



Biotech Daily

Tuesday August 27, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: NANOSONICS UP 33%; USCOM DOWN 14%**
- * **NANOSONICS REVENUE UP 39% TO \$84m, PROFIT UP 137% TO \$13.6m**
- * **CANN REVENUE UP 174% TO \$4m, LOSS UP 131% TO \$11m**
- * **RESONANCE REVENUE UP 25% TO \$3.6m, PROFIT UP 466% TO \$1.3m**
- * **CRYOSITE \$1m LEGAL SETTLEMENT**
- * **NOVITA RAISES \$485k OF HOPED FOR \$2m**
- * **FDA GUIDANCE FOR 2019 MESOBLAST CARDIAC TRIAL**
- * **BTC CHAIR DR RICHARD TREAGUS \$125k BONUS, \$15k PAY RISE**
- * **BRIAN LEEDMAN EXERCISES 5m ALCIDION 8c OPTIONS**
- * **COGSTATE REQUESTS 'CONTRACT, PLACEMENT' TRADING HALT**
- * **VIVAZOME, TOOLGEN COLLABORATE ON CRISPR-CAS9 RESEARCH**
- * **CANN LIFTS MILDURA MARIJUANA PRODUCTION BY 40% TO 70t**
- * **MGC APPROVAL FOR SLOVENIAN MEDICAL MARIJUANA RESEARCH**
- * **WESTMEAD HOSPITAL 2019 HOSPITAL WEEK**
- * **BIO-MELBOURNE 'FORMULA FOR SUCCESS' CONFERENCE**

MARKET REPORT

The Australian stock market was up 0.48 percent on Tuesday August 27, with the ASX200 up 31.1 points to 6,471.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and six were untraded. All three Big Caps were up.

Nanosonics was the best, up \$1.60 or 32.65 percent to \$6.50 with 7.4 million shares traded. Neuren climbed 17.7 percent; Dimerix and LBT were up 10 percent or more; Resonance was up 9.5 percent; Prescient improved five percent; Ellex, Polynovo and Pro Medicus were up more than four percent; Avita, Clinuvel and Opthea climbed more than three percent; Mesoblast rose 2.5 percent; Cochlear, Kazia, Resmed and Volpara were up one percent or more; with CSL, Cynata and Paradigm up by less than one percent.

Uscom led the falls, down 1.6 cents or 13.9 percent to 9.9 cents with 789,409 shares traded. Osprey lost 6.6 percent; Medical Developments, Starpharma and Telix were down more than one percent; with Compumedics and Next Science down by less than one percent.

NANOSONICS

Nanosonics says that revenue for the 12 months to June 30, 2019 was up 38.9 percent to \$84,324,000, with net profit after tax up 136.5 percent to \$13,602,000.

Nanosonics said that North American Trophon2 ultrasound probe disinfection systems revenue was up 40.6 percent to \$76.5 million, Europe and the Middle East climbed 26.7 percent to \$3.0 million and the Asia Pacific was up 21.2 percent to \$4.0 million.

The company said the increased revenue came from fixed payments, as well as continued growth in established regions, the launch of the Trophon 2 in North America, Europe, and Australia and the expanded distribution agreement with GE Healthcare in Europe.

Nanosonics chief executive officer Michael Kavanagh said the company had made "significant investments in our long-term strategy of establishing Nanosonics as a globally recognized leader in infection prevention".

"There were significant achievements across all aspects of our growth strategy including strong growth in the Trophon installed base which was up 18 percent to 20,930 units," Mr Kavanagh said. "This included 19 percent growth in North America, 21 percent growth in Europe and [the] Middle East and six percent in [the] Asia Pacific."

"This means that over 70,000 patients every day or approximately 18 million patients every year are protected from the risk of cross contamination because their probe has been decontaminated using Trophon," Mr Kavanagh said.

"Geographically, Nanosonics expanded into a number of new markets including Norway, Denmark, Finland, Spain, Portugal, Switzerland and Israel," Mr Kavanagh said.

"Market development efforts in Japan progressed with the establishment of a Nanosonics entity in Japan, the publication of the first pivotal study demonstrating probe contamination and the recent signing of an agreement with GE Healthcare Japan as well as the recent regulatory approval of Trophon2," Mr Kavanagh said.

The company said that in the next financial year it expected to increase upgrades of Trophon EPR to Trophon2 and increase spending on research and development.

Nanosonics said that revenue from Japan and the Asia Pacific region was expected to improve following the recent regulatory approval.

The company said research and development spending for the year to June 30, 2019 increased 15.15 percent to \$11.4 million, or 13.5 percent of revenue.

Nanosonics said that net tangible asset backing per share was up 21.8 percent to 32.16 cents, with diluted earnings per share up 135.1 percent from 1.91 cents to 4.49 cents.

The company said it had cash and cash equivalents of \$72,180,000 at June 30, 2019, compared to \$69,433,000 million at June 30, 2018.

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CANN GROUP

Cann says revenue for the year to June 30, 2019 was up 173.8 percent to \$3,994,857 with a net loss after tax up 131.2 percent to \$10,926,317.

Last year, Cann said it had a maiden revenue of \$616,000 from the sale of medical marijuana for the Victoria Government paediatric epilepsy trial (BD: Aug 23, 2018).

Today, the company said it had revenue from the Victoria Government of \$2,347,668, interest of \$1,644,702 and other revenue of \$2,487 compared to the prior year's \$560,000 revenue from customers, interest of \$897,745 and other revenue of \$1,544.

Cann said diluted loss per share was up 105.3 percent to 7.8 cents, net tangible assets per share fell 12.4 percent to 54.43 cents and it had cash and equivalents at June 30, 2019 of \$46,388,192, compared to \$49,566,890 at June 30, 2018.

Cann was up 18.5 cents or 10.85 percent to \$1.89.

RESONANCE HEALTH

Resonance says revenue for the year to June 30, 2019 was up 25.1 percent to \$3,624,545 with a net profit after tax up 465.5 percent to \$1,270,233.

Resonance said the revenue increase was from sales of its magnetic resonance imaging-based Ferriscan and other products, including a further 60 hospitals and imaging centres using its services, and clinical trial work valued at \$US1,530,200 (\$A2,263,737).

The company said 76 percent of revenue came from the US and Canada, 20 percent came from the UK, with the remaining revenue from Australia, Asia and the Middle East. Resonance chief executive officer Alison Laws said the profit “represents the successful implementation of concurrent sales revenue growth and cost control programs, with a 25 percent increase in revenue and a 16 percent decrease in operating costs”.

Resonance said it planned to increase revenue next year through continued third-party distribution amongst established customer bases to reduce customer acquisition and distribution costs, as well as continuing product development and conducting clinical trials. The company said that earnings per share were up 416.7 percent to 0.31 cents, with net tangible assets per share up 83.7 percent to 0.79 cents and it had cash and cash equivalents of \$3,081,192 at June 30, 2019 compared to \$1,549,088 at June 30, 2018. Resonance was up one cent or 9.5 percent to 11.5 cents with 4.6 million shares traded.

CRYOSITE

Cryosite says it will be “paid \$1,000,000 in settlement of a claim for loss and damage relating to legal services”.

In February, Cryosite said it would pay the Australian Competition and Consumer Commission (ACCC) \$1.1 million over 10 years for breaching Federal cartel laws in relation to the 2017 proposed licence of its umbilical cord blood and tissue business and sale of certain assets to Cell Care Australia sale (BD: Jun 23, 2017; Feb 8, 2019).

In August 2017, the ACCC announced an inquiry into the deal (BD: Aug 4, 2017).

Cryosite said at that time that the ACCC alleged, and the company agreed, that it “breached the [Competition and Consumer Act 2010] by including a competition restraint provision in the sale agreement, which required Cryosite to refer all sales enquiries to Cell Care from the date of signing of the contract to the date on which the transaction closed”.

The company said at that time that “this constituted a cartel provision”.

Cryosite said it retained external lawyers to advise it on the terms of the agreement, but the lawyers did not raise concerns about cartel provisions.

Today, Cryosite did not disclose who would pay the \$1,000,000 settlement but said it was payable within 30 days.

The company said that the settlement was for “loss and damage relating to legal services received by Cryosite in connection with the proposed 2017 transaction”.

Cryosite fell 0.3 cents or five percent to 5.7 cents.

NOVITA HEALTH

Novita says its five-for-11 rights issue at one cent a share has raised \$485,796 of a hoped-for \$2 million and would seek to place the shortfall.

Earlier this month, Novita said the funds were for its Detect and Train products, along with associated capital expenditures, operating costs and working capital (BD: Aug 7, 2019)

Novita said there were 155,650,608 shortfall shares and that it intended “to seek commitments ... from various professional and sophisticated investors”.

Novita was unchanged at one cent.

MESOBLAST

Mesoblast says the US Food and Drug Administration will allow a confirmatory phase III trial of Revascor for end-stage heart failure patients with left ventricular assist devices. Last year, Mesoblast said a 159-patient, phase II trial of mesenchymal precursor cells for heart failure at New York's Mt Sinai Hospital did not meet its primary endpoint, but showed benefit for gastrointestinal bleeding (BD: Nov 12, 2018).

In June, the company said the US Food and Drug Administration had granted orphan drug designation to Revascor for major mucosal bleeding associated with end-stage heart failure (BD: Jun 24, 2019).

Today, Mesoblast said the FDA confirmed that the phase II trial results could support product marketing authorization through a biologics licence application with confirmatory clinical data.

The company said that in line with FDA guidance, the confirmatory phase III trial would be conducted with the International Center for Health Outcomes Innovation Research at New York's Mount Sinai Hospital with reduction of mucosal bleeding reduction a primary endpoint.

Mesoblast said that secondary endpoints included the improvement in various parameters of cardiovascular function.

A spokesperson for Mesoblast told Biotech Daily that it expected to enroll its first of several hundred patients "by the end of the year".

Mesoblast chief executive Prof Silviu Itescu said "the FDA guidance on the pathway to registration for our heart failure product candidate in [left ventricular assist device] patients is a major step forward for our cardiovascular program".

"We will work closely with the FDA and the [International Center for Health Outcomes Innovation Research] to generate the confirmatory clinical data needed for full marketing approval of Revascor in the prevention of this life-threatening inflammatory complication of a [left ventricular assist device] implant in end-stage heart failure patients," Dr Itescu said. Mesoblast was up 3.5 cents or 2.5 percent to \$1.44.

BTC HEALTH

BTC says it will issue chair Dr Richard Treagus a bonus of \$125,000 to be paid as 892,857 shares at 14 cents a share, and a salary increase of \$15,000 a year.

BTC said that the bonus, subject to shareholder approval, was a reward for Dr Treagus' work on the acquisition of Admedus' hospital infusion business and subsequent integration into BTC Specialty Health (BD: May 31, 2019).

The company said the salary increase was effective from September 1, 2019.

BTC was up half a cent or 3.6 percent to 14.5 cents.

ALCIDION

Alcidion says former director Brian Leedman has exercised 5,000,000 options at eight cents each.

Alcidion said Mr Leedman was a non-executive director between July 28, 2016 and July 31, 2017 and was issued the options on November 29, 2016 following the company's listing on the ASX "via the reverse takeover of Naracoota resources".

The company said that the exercise of options brought the total number of shares on issue to 815,671,138 shares, with no further options held by any other party.

Alcidion fell half a cent or 2.9 percent to 17 cents with 5.1 million shares traded.

COGSTATE

Pharmaust has requested a trading halt “pending an announcement ... in relation to negotiation of a material commercial contract and a proposed placement”.

Trading will resume on August 29, 2019 or on an earlier announcement.

Cogstate last traded at 19.5 cents.

VIVAZOME THERAPEUTICS

Vivazome says it has a collaboration with the Seoul, South Korea-based Toolgen to explore gene-editing of cells for enhanced exosome production.

Vivazome said Toolgen would use its CRISPR-Cas9, or clusters of regularly interspaced short palindromic repeats-CRISPR-associated protein 9, technology to introduce gene edits into selected cell types.

The company said that the gene edits would be aimed at selectively altering the characteristics of exosome particles produced by the cells.

Vivazome said the CRISPR-Cas9 technology allowed scientists to modify the genome by inserting or deleting genes with “high efficiency and fidelity”.

The company said the gene-edited cells and exosomes would be analyzed for the company by Melbourne’s La Trobe University.

Vivazome said the agreement with Toolgen included an option for Vivazome to licence Toolgen’s technology and any intellectual property from the research program for the development and commercialization of exosome products for human therapy.

Vivazome is a private company.

CANN GROUP

Cann says it has redesigned its Mildura, Victoria-based greenhouse to increase production capacity by 40 percent to 70,000 kilograms of dry cannabis flower a year.

Cann said the increased capacity was expected to improve revenue by 21.4 percent to \$280 million a year, based on the current wholesale price of cannabis dry flower.

The company said it expected the facility to be completed by the end of 2020, with cultivation of mother plants to begin by October, 2020.

Cann said the medical marijuana manufactured at the facility would supply domestic and international markets under its five-year, \$10.75 million agreement with Aurora Cannabis (BD: Mar 19, 2019).

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has approval for a “large-scale research project on cannabis for medical purposes” with the Žalec-based Slovenian Institute of Hop Research and Brewing.

MGC said the research would focus on the cultivation of marijuana and the standardization of post cultivation production processes of active pharmaceutical ingredients derived from phyto-cannabinoids.

The company said the research would take place at the Institute of Hop Research’s facilities, which was large enough for MGC commercial activities.

MGC chief executive officer Romy Zomer said the research would further the company’s aim of “cost effective standardized medicines to treat under-served indications ... around the world, and to maintain our position as market leaders in research and tapping the full emerging potential of diverse phyto-cannabinoids as active pharmaceutical ingredients.”.

MGC fell 0.3 cents or seven percent to four cents with 9.96 million shares traded.

WESTMEAD HOSPITAL

Westmead Hospital says gene therapy, infectious diseases and artificial medicine were among the topics being discussed this week, at its 2019 Hospital Week.

Sydney's Westmead Hospital said that "world-leading" health experts would be at the hospital this week to discuss the future of medicine.

The Hospital said that King's College London's Prof Peter Goadsby was a leading migraine researcher and would lead the headache symposium with a focus on the history of Australia's contribution to migraine research.

Westmead Hospital said that cardiology, headaches and infectious diseases were among the symposiums, the first day centred on the 40th year of cardiology at the hospital.

The Hospital said cardiology director Prof Robert Denniss would conclude the first day with a presentation on the future of prevention and treatment of cardiology.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold its Biotech Development Lab on the theme 'Formula for Success' on September 13, 2019.

The Network said the full-day event would include an address from the Victoria Department of Jobs, Precincts and Regions and presentations from 12 speakers, with panel discussions with the speakers and expert panellists.

Bio-Melbourne Network chief executive officer Dr Julie-Anne White said that the topics to be addressed included 'Accelerating drug discovery and development through collaborations', 'Overcoming bioavailability hurdles - developing novel drug delivery systems to improve clinical efficacy', 'Lab to production - controlling the process' and 'From research to commercialization – who pays?'

The Network said that the event was being sponsored by the Victoria State Government, Watermark, Seer Pharma, Prime Accounting and Business and the Department of Industry, Innovation and Science – Business Entrepreneurs' Program.

The Network said that the workshop would will be held in Lecture Theatre B, Level 7, Peter MacCallum Cancer Centre, 305 Grattan Street, Melbourne on Friday, September 13, 2019, with registration from 8.15am and presentations from 9am until 5pm, to be followed by a networking session.

For more information go to: <http://biomelbourne.org/event/biotech-development-lab-2019/>.