



Biotech Daily

Wednesday July 30, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ACRUX UP 10%, OPTISCAN DOWN 8%**
- * **BRIL GROUP: 'SET ASIDE 25% OF MRFF FOR COMMERCIALIZATION'**
- * **GI DYNAMICS ENROLS 1st PATIENTS IN FRENCH ENDOBARRIER TRIAL**
- * **MEDICAL AUSTRALIA Q4 CASH FLOW POSITIVE**
- * **PROGEN: 'MEDIGEN PI-88 TRIAL GOES ON DESPITE INTERIM RESULTS'**
- * **HUNTER HALL TAKES 9% OF ALCHEMIA**

MARKET REPORT

The Australian stock market was up 0.62 percent on Wednesday July 30, 2014 with the S&P ASX 200 up 34.5 points to 5,522.9 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and three were untraded. All three Big Caps were up.

Acrux was the best, up 16.5 cents or 10.4 percent to \$1.75 with 2.8 million shares traded.

Pharmaxis and Prana climbed more than eight percent; Tissue Therapies and Universal Biosensors were up more than five percent; Atcor, Biotron and Psivida were up more than four percent; IDT, Medical Developments, Mesoblast and Nanosonics were up more than three percent; Osprey and Prima rose more than two percent; with Bionomics, Cochlear, CSL, Resmed and Sirtex up by less than one percent.

Optiscan led the falls, down 0.3 cents or 7.9 percent to 3.5 cents with 158,422 shares traded.

Avita and Starpharma fell more than four percent; Admedus, Ellex, GI Dynamics, Patrys and Phosphagenics were down more than three percent; Circadian shed 2.8 percent; Clinuvel was down 1.4 percent; with Benitec down 0.5 percent.

BIOTECHNOLOGY AND RELATED INDUSTRIES LEADERSHIP GROUP

The Biotechnology and Related Industries Leadership Group has called for 25 percent of the \$20 billion Medical Research Future Fund to be set aside for commercialization. In a submission to the Senate Standing Committee on Economics on Australia's Innovation System the BRIL Group welcomed the Federal Government's \$20 billion Medical Research Future Fund (MRFF) as a strong encouragement to basic medical research, but said that with the axing of the Innovation Investment Fund program in the 2014 Budget and the previous Government's axing of the Commercial Ready Program, there was no mechanism for translating Australian medical discoveries to commercial success.

The BRIL Group was formed in 2009 to respond to the inquiry to establish a Commonwealth Commercialization Institute and comprises: the Chancellor of Monash University Dr Alan Finkel; Walter and Eliza Hall Institute director Prof Doug Hilton; Ausbiotech chief executive officer Dr Anna Lavelle; Bio-Melbourne Network chief executive officer Dr Krystal Evans; Brandon Capital managing partner Dr Chris Nave; GBS Venture Partners' Dr Joshua Funder; and was convened by Biotech Daily editor David Langsam.

The BRIL Group proposed a self-funding and growing facility "to commercialize the excellent research and development already coming from our universities and research institutions and set to increase rapidly with the establishment of the \$20 billion Medical Research Future Fund".

The submission said that to achieve results similar to world innovation competitors, about \$1 billion a year would be required.

The submission said that when the MRFF was fully funded at \$20 billion and providing five percent a year (\$1 billion), the 25 percent provision equated to \$250 million and with matching private sector investment the MRFF commercialization arm would reach the levels proposed by the 2013 Simon McKeon-chaired Review of Health and Medical Research in Australia.

The Group said that "well-vetted and timely grants of \$2 million, \$5 million or \$10 million can make significant differences to innovation outcomes ... [and] small MRFF Commercialization grants would be the fulcrum to leverage sufficient funds for market-testing and early (phase I and phase II) clinical trials".

"Larger amounts would be considered on merit for 'verge of success' pivotal and phase III trials, but these are rare as anything significant is generally licenced before this point," the Group said.

The submission said that despite low levels of support for commercialization, pharmaceutical and medicinal products had become Australia's largest manufactured export industry, surpassing the car industry in 2009 and was a "sunrise industry creating jobs and income, that is not being eroded by low-cost and low salaried economies, unlike traditional manufacturing".

While welcoming the potential of the MRFF, "the Group believes that without a substantial commercialization mechanism any ground-breaking discoveries will continue to be picked up by off-shore pharmaceutical companies and Australia will lose the high-end value of marketing the drug, device and diagnostic discoveries."

The submission cited the Innovation Investment Fund seeding new venture managers and obtaining strong whole-of-fund returns such as GBS Biosciences Trust, as well as the Medical Research Commercialization Fund and Uniseed-backed Fibrotech, supported with \$3 million in Federal funds and returning \$24 million to the Federal Treasury, was sold to Shire Plc for an upfront fee of \$80.9 million in a total deal worth about \$600 million.

The full submission is available at: www.biotechdaily.com.au.

GI DYNAMICS

GI Dynamics says the first patients have been enrolled in its 174-patient, randomized, multi-center, clinical utility study of Endobarrier gastric liner.

GI Dynamics said that the trial at 10 centres in France was sponsored by the French Ministry of Social Affairs and Health.

The company said that the study was designed to evaluate the impact and cost of 12 months of treatment with Endobarrier therapy compared to 12 months of conventional treatment for obesity and type 2 diabetes, including dietary counseling, physical activity and lifestyle changes.

GI Dynamics said that about 174 obese patients, both with and without diabetes, were expected to be enrolled.

The company said that the trial, known as Endometab was part of the Soutien aux Techniques Innovantes Coûteuses (Support for Innovative and Expensive Techniques or STIC) program, which provided government funding for innovative medical technologies that had an established clinical profile, but where additional information concerning clinical utility and potential reimbursement status was sought.

GI Dynamics said the trial was expected to complete in 2016.

University Hospital Lille professor of general surgery and a principal investigator Prof François Pattou said that obesity and diabetes were “serious disorders that affect millions of people in France for whom the best available treatments are still suboptimal”.

“We need better and more effective treatments that can improve blood sugar and promote weight loss at the same time,” Prof Pattou said.

“The results we have seen patients achieve with Endobarrier therapy thus far have been very encouraging and we are pleased to be conducting this important study,” Prof Pattou said.

GI Dynamics chief executive officer Stuart Randle said that the enrolment of the first patient in the government-sponsored study was “a step toward securing reimbursement in France and is part of our long-term strategy to make Endobarrier therapy more broadly available”.

GI Dynamics fell 1.5 cents or 3.6 percent to 40 cents with 2.6 million shares traded.

MEDICAL AUSTRALIA

Medical Australia says that revenue for the three months to June 30, 2014 was up 9.3 percent to \$3,464,000 compared to the three months to March 31, 2014.

Medical Australia said it was cash flow positive for the three months at \$33,000 following two previous quarters of cash burn of \$475,000 and \$692,000 respectively.

The company said that the turnaround was “achieved by reducing operating expenses and a more efficient use of working capital”.

Medical Australia said it manufactured, distributed and sold a broad range of medical and veterinary devices used by healthcare facilities, critical care services and veterinarians in global markets, including intravenous medication delivery systems, surgical irrigation, suction and oxygen therapy, safety sharps collection and reuse prevention and specialized diagnostic and laboratory equipment.

The company said it had \$1.8 million in cash and no debt.

Medical Australia said it continued the rollout of new and existing products to Melbourne’s St Vincent’s Hospital and strengthened its animal healthcare team for its regenerative stem cell technologies.

Medical Australia was untraded at 14 cents.

PROGEN PHARMACEUTICALS

Progen says that Taiwan-based PI-88 licensee Medigen Biotechnology Corp will continue its phase III liver cancer trial despite negative interim results.

On Monday Progen reported Medigen's interim finding with 131 patients or 60 percent of the cohort that although PI-88 was safe the drug showed no significance for the primary endpoint of disease free survival (BD: Jul 28, 2014)

Today, Progen said that further data analysis by the independent US medical imaging company Bioclinica would be conducted by the end of the year and would be "an important reference for the efficacy of PI-88".

The company said that Medigen was continuing the phase III Patron trial in 25 clinical centres and expected to complete the final analysis on the total 218 patients in 2015, to ensure that a final analysis could be conducted on PI-88's compliance with various endpoints.

Progen said that the efficacy endpoints for the phase III PI-88 trial included disease-free survival, time to recurrence, tumor recurrence rate and overall survival and the final analysis would analyze all the efficacy endpoints.

Progen was up three cents or 13.0 percent to 26 cents with 1.9 million shares traded.

ALCHEMIA

Hunter Hall Investment Management has increased its substantial holding in Alchemia from 25,766,681 shares (7.94%) to 29,250,521 shares (9.02%).

Hunter Hall said it acquired the shares between June 2 and Jul 8, 2014, with the single largest purchase on June 18 of 951,026 shares for \$467,401 or 49.1 cents a share.

Alchemia was unchanged at 57 cents.