



Biotech Daily

Monday March 4, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: BENITEC UP 15%; PATRYS DOWN 9%**
- * **VOLPARA DENSE STUDY: 'INTERVAL CANCER DROPS DRAMATICALLY'**
- * **CYNATA, NSW UNI: 'CYMERUS HEART DISEASE EFFICACY, IN-VITRO'**
- * **AVITA EU RECELL 'SALES INTERRUPTION'**
- * **M3 TO MARKET, DISTRIBUTE AVITA'S RECELL IN JAPAN**
- * **FACTOR TELLS ASX: \$1.2m R&D INCENTIVE A 'FORECAST FIGURE'**
- * **G MEDICAL REVENUE UP 2709% TO \$4.3m, LOSS DOWN 40% TO \$23m**
- * **MONTOYA CEASES IN PHARMAXIS**
- * **JIM SUREK REPLACES OSPREY HEAD OF SALES HANK BUTCHER**
- * **GENETIC SIGNATURES APPOINTS CFO PETER MANLEY CO SEC**
- * **ALCIDION: MELANIE LEYDIN, MICHAEL SAPOUNTZIS JOINT CO SECS**
- * **G MEDICAL LOSES DIRECTOR LOUIS ANTONIOU**

MARKET REPORT

The Australian stock market was up 0.4 percent on Monday March 4, 2019, with the ASX200 up 24.7 points to 6,217.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Benitec was the best, up two cents or 14.8 percent to 15.5 cents with 853,392 shares traded. Osprey climbed 10 percent; Volpara was up 8.1 percent; Immutep rose 6.7 percent; Airxpanders improved 5.3 percent; Universal Biosensors was up 4.8 percent; Orthocell and Pro Medicus were up more than three percent; Clinuvel, Kazia, Nanosonics, Paradigm and Prana rose more than two percent; CSL and Starpharma were up more than one percent; with Cochlear, Cyclopharm, Neuren and Resmed up by less than one percent.

PatrYS led the falls, down 0.2 cents or 9.1 percent to two cents with 639,150 shares traded. Antisense and Imugene lost five percent or more; Avita was down 3.6 percent; Telix shed 2.1 percent; with Actinogen, Cynata, Dimerix, Medical Developments, Opthea, Prescient and Proteomics down more than one percent; and Mesoblast down 0.8 percent.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says its 40,000-patient Dense trial shows the number of interval cancers “drops dramatically” when x-rays, Volpara Density and breast MRI are combined.

Volpara said the trial results were presented by Prof Carla van Gils at the European Congress on Radiology in Vienna on March 1, 2019.

The company said interval cancers and false positives dropped for the combination of mammography, Volpara density screenings and magnetic resonance imaging (MRI).

Volpara said interval cancers affected 4.4 per thousand women with extremely dense breasts, and it used Volpara Density to “select women for breast MRI on the basis of their breasts’ being judged extremely dense”.

The company said the aim of the Dense trial was to determine whether breast MRI was cost-effective method in reducing interval cancers.

Volpara chief executive officer Ralph Highnam said, “this is a large trial involving approximately 40,000 women, with massive implications for breast cancer screening globally”.

“Screening programs have been waiting for randomized control trials to show the benefit of density-based screening,” Dr Highnam said.

Dr Highnam said that optimizing screening protocols would “lead to the early identification of many more cancers and a reduction in the devastating impact of breast cancer”.

“It will also mean increasing international interest in automated breast density solutions such as Volpara Density,” Dr Highnam said.

Volpara said the study was funded by the Leverkusen, Germany-based Bayer and multiple Dutch organizations.

Volpara climbed nine cents or 8.1 percent to \$1.20 with 882,548 shares traded.

[CYNATA THERAPEUTICS](#)

Cynata says a collaboration with the University of New South Wales shows its Cymerus stem cells have efficacy for coronary artery disease, in-vitro.

Cynata said its Cymerus mesenchymal stem cells (MSCs) induced neo-vascularization, the growth of new blood vessels, in an in-vitro assay.

The company said it modified the cell culture matrix, the material on which the cells are grown, to “prime” its Cymerus stem cells and improve its ability to induce neo-vascularization.

Cynata said pre-clinical results showed that “priming effects were maintained” after the stem cells were frozen and thawed.

The company said that the University of New South Wales research was led by Dr Kristopher Kilian.

“These results are highly encouraging, in particular the finding that the priming effects were maintained after the cells were frozen and then thawed, which is extremely important with respect to clinical use of the primed cells,” Dr Kilian said.

“In practical terms, these findings mean that Cynata’s Cymerus MSCs could potentially be used therapeutically to encourage healthy new blood vessel growth in the heart of patients in whom the existing blood supply has been compromised as a result of [coronary artery disease],” Dr Kilian said.

Cynata vice president of product development Dr Kilian Kelly said, “we are very pleased with the initial output from our collaboration with [the University] and we look forward to working with Dr Killian and his team to determine next steps for the development of these customized MSCs for coronary artery disease”.

Cynata fell two cents or 1.25 percent to \$1.58.

AVITA MEDICAL

Avita says it has a “temporary interruption of sales” of its Recell system for acute thermal burns in the European Union.

Avita said that its EU notified body reported “open items related to administrative and procedural non-conformities”.

The company did not explain which items of administration and procedure did not conform, but said they were “limited to product distributed within the EU and [were] not related to product quality”.

Avita said the notification it would not impact sales of Recell outside the EU, where sales were “immaterial” and it did not actively promote the products in the EU.

Avita chief executive officer Dr Mike Perry said the interruption was “unrelated to the performance and safety of our products and does not impact the US market” and the company expected to end the interruption by October 2019.

Avita fell half a cent or 3.6 percent to 13.5 cents with 1.8 million shares traded.

AVITA MEDICAL

Avita says it is working with the Tokyo-based M3 Group’s Cosmotec to market and distribute its Recell system for the treatment of burns in Japan.

Avita said that Cosmotec had filed a Japan Pharmaceuticals and Medical Devices Act application for approval to market the Recell system in Japan, with a review of the application expected to take nine to 12 months.

The company said that Cosmotec would be able to deliver Recell to more than 90 percent of Japan’s plastic surgeons and dermatologists.

FACTOR THERAPEUTICS

Factor has told the ASX the \$1.2 million Federal R&D Tax Incentive was a “forecast figure”, revised by tax advisor Deloitte on February 4, 2019 and published that day.

The ASX said the announcements entitled ‘Appendix 4C’ and ‘Update regarding anticipated R&D Tax Incentive rebate’ were released on its platform on January 31 and February 4, 2019 respectively, and asked the company how the estimated \$1.2 million R&D Tax Incentive was calculated and when it first became aware of the revised estimate.

Factor said the \$1.2 million forecast figure published in its Appendix 4C was “representative of management’s estimate of the R&D tax rebate based on its understanding of eligible R&D activities being undertaken” with a note that the amount was not final.

The company said it provided Deloitte with information to enable the research and development tax incentive process to be progressed in January, but “an indicative final number was never provided by Deloitte”.

Factor said it had no reason to believe the forecast figure “would be materially different to the number in its forecasts”.

The company said it first became aware of the research and development report, schedule and application on February 1, research and development activities were reviewed and approved on February 2 and a board meeting was held on February 3, 2019 to review the information, and it first became aware of the confirmed, revised figure on February 4, 2019 and published it as soon as it became aware, after it had been verified and confirmed by management.

“The announcement was then drafted for board approval and released,” Factor said.

Factor was up 0.1 cents or 25 percent to 0.5 cents with 1.4 million shares traded.

G MEDICAL INNOVATIONS

G Medical says revenue for the year to December 31, 2018 was up 2709.2 percent to \$US3,062,000 (\$A4,322,503) reducing net loss after tax by 39.39 percent to \$US16,262,000 (\$A22,917,390).

G Medical said revenue was up primarily due to sales of services in the US from acquired diagnostic testing companies, Cardiostaff and Telerhythmics.

G Medical said basic loss per share was down 54.5 percent to 5.0 US cents, net tangible assets per share turned from 2.5 US cents to a deficiency of 1.9 US cents at December 31, 2018, and it had cash and cash equivalents of \$2,634,000 at December 31, 2018 compared to \$14,158,000 at December 31, 2017.

G Medical was untraded at 29.5 cents.

PHARMAXIS

Montoya Investments says it has ceased its substantial shareholding in Pharmaxis.

In 2013, Montoya said it had increased its substantial shareholding in Pharmaxis from 16,991,165 shares (5.5%) to 19,123,830 shares (6.2%) (BD: Apr 15, 2013).

In today's substantial shareholder notice Montoya said it had sold 19,123,830 shares for 26.25 cents a share on February 28, 2019.

Pharmaxis was unchanged at 26.5 cents.

OSPREY MEDICAL

Osprey says Jim Surek has been appointed head of sales effective from March 1, 2019, replacing Hank Butcher.

Osprey said that Mr Butcher would be the director of sales for the Southern US, which was its strongest performing region."

The company said that Mr Surek had more than 25 years sales experience in the medical device sector, at companies including Stimwave Technologies, Entellus Medical, Advanced Bionics Cochlear, Advanced Bionics Pain and Medtronic.

Osprey said that Mr Surek held a Bachelor of Science from the University of Chicago and a Master of International Management from the American Graduate School of International Management.

Osprey was up one cent or 10 percent to 11 cents.

GENETIC SIGNATURES

Genetic Signatures says it has appointed chief financial officer Peter Manley as company secretary, replacing Anna Sandham.

Genetic Signatures was unchanged at 96 cents.

ALCIDION GROUP

Alcidion says it has appointed Melanie Leydin and Michael Sapountzis as joint company secretaries, replacing Duncan Craig, effective from March 1, 2019.

Alcidion said Ms Leydin had 13 years' experience as a company secretary, accountant and registered company auditor.

The company said Mr Sapountzis was a governance professional and company secretary. Alcidion was up 0.1 cents or 2.5 percent to 4.1 cents.

G MEDICAL INNOVATIONS

G Medical says director Louis Antoniou has resigned “due to family and personal reasons” effective immediately.