



# Biotech Daily

Monday November 3, 2014

*Daily news on ASX-listed biotechnology companies*

- \* OCTOBER BDI-40 DOWN 6%, ASX200 UP 4%, BIG CAPS UP 6%
- MEDICAL DEVELOPMENTS UP 23%, ALCHEMIA DOWN 86%, BENITEC DOWN 43%
- \* TODAY: ASX, BIOTECH DOWN: IMPEDIMED UP 65%, PATRYS DOWN 9%
- \* FEDERAL GOVERNMENT COMMERCIALIZATION ADVICE, \$1m GRANTS
- \* IMPEDIMED JUMPS 94% ON \$129 L-DEX REIMBURSEMENT
- \* SINGAPORE APPROVES EARLY ACCESS FOR ADMEDUS CARDIOCEL
- \* IDT TO BUY 23 GENERIC DRUGS, \$15m PLACEMENT, \$3m SHARE PLAN
- \* CYTOMATRIX, HEIQ J-V FOR 3-D STEM CELLS
- \* LIVING CELL COMPLETES NTCCELL PARKINSON'S RECRUITMENT
- \* BENITEC LICENCES ddRNAi TO CIRCUIT THERAPEUTICS FOR PAIN
- \* NOVOGEN ASX PLACEMENT TRADING HALT
- \* IMUGENE REQUESTS CAPITAL RAISING TRADING HALT
- \* TISSUE THERAPIES APPOINTS TIMOTHY HUGHES DIRECTOR
- \* ALCHEMIA DROPS 3m DIRECTOR OPTIONS, PAY RISE RESOLUTIONS

## MARKET REPORT

The Australian stock market fell 0.36 percent on Monday November 3, 2014 with the S&P ASX 200 down 19.7 points to 5,506.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and six were untraded.

Impedimed was the best, up as much as 93.5 percent to 89 cents before closing up 30 cents or 65.2 percent at 76 cents with 8.1 million shares traded, followed by Clinuvel up 30.7 percent to \$4.90 with 377,640 shares traded. Genetic Technologies was up 25 percent to two cents; IDT was up 11.1 percent; Atcor climbed 7.9 percent; Cellmid was up four percent; Prima rose 2.6 percent; Benitec, Bionomics, Cochlear, Neuren and Resmed were up more than one percent; with Nanosonics up 0.5 percent.

Patrys led the falls, down 0.2 cents or 8.7 percent to 2.1 cents with 476,236 shares traded. Phosphagenics lost 6.25 percent; Ellex and Pharmaxis fell more than five percent; Biotron, Compumedics and Tissue Therapies fell more than four percent; Alchemia, Anteo and Viralytics lost more than three percent; Analytica, Circadian and Starpharma shed more than two percent; with CSL and GI Dynamics down more than one percent.

### BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) fell a further 5.6 percent in October, while the S&P ASX200 was up 4.4 percent and the Big Caps climbed 6.0 percent.

Alchemia's failed phase III cancer trial was the big news, dragging down the BDI-40 by \$185 million, along with the GI Dynamics export halt reducing the cumulative market capitalization a further \$95 million, with smaller but significant falls from Acrux (\$75m), Mesoblast (\$55m), Benitec sliding a further \$50 million and curiously, Phosphagenics failed acne trial only reducing the index by \$11 million.

There was some very good news, including Clinuvel winning EU approval for Scenesse, Psivida earning \$28 million for US Iluvien approval, Biotron posting favorable trial results and Circadian, Prima and Starpharma raising significant funds. But it was not enough to keep the index up: just 13 BDI-40 companies rose, 23 fell and four were unchanged.

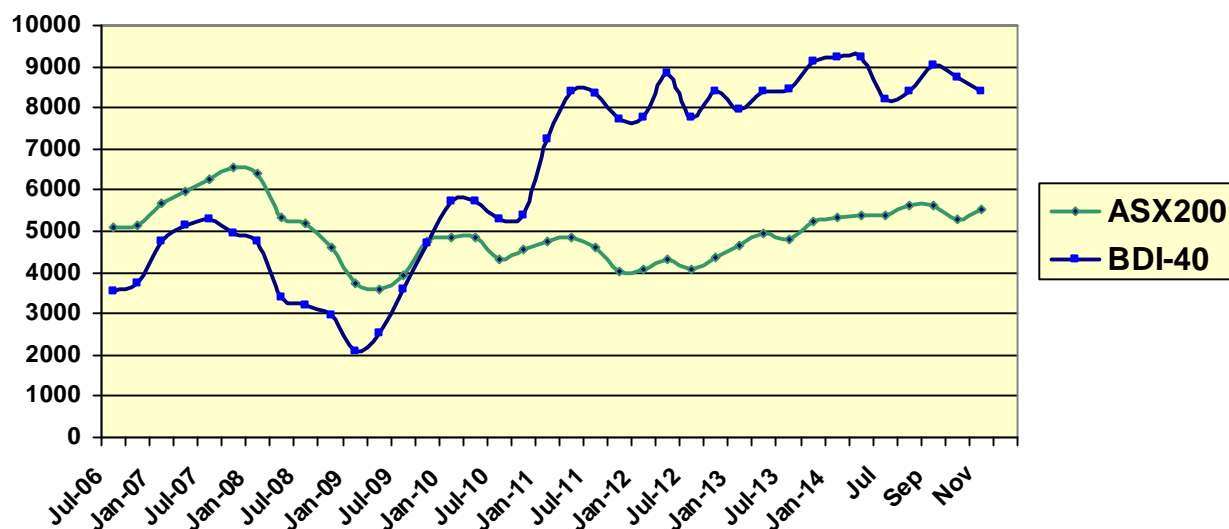
Medical Developments was the best by percentage, up \$14 million or 22.95 percent to \$75 million, followed by Sirtex up \$204 million or 16.4 percent to \$1,446 million, with Universal Biosensors (15.4%), Uscom (11.1%), Clinuvel (9.3%) and Atcor (7.1%).

Alchemia had the deepest fall, down 85.6 percent to \$31 million, followed by Benitec, sliding on the failure to advance its hepatitis C trial, down 43.1 percent to \$66 million; GI Dynamics (41.7%), Acrux (29.3%), Ellex (16.7%) and Genetic Technologies (13.3%).

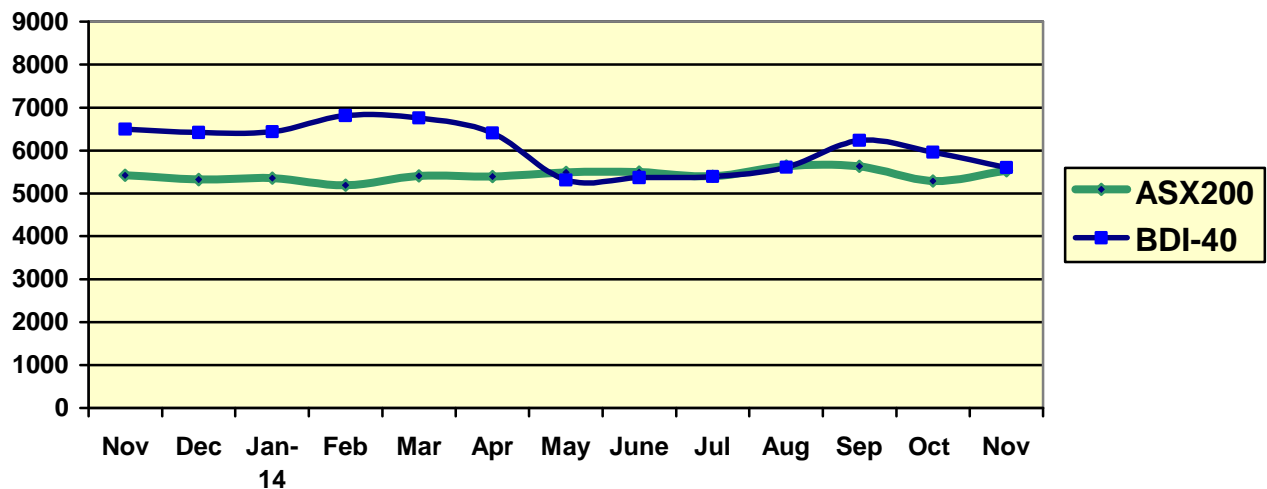
The three Big Caps (which are not in the BDI-40) climbed a cumulative 6.0 percent in October, with CSL up 6.7 percent to \$37,561 million, Cochlear up 4.8 percent to \$4,157 million and Resmed up 3.35 percent to \$8,236 million. For the year to October 31 the Big Caps climbed 11.2 percent, the BDI-40 fell 13.7 percent and the ASX200 rose 1.9 percent.

Outside the BDI-40, Isona fell to \$22 million, its lowest point since April 30, 2013 and a long way from its peak of \$194 million. Genera appears stable and has been moved from critical care to the recovery ward, along with Reva. On the Nasdaq, Biota slipped one percent, Heartware shed 1.3 percent and Sunshine Heart lost 14.7 percent.

### **BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2014 - Adjusted**



## BDI-40 (\$m) v S&P ASX 200 – Oct 31, 2013- Oct 31, 2014



### FEDERAL GOVERNMENT

The Federal Minister for Industry Ian Macfarlane launched Accelerating Commercialisation as part of its Entrepreneurs' Infrastructure Programme.

"Australia has some of the best researchers, inventors and entrepreneurs in the world, but our track record of turning great ideas into commercial products is not as good as it could be, or as good as it should be if we are to keep pace in evolving global markets," Mr Macfarlane said.

"Accelerating Commercialisation will help innovative Australian businesses to tackle the challenges they come up against in commercializing new ideas, by providing access to the expert advice, experience and networks crucial for attracting investment and getting new ideas into the marketplace," Mr Macfarlane said.

"Accelerating Commercialisation will drive business growth and competitiveness and achieve nationwide economic benefits by helping to ensure that more of Australia's wealth of intellectual property resource is effectively commercialized," Mr Macfarlane said.

"Start-ups and entrepreneurs say that the biggest hurdle can be finding people with the right skills to help to get products market ready, or to successfully demonstrate the market potential of their ideas to investors," Mr Macfarlane said.

"Accelerating Commercialisation ensures that experts and connections are available to help Australians find the right commercialization solutions for their new product, process or service," Mr Macfarlane said.

A Federal Government media release said that commercialization advisers would guide businesses through the commercialization process and eligible activities might receive financial assistance in the form of a matching grant of up to \$1 million.

The media release said that the Entrepreneurs' Infrastructure Programme was part of the Government's industry policy and worked in conjunction with the Industry Innovation and Competitiveness Agenda.

The Federal Government said that an additional \$60 million was also announced to co-fund commercialization projects through the program.

The media release said that Accelerating Commercialisation element would support entrepreneurs, start-ups and innovative businesses to create the technologies, jobs and industries of the future and builds on the Business Management and Research Connections streams of the Entrepreneurs' Infrastructure Programme.

More information on the services under the Entrepreneurs' Infrastructure Programme can be found at: [www.business.gov.au/entrepreneurs-infrastructure-programme](http://www.business.gov.au/entrepreneurs-infrastructure-programme).

## IMPEDIMED

Impedimed jumped as much as 93.5 percent to 89 cents on news of a \$US112.67 (\$A129.26) valuation for its L-Dex lymphoedema test.

Impedimed chief executive officer Richard Carreon told a teleconference that the Centers for Medicare and Medicaid Services' valuation for the current procedural terminology (CPT) category I code 93702 was "a major step forward in the reimbursement journey". The company said that from January 1, 2015, physicians and hospitals would be able to seek reimbursement for the L-Dex procedure through the new American Medical Association-designated CPT code.

Impedimed said that under the US reimbursement regime, the Centers for Medicare and Medicaid Services had assigned a payment rate when billed by a hospital outpatient facility of \$US112.67.

The company said that the valuation was "another major reimbursement milestone and should provide greater access for patients, facilitate claims processing and accelerate coverage from payers".

Mr Carreon said that the publication of the CPT category I code valuation was "a significant milestone and will be central to driving market adoption of L-Dex".

"We are pleased that today's announcement means that many US cancer patients will have access to this important test," Mr Carreon said.

"Our targeted launch begins in January 2015 and we are now armed with both compelling clinical evidence and a simplified, standardized reimbursement environment for physicians," Mr Carreon said.

A spokesperson for the company told Biotech Daily that one of the reasons for the jump in share price was that analysts previously based their valuations on a \$US30 reimbursement level.

Impedimed closed up 30 cents or 65.2 percent to 76 cents with 8.1 million shares traded.

## ADMEDUS

Admedus says the Singapore Health Sciences Authority has approved its bovine cardiac repair tissue Cardiocel for four surgeons to use it in an early access program.

Admedus said that Cardiocel was a bio-implant used in repairing heart defects, including the repair of heart valves and had received US Food and Drug Administration 510k clearance and Conformité Européenne (CE) mark approval in the US and Europe respectively and was in use at cardiac centres in those markets.

The company said that Cardiocel had a Canadian medical device licence in Canada and was used in Australia through the early access Authorised Prescriber Scheme.

Admedus chief executive officer Lee Rodne said that the Singapore approval was "a very encouraging milestone for the Admedus group, with surgeons in Singapore now granted approval to begin working with Cardiocel and establishing familiarity with this innovative medical device for the first time in Asia".

"The approval provides further endorsement of the benefits of Cardiocel and we hope it will pave the way to full marketing approval in this important health market," Mr Rodne said.

Admedus said that the special access program would enable four surgeons from different leading cardiac hospitals to use the product in the repair of cardiovascular defects.

The company said it was seeking marketing approval for Cardiocel in multiple markets in Asia as part of its strategy to launch the product in significant markets and continue to increase commercial revenues.

Admedus was unchanged at 12.5 cents with 4.3 million shares traded.

## IDT AUSTRALIA

IDT says that it will acquire 23 previously marketed US generic drug products for \$US18 million (\$A20.6 million), addressing a \$US460 million market.

IDT said that, pending shareholder approval, it would pay \$US13.5 million upfront and trailing payments of \$US4.5 million on regulatory and aggregate sales milestones.

The company said that it would become a supplier of its own products, increasing the use of its fixed plant and improve sales and margins.

IDT said the 23 tablet and capsule products were for conditions including Parkinson's disease, depression, infections, hypertension and pain.

The company said that on completing the acquisition it would begin the transfer of the products into its Melbourne manufacturing facilities and prepare the dossiers for product launches by July 2016.

IDT said that all of the products had been approved by the FDA as abbreviated new drug applications and for most the transfer process would involve "only a transfer of manufacturing site to IDT's facility" and discussions had begun with potential distributors.

IDT chief executive officer Dr Paul MacLeman said the acquisition "redefines the business of IDT as a manufacturer and supplier of its own range of specialty generic drugs".

"This builds upon the Temozolomide [abbreviated new drug application] filed by IDT in late 2013," Dr MacLeman said (BD: Nov 18, 2013).

IDT said that the acquisition would be funded through an underwritten \$15 million placement by Wilson HTM at 15 cents a share and a share plan to raise up to \$3 million.

IDT was up 2.5 cents or 11.1 percent to 25 cents.

## CYTOMATRIX

Cytomatrix has formed a joint venture with the Swiss-based Heiq Materials AG for the manufacturing and scalability of its three-dimensional haemopoietic stem cells.

Cytomatrix said that a new company called Heiq Australia had been formed and a manufacturing facility established in Geelong, Victoria, in partnership with Deakin University and the Advanced Manufacturing Cooperative Research Centre for the off-the-shelf product for bone marrow transplantations.

The company said that the facility would produce the short nanofibre materials required to produce and scale up its stem cell technology, one of four technology components in its three-dimensional stem cell expansion system, which allowed stem cells to be produced at volumes sufficient to treat all patients who required bone marrow transplants.

The company said that Heiq had the expertise to produce the short nanofibres at a commercial scale and would invest up to \$4 million in manufacturing plant scale-up and research into improved manufacturing methods for the short nanofibres.

Cytomatrix said that it retained an exclusive supply of short nanofibres into pharmaceutical applications, through Heiq Australia, to commercialize the short nanofibres into other markets and Heiq chief technology officer Dr Murray Height would lead the joint venture.

Cytomatrix chief scientific officer Prof Mark Kirkland said the venture was "a superb outcome from the research collaboration between Cytomatrix, the Advanced Manufacturing [Cooperative Research Centre] and Deakin University".

"The joint venture gives Heiq Materials access to the short nanofibre technology developed over the past three years between Cytomatrix and Deakin University and will allow us to manufacture our stem cell technology at commercial levels," Prof Kirkland said.

Cytomatrix said it would have a 50 percent holding in Heiq Australia and had swapped shares for a 10 percent stake in Heiq Materials, valuing the venture at about \$12 million.

Cytomatrix is a public unlisted company.

### LIVING CELL TECHNOLOGIES

Living Cell says it has completed recruitment of all patients for its phase I/IIa clinical trial of its NTCell encapsulated pig choroid plexus brain cells for Parkinson's disease.

Last year, Living Cell said the trial would have four patients (BD: Nov 25, 2013).

Today, Living Cell said that the trial was an open-label investigation of the safety and clinical effects of NTCell in patients who did not respond to current therapy, directed by the Auckland District Health Board's Dr Barry Snow.

Living Cell chief executive Dr Ken Taylor said the company looked forward to the clinical study outcome in 2015.

"We remain excited about the potential for NTCell to be the first disease modifying treatment for patients who are failing the current conventional treatment for Parkinson's disease," Dr Taylor said.

Living Cell was untraded at 6.4 cents.

### BENITEC BIOPHARMA

Benitec says it has licenced its DNA-directed RNA interference (ddRNAi) technology to the Menlo Park, California-based Circuit Therapeutics for use in intractable pain.

Benitec said that intractable pain was "a severe and constant pain which is not curable using current therapies ... [and] causes adverse biologic affects for sufferers, and untreated, can lead to death".

The company said that the licence terms were commercial in confidence, but broadly in line with previous agreements and within expected guidelines for biotechnology initiatives in the early stage of development.

Benitec said that the agreement covered the application of ddRNAi to target the inhibition of a Nav1.7, a voltage-gated sodium channel that was exclusively produced in certain sensory nerves and was critical for the generation of pain.

The company said that the ddRNAi technology would enable Circuit to use its novel gene silencing therapy to block Nav1.7 in particular neurons that controlled pain without the anticipated side effects of less specific and/or less targeted therapies.

Benitec chief executive officer Dr Peter French said that ddRNAi could "provide a unique solution to chronic intractable pain and as we are focusing internally on our hepatitis C, hepatitis B, non-small cell lung cancer and age-related macular degeneration programs, this licence allows us to advance the pain therapeutic potential of ddRNAi without taking resources from our other key programs".

"Success in this program will have implications for other forms of neuropathic pain, including cancer pain," Dr French said.

Circuit chairman Dr Fred Moll said that a "major focus for Circuit has been the development of novel, gene-based therapies to treat intractable pain".

"Accessing Benitec's ddRNAi approach, we believe, will enable the advancement of our programs targeting the Nav1.7 sodium ion channel," Dr Moll said.

Benitec said that discussions with other potential licencing partners were ongoing, with the expectation of further progressing the technology in a range of other serious chronic diseases with unmet needs.

Benitec was up one cent or 1.8 percent to 56 cents.



### NOVOGEN

Novogen says it hopes to raise \$3,000,000 through a placement on the ASX BookBuild facility with an opening price of 11 cents a share and up to \$7.5 million in total..

Novogen said its ASX Bookbuild trading code was NRTXBB.

In a media release, Novogen said that the placement would offer up to 80,000,000 shares and 80,000,000 attaching options, exercisable at 12.5 cents each, within 12 months.

The company requested a trading halt and said it would continue to a voluntary suspension to manage the ASX Bookbuild process and placement.

Novogen said it intended to raise a minimum of \$3 million in the Bookbuild and \$2.5 million through off-market placements.

The company said that CMC Market Stockbroking was the technical lead manager.

Novogen last traded at 12 cents.

### IMUGENE

Imugene has requested a trading halt "pending an announcement in relation to a proposed capital raising".

Trading will resume on November 5, 2014 or on an earlier announcement.

Imugene last traded at 1.1 cents.

### TISSUE THERAPIES

Tissue Therapies says it has appointed Timothy Hughes as a new non-executive director.

Tissue Therapies said that the Sydney-based Mr Hughes had experience in investment banking and finance from the senior positions he held with Rothschilds Australia and within the superannuation industry and had experience as a director of companies including Alchemia, Value Capital Management and South Endeavour.

Tissue Therapies fell 1.5 cents or 4.5 percent to 32 cents.

### ALCHEMIA

Alchemia says it has withdrawn resolutions proposing the issue of 3,000,000 options to directors and increase the directors remuneration pool by 50 percent to \$750,000.

The annual general meeting resolutions proposed to issue 1,000,000 options to Santo Costa and 500,000 options each to Dr Tracie Ramsdale, Nathan Drona, Susan Kelley and Tim Hughes, exercisable at 71.5 cents per option, vesting in three tranches from March 1, 2015 to March 1, 2017 and expiring five years from the date of issue.

The meeting resolutions included an increase in the pool of remuneration for directors from \$500,000 a year to \$750,000 a year.

The notice of meeting was filed to the ASX at the close of the market on Friday October 10, 2014.

On Monday, October 27, Alchemia announced that the phase III trial of hyaluronic acid-irinotecan (HA-irinotecan) for metastatic colo-rectal cancer failed to meet its primary endpoint (BD: Oct 27, 2014).

The meeting will be held at The Westin Hotel, 205 Collins Street, Melbourne on November 10, 2014 at 10am (AEDT).

Alchemia fell 0.3 cents or three percent to 9.6 cents with three million shares traded.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Nov-13	Oct-14	Nov-14
Cochlear	3,361	3,966	4,157
CSL	33,851	35,197	37,561
Resmed	7,699	7,969	8,236
<b>BDI-20</b>			
Acrux	446	256	181
Alchemia	170	216	31
Admedus	188	216	188
Benitec	51	116	66
Bionomics	289	261	225
Biotron	20	23	24
Clinuvel	59	140	153
GI Dynamics	320	228	133
Impedimed	31	106	107
Mesoblast	2,095	1,390	1,335
Nanosonics	229	262	256
Neuren	160	125	129
Osprey	86	71	70
Pharmaxis	39	16	16
Prima	47	47	49
Psivida	69	147	133
Sirtex	698	1,242	1,446
Tissue Therapies	54	79	83
Universal Biosensors	103	26	30
Viralytics	29	59	57
<b>Second 20</b>			
Analytica	11	32	29
Anteo	50	121	112
Antisense	22	17	17
Atcor	25	14	15
Avita	36	33	32
Cellmid	28	21	19
Circadian	12	9	9
Compumedics	13	20	18
Ellex	28	36	30
Genetic Technologies	40	15	13
IDT	30	17	17
Living Cell	32	25	26
Medical Developments	73	61	75
Oncosil	42	41	37
Optiscan	9	7	6
Patrys	15	15	16
Phosphagenics	138	112	101
Prana	223	115	103
Starpharma	254	204	198
Uscom	14	18	20

\* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Alchemia, Atcor, Avita, Circadian, Cochlear, Ellex, IDT, Impedimed, Innate Immunotherapeutics, Pharmaxis, Prana, Resmed and Sirtex. These holdings are liable to change.

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