



Biotech Daily

Friday July 31, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: TISSUE THERAPIES UP 8%, GI DYNAMICS DOWN 69%**
- * **GI DYNAMICS: 'US PROTOCOL MIGHT CAUSE HEPATIC ABSCESES'**
- * **VICTORIA APPOINTS PHILIP DALIDAKIS MINISTER FOR INNOVATION**
- * **CSL, NOVARTIS CLOSING SEQIRUS 'FLU VACCINE DEAL**
- * **AFRICAN PATENT FOR SUDA'S ARTIMIST FOR MALARIA**
- * **RESMED REVENUE UP 8% TO \$2b, PROFIT UP 2% TO \$483m**
- * **RHINOMED HAS ONE QUARTER CASH, EXPECTING SALES GROWTH**
- * **INVION HAS LESS THAN ONE QUARTER CASH, CONSIDERING OPTIONS**
- * **UP TO 45% OF PRIMA VOTES OPPOSE RIDGEBACK SHARES**
- * **BRENDAN MORAN TAKES 6.5% OF LBT**
- * **BIO-MELBOURNE: 'CHECK REGISTRATION FOR EPILEPSY BREAKFAST'**

MARKET REPORT

The Australian stock market was up 0.52 percent on Friday July 31, 2015 with the ASX200 up 29.7 points to 5,699.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell and 12 traded unchanged. All three Big Caps were up.

Tissue Therapies was the best, up half a cent or 8.3 percent to 6.5 cents with 195,881 shares traded.

Polynovo, Resmed, Reva and Universal Biosensors climbed more than six percent; Cellmid and IDT were up more than five percent; Bionomics and Biotron were up more than four percent; Benitec and Compumedics were up more than three percent; CSL, Impedimed and Nanosonics rose two percent or more; Mesoblast and Sirtex were up more than one percent; with Cochlear and Osprey up by less than one percent.

GI Dynamics led the falls, losing as much as 9.4 cents or 69.6 percent to 4.1 cents, before closing down 9.3 cents or 68.9 percent to 4.2 cents with 5.6 million shares traded.

Oncosil lost 7.7 percent; Clinuvel and Neuren were down more than five percent; Ellex fell 4.5 percent; Prima was down 3.8 percent; Admedus and Starpharma shed more than two percent; Actinogen, Prana and Viralytics were down more than one percent; with Acrux and Psivida down by less than one percent.

GI DYNAMICS

GI Dynamics chief executive officer Mike Dale says that a double-dose of proton pump inhibitors may be the cause of increased hepatic abscesses that terminated its US trial. Yesterday, GI Dynamics announced that it had closed its 500-patient US trial of the Endobarrier for obesity and type 2 diabetes, due to the higher than expected rate of hepatic abscess, a bacterial infection of the liver.

GI Dynamics said that seven patients of the 325 enrolled in the trial had developed the liver infection, the cause of the US Food and Drug Administration halt to the trial in March (BD: Mar 6, 2015).

The trial was randomized with two patients receiving the Endobarrier to every one patient undergoing a "sham" procedure.

In a teleconference today, Mr Dale said that outside the US the rate of hepatic abscesses was 0.7 percent, but in the US the rate was 3.2 percent to 3.5 percent.

Mr Dale said the only difference and possible explanation was that in the US there had been a strict adherence to a "double-dose" of proton pump inhibitor drugs to reduce stomach acid, which was hypothesized would reduce bleeding.

He said that the increased dose allowed "gut flora" such as natural bacteria to increase to higher than normal levels.

Mr Dale said there were no cases of hepatic abscess in the "sham" control group which had an endoscopic procedure but without any implantation.

Mr Dale said that the hooks used to anchor the Endobarrier penetrated the duodenum potentially allowing bacteria to enter the hepatic portal system.

He said that all patients in the trial would be "explanted" removing the Endobarrier.

Mr Dale said that other authorities would consider the US data and he expected to know whether European and Australia sales would be affected within 30 to 60 days.

"The preliminary results show that Endobarrier therapy is efficacious," Mr Dale said.

Mr Dale said the preliminary results showed that HbA1c, or glycated haemoglobin, levels in patients who completed 12 months with the Endobarrier dropped by 1.25 percent compared to 0.14 percent for the sham group, with a significance of $p = 0.008$. According to several diabetes websites, the healthy level for HbA1c is 4.0 percent to 5.9 percent.

Mr Dale said that trial patients assessed at 18 months, six months after explantation, had a treatment effect of 0.87 percent reduction in HbA1c.

Mr Dale said there no question about the efficacy of the Endobarrier, but the overall safety data was still being analyzed.

He said that data on weight loss was still being analyzed.

"The news is a tremendous disappointment," Mr Dale said.

"Without the US market we need to preserve cash," he said.

Mr Dale said that revenue had fallen from \$US1.7 million for the six months to June 30, 2014 to \$US900,000 for the six months to June 30, 2015, as a result of decreased sales across all markets.

In October 2014, the European Union halted shipments of the Endobarrier due to the company's method and timelines of reporting adverse events in clinical use, but the halt was lifted in December (BD: Oct 6, 7, Dec 1, 2014).

Mr Dale said that GI Dynamics had cash and cash equivalents of \$US32.8 million at June 30, 2015 compared to \$US51.2 million at December 31, 2014 and \$US40.0 million at March 31, 2015.

GI Dynamics fell as much as 9.4 cents or 69.6 percent to 4.1 cents, before closing down 9.3 cents or 68.9 percent at 4.2 cents with 5.6 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government says that Philip Dalidakis has been appointed as the Minister for Small Business, Innovation and Trade.

A media release from Premier Daniel Andrews said that Mr Dalidakis was elected to Parliament as Member for Southern Metropolitan Region at the 2014 election.

The Victoria Government said that Mr Dalidakis previously worked as an analyst at Deloitte, founded SCG Advisory, worked for Centro Properties Group and was the chief executive officer of the Victorian Association of Forest Industries.

A spokesman for the Premier told Biotech Daily that Mr Dalidakis previously held ministerial advisory jobs including working for the then Communications Minister Stephen Conroy.

The spokesman said that Mr Dalidakis was an energy and industry advisor under the previous State Governments of Steve Bracks and John Brumby.

The spokesman said that Mr Dalidakis held a Bachelor of Business degree from Monash University and a Masters of Commerce from the University of New South Wales.

The previous Minister, Adem Somurek, resigned following allegations of bullying.

CSL

CSL says it has the necessary approvals to proceed with the acquisition of the influenza vaccines business of Novartis and is working to close the transaction.

Last year CSL said it would acquire the Novartis influenza vaccines business of Novartis for \$US275 million and combine it with Bio-CSL (BD: Oct 27, 2014).

Today, CSL said that the new subsidiary would be called Seqirus, derived from the term "securing health for all of us".

The company said it previously expected to close the transaction on December 31, 2015 but the two companies had agreed to expedite the close and complete in the next few days.

CSL said its net earnings in the current financial year were not expected to be materially affected by the change in close date.

The company said that Seqirus would be the second largest influenza vaccines business in the \$US4 billion global industry, after Sanofi, and would have manufacturing plants in the US, UK, Germany and Australia, commercial presence in about 20 countries, a differentiated product portfolio and strong pandemic and pre-pandemic franchises.

CSL chief executive officer Paul Perreault said it was "a significant acquisition for CSL as a leading global bio-therapeutics company which has long been at the forefront of protecting people's health".

"We are pleased to clear the necessary hurdles and work towards an earlier close," Mr Perreault said.

CSL restated that chief financial officer Gordon Naylor would lead the new business and continue to serve as CSL chief financial officer until his successor began work.

The company said the Seqirus corporate office would be in Maidenhead, near London.

CSL said that the Seqirus name would take effect in October 2015 and until then Bio-CSL would continue to operate under its existing name and Novartis influenza vaccines as NVS Influenza Vaccines.

CSL climbed \$2.61 or 2.7 percent to \$98.96 with 3.2 million shares traded.

SUDA

Suda says the African Regional Intellectual Property Organization has granted a patent for its Artimist oro-mucosal spray anti-malarial spray.

Suda said that the Harare, Zimbabwe-based Organization comprised 19 member states, including the major countries in malaria-endemic Sub-Saharan Africa.

The company said that the patent covered the pharmaceutical composition of Artimist, the route of delivery, the device and methods for the treatment of uncomplicated and complicated malaria and provided coverage to 2026.

Suda said that its phase III trial in severe paediatric malaria was completed in Sub-Saharan countries with the results demonstrating the superiority of Artimist over intravenous quinine (BD: Apr 30, Jul 30, 2013).

The company said that it was in dialogue with the Medicines for Malaria Venture, the World Health Organisation and philanthropic groups to expand the opportunity for Artimist including as an early interventional treatment for malaria in the pre-referral setting.

Suda chief executive officer Stephen Carter said the new patent "further strengthens our intellectual property in key malaria-endemic countries in Africa".

Suda was up 0.2 cents or 6.7 percent to 3.2 cents with 1.2 million shares traded.

RESMED

Resmed says revenue for the year to June 30, 2015 was up eight percent to \$US1.7 billion (\$A2.3 billion) with net profit after tax up two percent to \$US352.9 million.

Resmed said that diluted earnings per share for the year was up three percent to \$US2.47 and a three-month dividend of 30 US cents per share, up seven percent compared to the previous dividend, would be paid on September 17 for shareholders at the record date of August 20, 2015.

Resmed was up 48 cents or 6.4 percent to \$8.00 with 17.3 million shares traded.

RHINOMED

Rhinomed says its net operating cash burn for the three months to June 30, 2015 was \$1,449,000 with cash at the end of the quarter of \$1,369,000.

Rhinomed chief executive officer Michael Johnson told Biotech Daily that the company was "confident that our current business development activities underpin a strong revenue growth [and] the board will continue to consider all options available".

Rhinomed fell 0.1 cents or 2.9 percent to 3.3 cents with 3.9 million shares traded.

INVION

Invion says its net operating cash burn for the three months to June 30, 2015 was \$4,351,000 with cash at the end of the quarter of \$2,285,000.

Invion said that "the cash position of the company is under constant review by the board, and the board is considering its options to ensure that cash resources are in place to see the company through its forthcoming clinical development and business milestones".

Invion chief executive officer Dr Greg Collier told Biotech Daily that the company had completed its major expenditure on its clinical trials and the cash burn rate was expected to be much lower than the previous three months.

In April, Invion said a rights issue had raised \$5.4 million taking the total raised with a March placement to \$6.3 million (BD: Mar 20, Apr 22, 2015).

Invion fell 0.1 cents or 3.85 percent to 2.5 cents.

PRIMA BIOMED

Prima shareholders have passed all extraordinary general meeting resolutions but with strong opposition to the issue of 100,206,500 shares to Ridgeback Capital Investments. In May, Prima said the New York-based Ridgeback would invest \$15 million primarily to fund two clinical trials of IMP321 for breast cancer (BD: May 14, 2015).

Today, Prima said that 97,592,760 votes (55.04%) supported the issue of the shares to Ridgeback with 79,717,346 votes (44.96%) opposed.

The company said that 22,989,714 votes (13.1%) opposed the issue of "performance rights" to chief executive officer Marc Voigt, with 152,460,493 votes (86.9%) in favor and all other resolutions were passed by wider margins.

Prima's most recent Appendix 3B new issue announcement said the company had 1.951,494,601 shares on issue, meaning the strongest opposition amounted to 4.08 percent of all shares on issue, not sufficient to call an extraordinary general meeting. Prima fell 0.2 cents or 3.8 percent to 5.1 cents with 10.6 million shares traded.

LBT INNOVATIONS

Brendan Moran and Morcap Pty Ltd have increased their substantial shareholding in LBT from 6,363,571 shares (5.55%) to 7,514,726 shares (6.55%).

A previous substantial shareholder notice said that the Rose Bay, Sydney-based Mr Moran was a 50 percent owner of Morcap, which increased its holding from 440,496 shares to 640,210 shares.

Mr Moran said the shares were acquired between June 1 and July 21, 2015 with the largest single purchase on July 21 of 199,714 shares for \$13,980 or 7.0 cents a share. LBT fell half a cent or 6.7 percent to 7.0 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it has had technical issues and attendees should re-confirm their registration for the August 6, 2015 epilepsy Bio-Breakfast.

The Network said the breakfast, entitled 'Innovation in Epilepsy at the Interface of Industry and Research' would discuss technologies, reimbursement, clinical trial innovation and funding, as well as industry, academic and clinical partnerships for research and development and commercialization.

The Network said that Australian Healthcare Solutions strategic director Matt Godden would lead a panel of experts in epileptic seizure detection, prediction and control who had experience working at the interface of industry and research.

The Bio-Melbourne Network said that novel forms of treatment approaches were being developed across a variety of industry sectors from pharmaceuticals, to bionic devices, through to brain monitoring systems, providing significant opportunities for growth.

The August 6, 2015 Bio-Breakfast will be held at the Ian Potter Auditorium, Melbourne Brain Centre, Kenneth Myer Building, 30 Royal Parade, Parkville, with registration from 7.15am for breakfast with the panel discussion from 7.35am to finish 8.40am

To register or reconfirm email Nicole Pitcher at npitcher@biomelbourne.org.