



Biotech Daily

Tuesday January 23, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: RESMED UP 8%; GENETIC SIGS DOWN 11%**
- * **RESMED H1 REVENUE UP 13% TO \$1.4b, PROFIT DOWN 37% TO \$120m**
- * **PROBIOTEC UPGRADES H1 PROFIT 10% TO \$1.5m**
- * **CYNATA, CELULARITY WORK ON PLACENTAL STEM CELL PRODUCTION**
- * **JAPAN STUDY BACKS ATCOR SPHYGMOCOR**
- * **GI DYNAMICS RAISING \$2.1m**
- * **BENITEC RECEIVES \$4m FEDERAL R&D TAX INCENTIVE**
- * **IMMURON RECEIVES \$2.2m FEDERAL R&D TAX INCENTIVE**
- * **FACTOR MOVES FINANCIAL REPORTING FOR TRIAL RESULTS**
- * **MEDLAB CLINICAL REQUESTS PLACEMENT TRADING HALT**
- * **MGC REQUESTS 'EUROPEAN GMP CERTIFICATION' TRADING HALT**
- * **PETER DIAMOND, CRAZY DIAMOND, DAK DRAFTING TAKE 8% OF NOVITA**
- * **DORSAVI DR ANDREW RONCHI TO US, MATT MAY G-M, BDM WANTED**
- * **POLYNOVO APPOINTS GREG LEWIS COO, CFO, CO SEC; GAVIN SMITH**

MARKET REPORT

The Australian stock market climbed 0.75 percent on Tuesday January 23, 2018, with the ASX200 up 45.1 points to 6,037.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and five were untraded. All three Big Caps were up.

Resmed was the best, up 93 cents or 8.4 percent to \$11.97 with 5.0 million shares traded. Polynovo and Starpharma climbed more than five percent; Medical Developments was up 4.9 percent; Acrux, Oncosil, Universal Biosensors and Viralytics were up more than three percent; Volpara rose 2.1 percent; with Cochlear, Mesoblast, Nanosonics and Sirtex up more than one percent.

Genetic Signatures led the falls, down 3.5 cents or 10.8 percent to 29 cents with 149,598 shares traded. Immutep (Prima) fell 4.2 percent; Dimerix lost 3.85 percent; Benitec, Bionomics, Factor Therapeutics and LBT shed more than two percent; with Admedus, Impedimed, Neuren, Optiscan, Osprey and Pharmaxis down one percent or more.

RESMED

Resmed says revenue for the six months to December 31, 2017 was up 13.0 percent to \$US1,124,932,000 (\$A1,408,887,840) with net profit after tax down 37.4 percent to \$US95,651,000 (\$A119,792,200).

Resmed said that “non-GAAP” net profit after tax was up percent to \$US237,964,000 allowing for US tax reform transition impact and deferred tax impact as well as amortization of acquired intangible assets.

Resmed declared a three-month dividend of 3.5 US cents a share, for a record date of February 8, payable on March 15, 2018 and said that diluted earnings per share fell 38.0 percent to 67 US cents, and up 23.9 percent to non-GAAP \$US1.66, with cash and cash equivalents of \$US858,899,000 at December 31, 2017, compared to \$US788,146,000 at December 31, 2016.

Resmed was up 93 cents or 8.4 percent to \$11.97 with 5.0 million shares traded.

PROBIOTEC

Probiotec says it expects net profit before tax for the six months to December 31, 2017 to be \$1.5 million to \$1.6 million, 10 percent above previous guidance.

Probiotec said that the expected profit was 115 percent to 130 percent above the prior corresponding period.

The company said that unaudited figures provided at a meeting of directors today showed that trading in December had been stronger than expected, which led to the upgrade.

Probiotec was up two cents or 2.35 percent to 87 cents.

CYNATA THERAPEUTICS

Cynata says Celularity Inc will undertake a commercial evaluation of its Cymerus production technology for use with Celularity’s therapeutic stem cell technologies.

Cynata said the Warren, New Jersey-based Celularity used its technology to harness cells from the post-partum placenta to address serious and life-threatening diseases, with strategic assets contributed from Celgene Corp, Sorrento Therapeutics, United Therapeutics and Human Longevity Inc.

The company said the agreement was an opportunity to expand its target disease areas into a broad range of degenerative and immunological diseases, with Celularity benefitting from Cynata’s Cymerus stem cell production technology.

Cynata said the agreement followed “encouraging early clinical data” in its phase I trial of CYP-001 in acute steroid resistant graft versus host disease (BD: Jan 22, 2018).

The company said that Celularity’s placental-based technology was pioneered by Dr Robert Hariri, who discovered placental pluripotent stem cells and invented the first placental amniotic membrane product for wound care more than 15 years ago and had expanded the use of placental cells to other indications and commercial products.

Cynata chief executive officer Dr Ross Macdonald that Celularity was “the perfect partner to explore our unique Cymerus technology”.

Celularity founder and executive chairman Dr Hariri said the value in the Cymerus platform was “its unique ability to produce therapeutic grade mesenchymal stem cells at scale”.

“Our stem cell therapies would immensely benefit from mass production and it is for this reason we have chosen to enter into a [memorandum of understanding] with Cynata,” Dr Hariri said.

Cynata was up three cents or 4.7 percent to 67 cents.

ATCOR MEDICAL

Atcor says an independent study has shown the validity of its Sphygmocor XCEL device for augmentation and amplification parameters against invasive measurements.

Atcor said that the study, entitled 'Validity of the augmentation index and pulse pressure amplification as determined by the Sphygmocor XCEL device; a comparison with invasive measurements' was published in the Hypertension Research, the official journal of the Japanese Society of Hypertension, with an abstract available at:

<https://www.ncbi.nlm.nih.gov/pubmed/28978987>.

The company said that the article "showed a strong correlation between non-invasive Sphygmocor XCEL measurements and traditional invasive measures".

Atcor said that central aortic pressures and indices derived non-invasively by Sphygmocor XCEL were compared with invasive measurements.

The company said the study included a range of values and ages with results applicable to a wide range of the adult population and the authors concluded that they "demonstrated the validity of the Sphygmocor XCEL device in measuring the augmentation and amplification parameters against invasive measurements".

Atcor chief executive officer Craig Cooper said the publication was "a significant independent validation of our Sphygmocor XCEL central measures related to arterial stiffness and cardiac load and we are delighted by the results".

"The study further solidifies our strong patent protected position as the only medical device company which can accurately produce, non-invasively through a traditional blood pressure cuff, the central waveform and measures equivalent to those measured by an invasive pressure catheter placed at the heart," Mr Cooper said.

Atcor was unchanged at 3.8 cents.

GI DYNAMICS

GI Dynamics says it has binding commitments to raise \$2,057,321 in a private placement at 3.5 cents per Chess depository interests (CDIs).

GI Dynamics said the placement would be in two tranches to sophisticated and professional investors in Australia, the US and the UK, with the first tranche closing today, raising \$996,347 and the second tranche expected to raise \$1,060,974, subject to shareholder approval.

The company said the funds would be used for the development of its Endobarrier duodenal insert for obesity and type 2 diabetes and for general working capital purposes.

GI Dynamics said it "continues to operate with substantial doubt about its ability to continue as a going concern".

GI Dynamics chief executive officer Scott Schorer said the company was "focused on securing approval for a study from the [US Food and Drug Administration] for a new pivotal clinical trial of Endobarrier".

GI Dynamics was up 0.1 cents or 4.2 percent to 2.5 cents.

BENITEC BIOPHARMA

Benitec says it has received \$4,112,058 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Benitec said the rebate related to the costs of research and development "for the year ended 2017" and the funds would be used for its gene silencing programs.

Benitec fell half a cent or 2.2 percent to 22.5 cents.

IMMURON

Immuron says it has received \$2,156,206 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program, for the year to June 30, 2017.

Immuron was up half a cent or 2.2 percent to 23.5 cents.

FACTOR THERAPEUTICS

Factor says it will change its financial reporting year to December 31 “to facilitate the company’s preparations for the readout from the VF00102 clinical trial”.

Factor said it would have a six-month transition period from July 1 to December 31, 2017, then report 12-monthly thereafter and hold an annual general meeting by May 31, 2018.

Factor Therapeutics fell 0.1 cents or 2.2 percent to 4.5 cents.

MEDLAB CLINICAL

Medlab Clinical has requested a trading halt “pending an announcement in relation to a placement”, with trading to resume on January 25, 2018 or on an earlier announcement. Medlab Clinical last traded at \$1.015.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested a trading halt pending an announcement about “good manufacturing practice certification approval process” for its European facility.

Trading will resume on January 25, 2018 or on an earlier announcement.

MGC last traded unchanged at 10.5 cents with 5.0 million shares traded.

NOVITA HEALTHCARE (FORMERLY AVEXA)

Peter Diamond, Crazy Diamond and Dak Drafting Services say they have increased their holding in Novita from 20,000,000 shares (5.56%) to 30,000,000 shares (8.35%).

A notice signed by director Peter Diamond, said that Crazy Diamond Pty Ltd bought the 10,000,000 shares for \$452,668 or 4.5 cents a share between January 11 and 22, 2018.

Novita was up 0.2 cents or 4.4 percent to 4.7 cents.

DORSAVI

Dorsavi says chief executive officer Dr Andrew Ronchi has moved to the US, effective from January 22, 2018, to focus on strategic relationships in the US and Europe.

Dorsavi said it had increasing US revenue and the move would allow the company to build relationships with stakeholders and clinical and insurance groups, but the relocation did not affect Mark Heaysman’s role as head of US sales and operations.

Dorsavi said Dr Ronchi would cease to be an Australian employee, would be employed by Dorsavi USA on a salary of \$US300,000 (\$A375,441) a year, with relocation expenses up to \$US60,000 and Dorsavi executive director fees of \$25,000 a year.

The company said that its Australia head of sales and operations Matt May was an experienced operations executive and had lead its sales and operations since 2014 and had been promoted to general-manager.

Dorsavi said it was searching for a senior business development manager in Australia.

Dorsavi was unchanged at 28.5 cents.

POLYNOVO

Polynovo says Greg Lewis has been appointed as chief operating officer, chief financial officer and company secretary, effective from January 24, 2018.

Polynovo said that Mr Lewis would also oversee production, logistics and head office functions, enabling chief executive officer Paul Brennan “to drive the commercialization, product pipeline and international sales”.

The company said that Mr Lewis was previously Jamestrong Packaging chief financial officer and chief operating officer overseeing production facilities in Australia and New Zealand, and prior to that worked for Byron Group Holdings, ITL Healthcare, Tapex and Stryker Australia.

Polynovo said that Mr Lewis’s operational experience would allow it “to improve processes and inventory management in anticipation of increasing product demand from the US and other markets”.

The company thanked Gavin Smith who filled the role as a contract position.

Polynovo said that Mr Smith “made a very significant contribution to the business, our financial reporting and the working of our teams” and would assist in the transition to the new chief financial officer until the half year reporting process was finalized.

Polynovo was up three cents or 5.9 percent to 54 cents with 2.1 million shares traded.