society of North America in November 25 to 30, 2018 in Chicago], the world cup of radiology, where we'll be showing the world the progress we've made over the last year, including the launch of new innovative Volpara products," Dr Highnam said.

Volpara fell seven cents or 4.9 percent to \$1.35.

IMAGION BIOSYSTEMS

Imagion says its rights offer shortfall placement at four cents a share has raised \$3.9 million, taking the total raised to the hoped-for \$4.3 million.

In October, Imagion said the rights issue raised \$410,924 with the shortfall to be placed by the Perth, Western Australia-based Pamplona Corporate (BD: Oct 22, 2018).

Imagion said the funds from the rights issue would be used for a first-in-human study of its nanoparticles for the detection of cancer to be conducted at the Houston, Texas-based MD Anderson Cancer Centre in early 2019 (BD: Sep 10, Nov 8, 2018). Imagion was untraded at 4.5 cents.

CYNATA THERAPEUTICS

Cynata says it has received \$1,308,552 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Cynata said that Federal R&D Tax Incentive refund related to expenditure in the year to June 30, 2018.

Cynata fell two cents or 1.8 percent to \$1.08.

FACTOR THERAPEUTICS (FORMERLY TISSUE THERAPIES)

Allan Gray and related companies say they have sold their entire 122,588,416 shareholding (13.32%) in Factor Therapeutics following last week's trial results. In April, Allan Gray said it bought 25,363,113 shares taking its holding to 13.2 percent, with the single largest acquisition 8,173,138 shares for \$326,926 or 4.0 cents a share (BD: Apr 24, 2018).

Today, the company said that between Jul 12 and Nov 14, 2018 it sold all of its shares in Factor, with most sold on Nov 14, 2018 and for \$368,239 or 0.3 cents a share.

Last week, Factor fell 95.9 percent to 0.3 cents on news that its 157-patient, phase II trial of VF001 for venous leg ulcers "failed to meet all endpoints" (BD: Nov 14, 2018). Factor was up 0.1 cents or 50 percent to 0.3 cents with 103.25 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has filed a prospectus to raise up to \$15 million from Melbourne's Kentgrove Capital or other investors.

Genetic Technologies said the prospectus was filed with the Australian Securities and Investments Commission and would allow it to issue 1,362,066,065 shares.

The company said it previously issued 100,000,000 shares to Kentgrove and received funds of \$1,350,000.

Genetic Technologies was unchanged at one cent with 6.8 million shares traded.

DIMERIX

Dimerix says the first of 40 patients has been dosed in its phase II clinical trial of DMX-200 for diabetic kidney disease, with results expected by the end of 2019.

Dimerix said that the first patient was dosed at the Gosford, New South Wales-based Renal Research with multiple Australian sites involved in the trial (BD: Jul 18, 2018).

The company said the study followed the initial study of DMX-200 for chronic kidney disease, in which the subgroup of patients with diabetic kidney disease "showed a statistically and clinically compelling response" (BD: Nov 2, 2017).

Dimerix said that the patients would receive two treatment blocks of 12 weeks, separated by a six-week washout period, receiving either placebo or DMX-200 in the first treatment block, then switched to the alternative in the second treatment block.

The company said that all patients would receive 300mg of irbesartan daily for at least three months prior to screening, so that any reduction in proteinuria could be "solely attributed to the potential benefits of DMX-200".

Dimerix chief executive officer Dr Nina Webster said that the progressive nature of kidney disease "inevitably results in poor outlook for patients, as it most often results in total kidney failure and a poor quality of life".

"A kidney transplant costs in the region of \$260,000 per patient, with ongoing and expensive anti-rejection drugs also costing thousands of dollars per year," Dr Webster said.

"Dialysis costs are in the region of \$100,000 per patient per year and consume about 12 hours per week in regular clinic visits," Dr Webster said.

"This is a huge burden on both the patient and the healthcare system," Dr Webster said. "We believe DMX-200 has the potential to increase the life of the kidney by three to five years, which is significantly better for both the patient and the healthcare system," Dr Webster said.

Dimerix said it was also enrolling patients for a separate, concurrent phase II trial of DMX-200 for focal segmental glomerulosclerosis.

Dimerix was up 0.3 cents or 3.2 percent to 9.7 cents.

CELLMID

Cellmid says it has appointed Pharmaceutical Services Ltd as New Zealand distributor of its Évolis and Fillerina anti-aging hair and skin products.

Cellmid said that Pharmaceutical Services was owned by the Pharmacy Guild of New Zealand and supplied most of its members, which was more than 1,000 pharmacies.

The company said that the first commercial shipment was expected this month.

Cellmid was up one cent or 3.1 percent to 33 cents.

<u>USCOM</u>

Uscom says that China has granted four copyrights and published four trademarks related to its non-invasive Uscom 1A, BP+ and Spirosonic diagnostics.

Uscom said the copyrights were issued by the National Copyright Administration of the People's Republic of China, while the trademarks were published by the Trademark Office for the State Administration of Industry and Commerce.

The company said that copyright protection for the Uscom 1A, BP+ and Spirosonic had been granted, while the trademarks were expected to be granted 12 months following publication on September 26, 2018.

Uscom said the trademarks were in effect but could be challenged over the next 10 months and were granted in perpetuity, while the copyrights remained active as long as an annuity was paid.

The company said the applications were generated from its office in Beijing and would provide "on-going commercial protection of the Uscom products in China" as new devices were approved and the markets expanded.

Uscom said that supporting patents were in review and would provide a secondary intellectual property strategy for protecting market development in China.

Uscom executive chair Prof Rob Phillips said that "after 10 years in China these are the first successful applications for Chinese [intellectual property] for Uscom".

Prof Phillips said the submissions were driven by the Uscom China team who were familiar with the processes and pathways of Chinese intellectual property law, regulatory pathways and speak the language, thus accelerating and simplifying the intellectual property and regulatory applications.

"The Uscom 1A is already approved for sale in China, with Chinese sales responsible for more than 60 percent of Uscom's total annual revenue," Prof Phillips said. Uscom was up 1.5 cents or 11.1 percent to 15 cents.

<u>INVION</u>

Invion says that 2,750,000,000 shares issued for the acquisition of the Photosoft technology for cancer will be released from voluntary escrow on December 4, 2018. Invion said that following the release from escrow, the company would have 5,492,272,967 shares available for trading.

Invion fell 0.4 cents or 16.0 percent to 2.1 cents with 1.2 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says that with the Royal Melbourne Institute of Technology and the Hebrew University of Jerusalem it will launch Cannahub for medical marijuana research. MGC said that the hub would be launched by April 2019 and initially focus on the use of medicinal cannabis for cancer, the effectiveness of traditional and medicinal cannabis combination treatments and drug delivery systems.

The company said the hub was "a key milestone" and Cannahub would be its "primary research and new product development engine, supporting its seed-to-pharma business model through the innovation and development of new medicinal cannabis products and technologies".

MGC said that all findings, outcomes and conclusions would be the property of the Cannahub partners, MGC, RMIT and the Hebrew University of Jerusalem.

MGC was up 0.1 cents or 2.4 percent to 4.2 cents with 5.7 million shares traded.

IMMURON

Immuron says it has appointed former Synergy Pharmaceuticals Inc executive chair Dr Gary Jacob as chief executive officer starting on \$US350,000 (\$A478,808). Immuron said that along with the base salary, Dr Jacob would be eligible for up to \$US45,000 a year for eligible health insurance and other employment related compensation.

The company said that interim chief executive officer Dr Jerry Kanellos would return to his previous position as chief operating officer (BD: Aug 3, 2017).

Immuron said that Dr Jacob was previously New York's Synergy Pharmaceuticals chairman, president and chief executive officer.

The company said that Dr Jacob has more than 30 years of experience in the pharmaceutical and biotechnology industries, including research and development, operations, business development, capital financing activities and senior management. Immuron said that Dr Jacob was the co-inventor of the US Food and Drug Administration approved Trulance, or plecanatide, for chronic gastro-intestinal disorders.

The company said that Dr Jacob had raised more than \$US500 million in public markets. Immuron said that Dr Jacob currently was Contravir chair and a director of Trovagene, which was developing drugs for cancer.

The company said that Dr Jacob held a Bachelor of Science from the University of Missouri St Louis and a Doctor of Philosophy from the University of Wisconsin-Madison. Immuron was up 2.5 cents or 9.8 percent to 28 cents.

INVITROCUE

Invitrocue says it has appointed Dr Andreas Lindner as Europe chief executive officer and Prof David Waugh as a senior advisor, effective from today.

Invitrocue said Dr Lindner was appointed a director in February, overseeing business direction and providing advice (BD: Feb 8, 2018).

The company said Dr Lindner would establish commercial operations in Europe, focusing on the roll-out of its cancer patient-derived organoids, or Onco-PDO, cancer screening technology.

Invitrocue said Prof Waugh was the head of Queensland University of Technology's School of Biomedical Sciences and was formerly the director of the Queen's University Belfast Centre for Cancer Research and Cell Biology and a professor of molecular oncology and therapeutics.

The company said Prof Waugh had published more than 100 articles and participated in research projects including trials of treatments for solid tumors and prostate cancer. Invitrocue said Prof Waugh would advise the company on prostate cancer. Invitrocue was up 0.9 cents or 12.9 percent to 7.9 cents.

<u>SOMNOMED</u>

Somnomed says it has appointed chief financial officer Neil Verdal-Austin as its chief executive replacing Derek Smith, on a base salary of \$480,000 effective from today. Somnomed said Mr Verdal-Austin would be entitled to bonuses up to \$200,000.

The company said it had "reached agreement with its chief executive Derek Smith to step down from his position effective November 16, 2018".

The company said Mr Smith was appointed chief executive officer on September 1, 2016 and Mr Verdal-Austin has been the chief financial officer since October 2008. Somnomed was up five cents or 3.2 percent to \$1.60.

ADMEDUS

Admedus says chief financial officer Catherine Costello resigned on November 16, 2018. Admedus said Ms Costello had other roles in the company, including as company secretary and director.

In October, Admedus said that then interim executive director and company secretary Ms Costello had resigned, effective from October 27, 2018 (BD: Oct 29, 2018).

Admedus said that Ms Costello was appointed interim executive director on May 23, 2018 and company secretary on March 15, 2018 (BD: Oct 29, 2018).

In May, Admedus said the appointment followed the resignation of then director Mathew Ratty and fulfilled the requirement to have two resident Australian directors and it had begun a search for an Australian director (BD: May 21, 23, Oct 29, 2018).

Also in October, Admedus said that Star Bright Holding nominee Dr Wenyi Gu would replace retiring director Dr Simon Buckingham (BD: May 21, Oct 4, 29, 2018).

In September, Admedus said that Hong Kong interests had taken a 19.99 percent stake in the company (BD: Apr 27, Aug 2, 6, 8, 20, Sep 3, 17, 29, 2018).

Today, Admedus chairman John Seaberg said "the restructure of Admedus in Australia will see a change to the functions and responsibilities of the role".

Admedus said it was "undertaking a restructure with a view to re-capitalization of the company and expected to provide further details of the restructure on due course". Admedus was in an extended suspension and last traded at 13.5 cents.

<u>MEDIBIO</u>

Medibio says it has appointed Mathew Watkins as joint company secretary with Melanie Leydin, effective from today.

Medibio said Mr Watkins was an accountant with experience in ASX companies across biotechnology, bioscience, resources and informational technology.

Medibio was unchanged at 3.8 cents.