



Biotech Daily

Monday September 15, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CLINUVEL UP 16.5%
- GENETIC TECHNOLOGIES DOWN 8%**
- * **GENETIC TECHNOLOGIES \$2m NOTES, RESTRUCTURE, NAME CHANGE**
- * **COMPUMEDICS, BEIJING BESTMED SIGN 3-YEAR \$5.6m CONTRACT**
- * **IMUGENE HER-VAXX READY FOR CLINICAL TRIAL PRODUCTION**
- * **RESONANCE \$650k SHORTFALL TAKES TOTAL RAISED TO \$1.9m**
- * **BERNARD STANG LIGHTENS TO 9% OF NANOSONICS**
- * **COGSTATE LOSES RODOLFO CHAPA; QUIXOTE SHARES TO DOLBY, MYER**
- * **AVITA REQUESTS 'REGULATORY UPDATE' TRADING HALT**

MARKET REPORT

The Australian stock market fell 1.04 percent on Monday September 15, 2014 with the S&P ASX 200 down 57.6 points to 5,473.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, three traded unchanged and four were untraded.

Clinuvel was the best for the second trading day in a row, up 61 cents or 16.5 percent to \$4.30 with 174,006 shares traded under pressure from Retropin (BD: Sep 12, 2014), followed by Compumedics up 13.0 percent to 13 cents with 322,616 shares traded.

Osprey climbed 7.9 percent; Acrux was up 5.2 percent; Patrys climbed 4.35 percent, Antisense, Bionomics, Cellmid and Pharmaxis were up more than three percent; Impedimed rose 2.1 percent; Phosphagenics, Starpharma and Tissue Therapies were up more than one percent; with Alchemia, Cochlear and Prana up by less than one percent.

Genetic Technologies led the falls, down 0.2 cents or eight percent to 2.3 cents with 1.1 million shares traded.

Universal Biosensors fell 7.9 percent, Admedus lost 6.9 percent; Living Cell and Medical Developments fell more than four percent; Anteo, Atcor, Nanosonics, Oncosil and Viralytics were down more than three percent; Analytica, Ellex and GI Dynamics shed two percent or more; Benitec, Mesoblast, Neuren and Psivida fell one percent or more; with CSL and Sirtex down by less than one percent.

GENETIC TECHNOLOGIES

Genetic Technologies says it expects to raise \$2.15 million, will review costs, divest non-core assets, appoint new directors, focus on molecular diagnostics and change its name. Genetic Technologies said that, pending shareholder approval, it had commitments for \$2.15 million in \$1.00 convertible notes carrying a 10 percent interest rate and convertible at a 10 percent discount to the five-day volume weighted average price, with notes carrying free attaching options.

The company said that the number of options to be issue to each note-holder would be calculated by dividing the subscription amount by the lesser of the five-day volume weighted average price to the time of the announcement of the entry into the note, namely 2.5 cents and following the extraordinary general meeting for approval of the grant of options.

Genetic Technologies said that Lodge Corporate was the exclusive placement agent for the transaction and the funds raised would support short-term capital requirements and, together with existing cash reserves, support the refocused US molecular diagnostics strategy.

The company said it also expected to receive additional funding and cost benefits in the next three months from the proposed sale of non-core assets.

Genetic Technologies said its plans would be implements in the next three months to create "a focused [molecular diagnostics] company and refined US commercialization strategy for Brevagen, with a significantly reduced operating cost base".

The company said it would maintain its patent assertion program based on its non-coding patent estate, in a revised, targeted and cost-effective manner.

Genetic Technologies said that its Brevagen diagnostic test informed clinicians and patients about individual, non-familial, sporadic risk of breast cancer and was approved for sale in the US.

The company said that the current generation of product was applicable to Caucasian women and the next generation product Brevagenplus would be suitable for use with African American and Hispanic women to be launched in October 2014 to coincide with breast cancer awareness month (BD: Mar 18, 2014).

Genetic Technologies said that Brevagenplus should be "very appealing to the larger breast centres" and provided a more reliable and accurate assessment of a patient's breast cancer risk.

The company said that the addressable market of eligible women who met the criteria for Brevagenplus in the US was more than seven million women.

Genetic Technologies said that to support marketing and reimbursement efforts, it planned to conduct clinical utility studies to demonstrate the benefit of the Brevagenplus test to patients, physicians and importantly insurers.

The company said that Brevagenplus could assist physicians meet legislative changes in some US states requiring patients to be notified of post-mammogram dense breast tissue, which was an independent risk factor for breast cancer, as well as potentially masking an existing lesion.

Genetic Technologies chief executive officer Alison Mew said that Brevagenplus was expected to "deliver improved outcomes over our first generation test and will, very importantly, be applicable for each of the major ethnic groups in the United States".

"Not only will this make physicians more likely to use and recommend the test, but it will also greatly simplify the sales and marketing efforts required to support the enhanced product," Ms Mew said.

Genetic Technologies fell 0.2 cents or eight percent to 2.3 cents with 1.1 million shares traded.

COMPUMEDICS

Compumedics says it has a contract with China distributor Beijing Bestmed to provide revenue of \$US5 million (\$A5.55 million) over the coming three years.

Compumedics said that the contract committed Bestmed to the revenue for its electronic health platform, with potential growth within five years to \$US13.2 million.

The company said that it and with Bestmed were “currently number one in the Chinese market for imported sleep diagnostic equipment”.

Compumedics described the contract as “another critical milestone in the development of its new mobile health ... platform”.

The company said that since 2013 it had focused on transforming its sleep-diagnostic technology into a fully integrated internet cloud-based product for monitoring and diagnosing sleep applicable within laboratories under physician care as well as to the consumer at home.

Compumedics said its medical innovation services had “a highly promising five-year market growth outlook estimated between \$US50 billion and \$US70 billion for wearable technology, \$US8 billion for mobile health and \$US35 billion for telemedicine”.

The company said it had initial partners to finalize the products, technology and the platform, four contracts in other key markets in Asia totalling \$US4.1 million and it was continuing discussions with additional partners.

Compumedics executive chairman Dr David Burton said his company was “uniquely placed to develop and introduce this next generation of sleep and neurology-diagnostic technology”.

“Enabling unique online [electronic] health services enhances user experience outcomes for consumers, patients and professional health-carers, alike,” Dr Burton said.

“These developments serve as a precursor for discussions with major web technology and global orientated telecommunications companies, who share the vision to provide highly Compumedics was up 1.5 cents or 13.0 percent to 13 cents.

IMUGENE

Imugene says the Swiss-based contract manufacturers Bachem AG and Mymetics SA are able to manufacture its Her-Vaxx cancer immunotherapy for clinical trials.

Imugene said that Bachem completed a feasibility study earlier this year of the Her-Vaxx peptide, combining three individual peptide B-cell epitope antigens, and was developing and validating analytical test methods used in the manufacture of clinical grade Her-Vaxx, to be manufactured by Mymetics.

Imugene executive director Dr Nick Ede told Biotech Daily that Bachem manufactured the peptide antigen for the immunotherapy, while Mymetics developed the influenza virosome used to convey the immunotherapy to the cancer.

The company said that the Bachem data would be part of its US Food and Drug Administration investigational new drug application.

Imugene said that Her-Vaxx was a therapeutic gastric and breast cancer immunotherapy that stimulated a polyclonal antibody response to HER-2/neu, the same biomarker targeted by the \$US6.9 billion a year drug Herceptin.

The company said that Her-Vaxx completed a phase I study in breast cancer and the next stage of development would be a phase Ib/II gastric cancer study.

Imugene said that gastric or stomach cancer was the second most common cause of cancer-related death in the world and the fourth most commonly diagnosed cancer with more than one million new cases diagnosed each year.

Imugene was untraded at 1.6 cents.

RESONANCE HEALTH

Resonance says it has raised a further \$650,000 through the placement of 13,000,000 shortfall shares at five cents a share taking the total raised to \$1.9 million.

Resonance said that with the funds from its placement and rights issue it had a net cash balance of about \$2.7 million and the funds provided the resources to take Hepafat Scan into the US, Europe and Asia, participate in validation studies and fund fibrosis work.

Resonance said that the validation studies would further build and enhance the credentials of its magnetic resonance imaging-based technologies.

Resonance was up 0.3 cents or 5.9 percent to 5.4 cents.

NANOSONICS

Bernard Stang has reduced his holding and been diluted in Nanosonics from 28,377,000 shares (14.6%) to 24,713,255 shares (9.35%).

The Rose Bay, Sydney-based Mr Stang and brother of chairman Maurice Stang said that he sold 3,000,000 shares on line for \$3,240,000 or \$1.08 each.

Mr Stang has held the shares since the company listed on the ASX, when the price climbed 80 percent above its 50 cents offer price to 90 cents (BD: May 17, 2007).

Nanosonics fell four cents or 3.5 percent to \$1.11.

COGSTATE

Cogstate says Rodolfo Chapa has resigned as a non-executive director.

Cogstate said that Mr Chapa was appointed a director in August 2011, when the company acquired Axon Sports as a wholly-owned subsidiary of Cogstate.

The company said that Axon was originally a 50-50 joint venture with Mr Chapa's Quixote Investment LLC and following the announcement that it would divest Axon, Mr Chapa decided to retire from the board.

In 2010, Cogstate partnered with a then unnamed Portland Oregon-based investment group to create Axon Sports to "focus on the delivery of products to both protect and train athlete's brains" (BD: Jun 10, 2010).

In June this year Cogstate said it expected revenue for the year to be less than the previous year with an increase in loss and in 2013 said that the then loss reflected "expenditure in Axon Sports and Healthcare business" (BD: Aug 21, 2013; Jun 6, 2014).

In June, Cogstate said it planned cost saving measures including the sale of Axon Sports.

Today, Cogstate said that 12,961,831 shares held by Quixote had been sold, with 6,170,000 shares acquired by the Dagmar Dolby Trust a related entity of director David Dolby, taking Dagmar Dolby Trust's holdings to 19,776,389 shares or 19.98 percent, and 1,000,000 shares acquired by the Myer Family, a related entity to chairman Martyn Myer and the Myer Family held 18,493,214 million shares or 18.68 percent.

Cogstate was up 2.5 cents or 8.6 percent to 31.5 cents.

AVITA MEDICAL

Avita has requested a trading halt pending an announcement regarding "a regulatory update" and trading will resume on September 17, 2014 or on an earlier announcement.

Avita last traded at 10.5 cents.