



Biotech Daily

Monday August 3, 2015

Daily news on ASX-listed biotechnology companies

- * **AUGUST BDI-40 UP 6%, ASX200 4%, BIG CAPS 10%**
 - **TISSUE THERAPIES UP 80%, UNIVERSAL BIOSENSORS 35%;**
 - **GI DYNAMICS DOWN 72%, ANALYTICA 20%**
- * **TODAY: ASX, BIOTECH DOWN: ATCOR UP 20%, BIOTRON DOWN 9%**
- * **SUNSHINE HEART TRANSCUTANEOUS ENERGY TRIAL IN 2016**
- * **HEARTWARE H1 REVENUE UP 5% TO \$197m, LOSS UP 277% TO \$57m**
- * **ALCHEMIA HYACT BUYER PANTHER BEHIND SCHEDULE**
- * **CSL, NOVARTIS CLOSE SEQIRUS 'FLU VACCINE DEAL**
- * **MMJ PHYTOTECH M-D ANDREAS GEDEON STARTS ON \$345k**
- * **CSL CALL FOR MRFF TRANSLATION COMPONENT; BIO-MELBOURNE**
- * **MEDIBIO ONE QUARTER CASH: 'BURN REDUCED, \$1m R&D TAX CREDIT'**
- * **BIONOMICS APPOINTS TONY COLASIN CHIEF BUSINESS OFFICER**

MARKET REPORT

The Australian stock market fell 0.35 percent on Monday August 3, 2015 with the ASX200 down 19.9 points to 5,679.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and one was untraded. All three Big Caps were down.

Atcor was the best, up four cents or 20 percent to 24 cents with 879,550 shares traded.

Polynovo climbed 9.5 percent; Circadian was up 7.3 percent; Clinuvel was up 6.8 percent; Compumedics and Orthocell rose five percent or more; Starpharma was up 3.1 percent; Cellmid rose 2.6 percent; Nanosonics, Neuren and Osprey were up more than one percent; with Impedimed and Sirtex up by less than one percent.

Biotron led the falls, down one cent or 9.1 percent to 10 cents with 460,249 shares traded.

Tissue Therapies lost 7.7 percent; Actinogen and IDT fell five percent or more; Pharmaxis was down 4.4 percent; Benitec was down 3.3 percent; Admedus, Avita, Living Cell, Psivida and Reva shed two percent or more; Prima, Resmed and Universal Biosensors were down more than one percent; with Cochlear, CSL, Medical Developments, Mesoblast and Viralytics down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

An array of modest to strong rises and few falls have pushed the Biotech Daily Top-40 Index (BDI-40) nearly 1,000 points clear of the ASX200 at the end of July 2015.

With 24 of the Top 40 companies increasing in market capitalization and just 12 falling in July, the BDI-40 was up 6.2 percent while the ASX200 rose 4.4 percent. For the year to July 31, 2015, the ASX200 was up 0.12 percent, while the BDI-40 recovered from the previous year's falls, up 19.1 percent for the 12 months. In April 2014, the Index lost \$1,094 million in tumbles by Acrux, Mesoblast, Prana and QRX.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a further 10.1 percent in the month of July and up 39.1 percent for the year to July 31, 2015. Cochlear was up 13.3 percent in July to \$5,184 million, CSL climbed 11.4 percent to \$44,787 million and Resmed rose 3.4 percent to \$10,592 million.

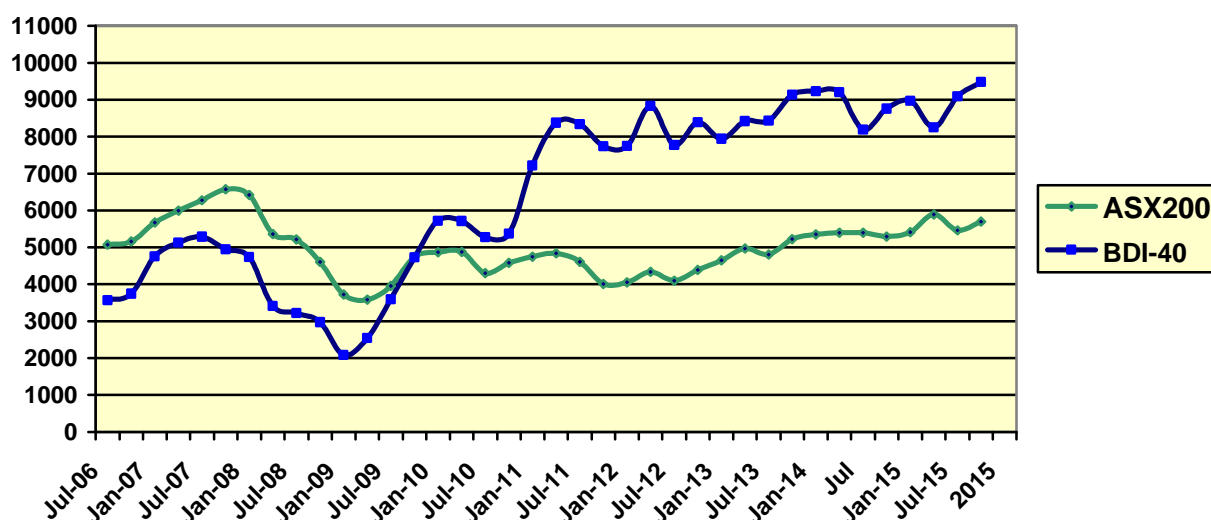
Tissue Therapies led the recovery, up 80 percent to \$18 million, followed by Universal Biosensors up 34.7 percent to \$66 million – its value prior to revealing the lump sum service fee option (BD: May 12, 2014). Anteo was up 32.8 percent to \$99 million, with Impedimed up 31.1 percent to \$333 million, followed by Benitec (30.0%), Oncosil (27.8%), Admedus (27.1%), Osprey (26.4%), Neuren (24.8%) and Atcor (21.2%).

GI Dynamics led the falls following last week's serious adverse events news, down 71.8 percent to \$20 million - despite June 30 cash of \$44.9 million - but a long way from the \$201 million valuation a year ago. Analytica fell 20 percent to \$8 million, followed by Acrux down 19.7 percent to \$114 million, Actinogen (15.9%) and Prima (15.5%).

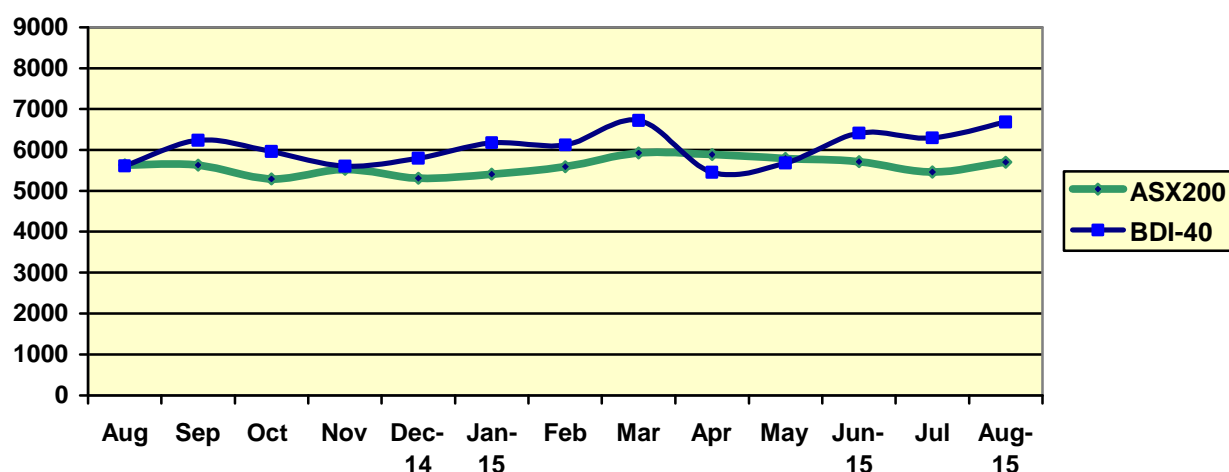
Outside the BDI-40, Orthocell recovered 138.9 percent in July to \$43 million, Medibio was up 30 percent, Simavita was up 20 percent and Pro Medicus rose 15.7 percent. On the Nasdaq, Biota climbed 21.3 percent to \$114 million, Heartware was up 31.5 percent to \$2,143 million and Sunshine Heart fell a further 4.9 percent to \$78 million.

Orthocell has replaced GI Dynamics in the Biotech Daily Second 20 Index.

BDI-40 v ASX200 Jun 30, 2006 to Jul 31, 2015 - Adjusted



BDI-40 (\$m) v S&P ASX 200 – Jul 31, 2014- Jul 31, 2015



SUNSHINE HEART

Sunshine Heart says it will begin a first-in-human study of its transcutaneous energy transmission system and a smaller implantable pump by October 2016.

In 2011, Sunshine Heart said a sheep study of its transcutaneous powered C-Pulse aorta cuff heart assist system had been successful (BD: Jun 9, 2011)

Sunshine Heart said that the study would initially enrol patients at hospitals outside the US, targeting patients with advanced class III/IV heart failure, similar to the current ongoing C-Pulse aorta cuff pump Counter HF study.

The company said that the primary objectives of the transcutaneous energy transmission (TET) system and smaller pump study would be feasibility of implant, safety and short term durability.

Sunshine Heart said that performance and efficacy data would be collected to evaluate patient quality of life, freedom from heart failure symptoms and other standard heart failure measures including the ability to bridge to other therapies.

The company said that the Texas Heart Institute's Dr William Cohn would lead the study.

"The development of a completely implantable circulatory assist device that obviates the need for a driveline will be an important milestone in the evolution of heart failure therapies," Dr Cohn said.

"The system will also be non-blood contacting and non-obligatory and may prove to be a real game changer for patients with intermediate stage heart failure," Dr Cohn said.

Sunshine Heart said the development of a fully implantable system would eliminate the need to manage a driveline and would address the risk of exit site infections and the smaller, lighter wearable components were designed to provide an improved quality of life for patients.

In 2013, the company implanted the first of up to 388 patients in the Counter HF US pivotal trial of its C-Pulse aorta cuff system for heart failure, which was halted following four patient deaths in March this year but the US Food and Drug Administration approved the resumption of the trial in May (BD: Sep 13, 2013; Mar 9, May 27, 2015).

On the Nasdaq on Friday, Sunshine Heart rose 11 US cents or 3.7 percent to \$US3.11 (\$A4.26, equivalent to 2.1 cents prior to departing the ASX) with 27,603 shares traded.

HEARTWARE INTERNATIONAL

Heartware says the total revenue for the six months to June 30, 2015, was up 5.1 percent to \$US143.6 million (\$A196.6 million), compared to the same period in 2014.

Heartware said that for the six months to June 30, 2015, it recorded a net loss of \$US41.9 million (\$A57.4 million), compared to a net loss of \$US11.1 million for the six months to June 30, 2014.

The company said that revenue for the three months to June 30, 2015 was up 5.0 percent to \$US73.6 million compared to the three months to June 30, 2014.

Heartware said it had \$US252 million in cash, cash equivalents and investments at June 30, 2015.

The company said that in the three months to June 30, 2015, a total of 773 Heartware ventricular assist device systems were sold globally, an increase of 15 percent from 674 units sold in the previous corresponding period, with US revenue for the sale of 391 units of \$US42.9 million and revenue of \$US30.7 million from the sale of 382 units outside the US.

Heartware chief executive officer Doug Godshall said that “in addition to this strong financial performance, we were pleased to have recently begun patient enrolment in our [miniaturized ventricular assist device system Conformité Européenne mark] trial, a significant accomplishment for the company and an important step forward for this innovative, new device”.

On the Nasdaq on Friday, Heartware was up \$US1.98 or 2.23 percent to \$US90.71 (\$A124.225, equivalent to \$3.55 prior to departing the ASX) with 746,669 shares traded.

ALCHEMIA

Alchemia says it is in discussions with the La Jolla, California-based Panther Biotechnology to extend the 30-day exclusivity period to buy Alchemia Oncology.

Alchemia said that the “binding term sheet ... [was] subject to a number of material conditions precedent, including Panther successfully filing their prospectus (Form S-1) with the US [Security and Exchange Commission] prior to the conclusion of the initial exclusivity period”.

In July, Alchemia said that Panther would buy its oncology assets including the Hyact platform for cash and stock worth more than \$US16 million (BD: Jul 1, 2015).

Today, the company said that Panther “did not file its prospectus within the initial exclusivity period and consequently, the term sheet will remain expired unless agreement to extend can be reached”.

Alchemia said there could be “no certainty of reaching an agreement to an extension with Panther”.

The company said that completion of the sale was also subject to Panther raising funds and listing its shares on the Nasdaq by October 28, 2015.

Alchemia fell 0.1 cents or 2.7 percent to 3.6 cents.

CSL

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

On Friday, CSL said the subsidiary would be called Seqirus from “securing health for all of us” and the two companies had agreed to expedite the close (BD: Jul 31, 2015).

CSL fell 13 cents or 0.1 percent to \$98.83 with 869,969 shares traded.

CSL, BIO-MELBOURNE NETWORK

CSL has added its voice to the call for the Federal Government to fund commercialization within the proposed \$20 billion Medical Research future Fund

CSL chief financial officer Gordon Naylor and chief scientific officer Dr Andrew Cuthbertson said that Australia's "system of innovation" had "the potential to deliver significantly more in terms of economic productivity".

CSL said that Mr Naylor and Dr Cuthbertson told the Senate References Committee Inquiry into Australia's System of Innovation that "Australia has a world class medical research sector but too often the intellectual property it generates is either not translated from an idea into a product or goes offshore for development at a very early stage and Australians miss out on the real economic payoff".

Dr Cuthbertson said that if 20 percent of grants made from the Medical Research Future Fund were targeted at translational research, "that is, assisting fundamental science move closer to its practical application, it would increase the likelihood that the large investment the Australian Government makes in basic research would actually translate into products that can be taken through to market".

The Biotech and Related Industries Leadership Group also wrote to the Senate Inquiry calling for 25 percent of all funds available to be set aside for commercialization to avoid inventions going off-shore (BD: Jul 30, 2014).

The BRIL Group comprised Monash University chancellor Dr Alan Finkel, WEHI 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, then GBS Partner Dr Joshua Funder and was convened by Biotech Daily. Today, CSL said that "for Australia to reap the full economic benefits of locally developed intellectual property ... the inquiry [should] focus on increasing the country's attractiveness as a location for advanced manufacturing".

"Translating science to proof-of-concept increases the value of intellectual property enormously, but when Australia earns royalties on [products] invented here but does not get the returns on [products] made here it does not secure the full range of benefits from its innovation system", Mr Naylor said.

"It is the final stage of product commercialisation, the large scale manufacturing for supply to global markets, which is one of the most lucrative from a national productivity perspective," Mr Naylor said.

CSL said that "to become competitive internationally and capture high-tech investment that would not otherwise take place here, Australia could introduce a highly targeted differential corporate tax rate for advanced manufacturing based on Australian intellectual property".

"We shouldn't be content with underwriting medical research for other nations to commercialise," CSL said. "With some sensible, strategic reforms Australia could be reaping those benefits for itself."

BIO-MELBOURNE NETWORK

Bio-Melbourne Network chief executive officer Dr Krystal Evans also addressed the Senate inquiry and said that her Network's members had identified the three priority areas for Government as "the need to increase access to capital, to maintain a stable supportive policy environment and to invest in human capital" and Government investment in innovation brought economic and social benefits to Australia.

"The first is the creation of high-value jobs and the transition toward a high-tech growth economy [and] the second is the training and retaining high-calibre talented people who power the innovation ecosystem," Dr Evans said.

MEDIBIO (FORMERLY BIOPROSPECT)

Medibio says its net operating cash burn for the three months to June 30, 2015 was \$838,000 with cash at the end of the quarter of \$948,000.

A spokesman for Medibio told Biotech Daily that the previous three months expenses included funds for ongoing activities and the following quarters would be at a much reduced rate.

The spokesman said that the company expected to receive about \$1 million from a Federal Government Research and Development Tax Incentive in the next three weeks, with a further \$440,000 later this year.

The Medibio spokesman said there were no plans for going back to the market for further funds.

Medibio was unchanged at 38 cents.

MMJ PHYTOTECH

MMJ Phytotech says that managing director Andreas Gedeon will have a base salary of \$C330,000 (\$A344,757).

MMJ said that Mr Gedeon could receive a performance-based bonus up to 50 percent of the base salary at any time during the initial term of three years.

The company said that Mr Gedeon was a vendor of MMJ Bioscience and acquired securities in MMJ Phytotech in the merger.

MMJ said that should it achieve the relevant milestones, Mr Gedeon and/or his related entities would receive consideration for those milestones.

MMJ Phytotech was up eight cents or 15.7 percent to 59 cents with 2.8 million shares traded.

BIONOMICS

Bionomics says it has appointed the San Diego, California-based Tony Colasin as chief business officer.

Bionomics said Mr Colasin had more than 20 years' experience in business development, product commercialization and corporate finance roles at biopharmaceutical companies, "contributing to the success of brands including Epogen and Cialis.

The company said that Mr Colasin was previously the head of corporate development of Ironwood Pharmaceuticals, which licenced Bionomics BNC210 for anxiety in 2012, but Bionomics re-acquired the compound (BD: Jan 22, 2012; Nov 11, 2014).

Bionomics said that at Ironwood Mr Colasin was responsible for strategy and tactical oversight of in-licencing, and mergers and acquisitions.

The company said Mr Colasin was previously ICOS Corp business development senior director for six years and before that held positions at Amgen in marketing, corporate finance and corporate development.

Bionomics said that Mr Colasin held a Bachelor of Science from the University of Southern California and a Masters of Business Administration from the University of California, Los Angeles.

Bionomics was unchanged at 45 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT JUL 31, 2015

Company \$Am	Aug-14	Jul-15	Aug-15
Cochlear	3,632	4,575	5,184
CSL	32,177	40,194	44,787
Resmed	7,730	10,240	10,592
BDI-20			
Acrux	306	142	114
Admedus	180	129	164
Benitec	115	80	104
Bionomics	205	174	180
Biotron	27	37	33
Circadian	9	27	31
Clinuvel	91	127	131
Impedimed	72	254	333
Medical Developments	69	155	158
Mesoblast	1,373	1,267	1,314
Nanosonics	221	481	498
Neuren	164	129	161
Osprey	60	92	116
Pharmaxis	21	69	71
Prima	49	110	93
Psivida	141	147	165
Reva	54	158	158
Sirtex	1,067	1,642	1,735
Universal Biosensors	32	49	66
Viralytics	50	140	140
Second 20			
Actinogen	4	44	37
Analytica	29	10	8
Anteo	121	67	99
Antisense	19	20	18
Atcor	16	33	40
Avita	34	31	37
Cellmid	21	24	29
Compumedics	24	45	48
Ellex	39	36	36
Genetic Technologies	21	48	50
IDT	21	44	51
Living Cell	18	21	20
Oncosil	46	36	46
Optiscan	6	10	10
Orthocell	40	18	43
Polynovo (Calzada)	50	38	41
Prana	125	80	87
Starpharma	215	233	209
Tissue Therapies	75	10	18
Uscom	20	16	14

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: <http://www.australianethical.com.au/who-we-invest-in>. These holdings are liable to change.

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