



Biotech Daily

Monday May 1, 2017

Daily news on ASX-listed biotechnology companies

- * APRIL BDI-40 UP 3.5%, ASX200 UP 1%, BIG CAPS UP 4%
- OPTHEA UP 49%, ACTINOGEN 45%, MESOBLAST 38%; CELLMID DOWN 22.5%
- * TODAY: ASX UP, BIOTECH DOWN: GENETIC SIGNATURES, ADMEDUS UP 12%
- DIMERIX DOWN 14%
- * LIVING CELL COMPLETES NTCCELL PARKINSON'S TREATMENT
- * ORTHOCELL READY FOR ORTHO-ATI ROTATOR CUFF TRIAL
- * ANALYTICA RELEASES PERICOACH VERSION 3
- * MGC SIGNS EURO CANNABIS COSMETICS DEALS; TRADING HALT
- * OVENTUS READY FOR O2VENT PAP HYBRID APNOEA TRIAL
- * US ORPHAN STATUS FOR PRESCIENT PTX-200 FOR AML
- * LIFESPOT MEDICAL MARIJUANA VAPORIZER JOINT VENTURE
- * STEMCELL PLEADS SCHULTZ TO ASX 83% QUERY
- * SIMAVITA LESS THAN ONE QUARTER CASH; RAISING TRADING HALT
- * BAILLIE GIFFORD REDUCES TO 9% OF COCHLEAR
- * CRYSTAL AMBER TAKES 41% OF GI DYNAMICS
- * DIMERIX APPOINTS HATCHTECH CEO HUGH ALSOP DIRECTOR
- * USCOM APPOINTS DAMIEN LINNETT FOR SALES, MARKETING

MARKET REPORT

The Australian stock market was up 0.55 percent on Monday May 1, 2017 with the ASX200 up 32.4 points to 5,956.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell and eight traded unchanged. All three Big Caps were up.

Admedus and Genetic Signatures were both up 12.3 percent to 36.5 cents and 41 cents, respectively, with 1.3 million shares and 16,098 shares traded, respectively. Prana climbed 6.25 percent; Atcor was up 5.45 percent; ITL, Orthocell and Sirtex were up more than three percent; Airxpanders, Ellex and Uscom improved more than two percent; with Avita, Pro Medicus and Viralytics up more than one percent.

Dimerix led the falls, down 0.1 cents or 14.3 percent to 0.6 cents with 721,475 shares traded. Actinogen and Psivida lost more than seven percent; Compumedics shed 6.4 percent; Polynovo fell 4.2 percent; Factor Therapeutics, Living Cell, IDT, Reva and Universal Biosensors were down more than three percent; Osprey and Starpharma shed more than two percent; with Acrux, Impedimed, Medical Developments and Pharmaxis down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) climbed 3.5 percent in April, beating both the ASX200, up 1.0 percent, and the Nasdaq Biotech Index, up 1.5 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a further 4.3 percent in April, again led by CSL, up 5.7 percent, with Cochlear up 3.4 percent and Resmed retreating a further 1.4 percent. For the year to April 30, the collective Big Caps were up 25.4 percent.

While Opthea was the best improved in the BDI-40, on the back of both good trial results and a capital raising, Mesoblast's \$372 million (38.1%) increase in market capitalization more than compensated the array of small falls, including the Sirtex \$136 million tumble.

Fifteen BDI-40 companies were up, 21 fell and four were unchanged.

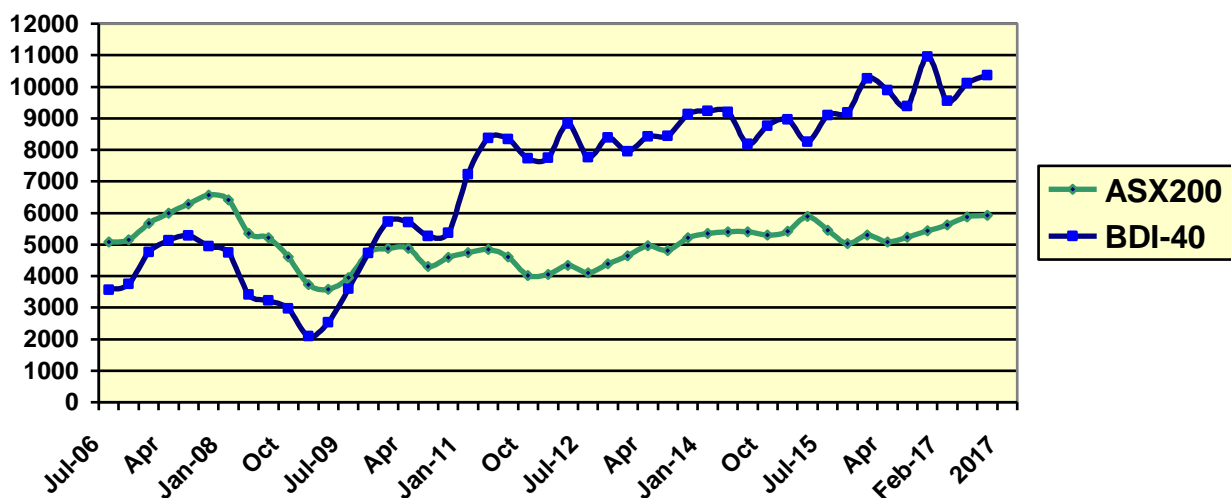
Opthea climbed 48.8 percent to \$183 million, followed by Actinogen up 44.7 percent to \$55 million, and Mesoblast finally overtook Sirtex as the sector's largest company with a market capitalization of \$1,348 million. Oncosil climbed 31.1 percent, followed by ITL (24.4%), Nanosonics (19.5%) and Starpharma (10.5%).

Cellmid led the April falls, down 22.5 percent to \$31 million, followed by Genetic Signatures (15.9%), Compumedics (13.5%), Sirtex (13.2%), Factor Therapeutics (11.8%), Viralytics (11.5%), Polynovo (11.2%) and Prana (10.5%).

Outside the BDI-40, Optiscan climbed 65.4 percent to \$43 million, up 975 percent for the year and apparently shaking off the doldrums of the past under its new board and management and refocusing its confocal microscopes. Phylogica has trebled its market capitalization over the past year to \$90 million, while Immuron has doubled to \$60 million.

On the Nasdaq, Aviragen (Biota) slid 6.1 percent to \$30 million, Queensland's Protagonist shed 18.9 percent to \$228 million and Israel's Redhill (with Giacomda's assets) climbed 6.5 percent to \$229 million.

BDI-40 v ASX200 Jun 30, 2006 to Apr 30, 2017- Adjusted



LIVING CELL TECHNOLOGIES

Living Cell says it has completed treatment of the third and final cohort of its 18-patient, phase IIb trial of NTCell encapsulated pig choroid cells for Parkinson's disease.

Living Cell said that four of the six patients had 120 NTCell microcapsules implanted into the putamen on each side of their brain and two patients had sham surgery with no cells implanted.

The company said that to date there had been no safety issues in any of the six patients. Living Cell said it was blind to the results until 26 weeks after the completion of the trial and the results would be analysed and were expected to be announced in November 2017.

The company said that the patients who had the placebo treatment would receive the optimal dose.

Living Cell said the trial aimed to confirm the most effective dose, define any placebo component and further identify the initial target Parkinson's disease patient sub-group.

In 2015, Living Cell said that at 42 weeks post-implant NTCell "stopped the progression of Parkinson's disease" in the four patients in its phase I/IIa clinical study of NTCell and last year began the 18-patient phase IIb trial in (BD: Oct 27, 2015; Mar 24, 2016).

Living Cell fell half a cent or 3.7 percent to 13 cents.

ORTHOCELL

Orthocell says it has ethics approval for a 30-patient study comparing autologous tenocyte implantation (Ortho-ATI) tendon regeneration to corticosteroid injection.

Orthocell said the study aimed to demonstrate the safety and feasibility of Ortho-ATI for shoulder rotator cuff tendinopathy and tear and would be performed in collaboration with Johnson & Johnson's DePuy Synthes Products, a collaboration facilitated by Johnson & Johnson Innovation.

The company said that the study was entitled 'Defining a randomized, controlled study of Ortho-ATI versus corticosteroid injection for treatment of rotator cuff tendinopathy and tear' and would be led by its chief scientific officer Prof Ming Hao Zheng and the Australian Elbow and Shoulder Society president Prof Allan Wang.

Orthocell said that rotator cuff tendinopathy and tear was a common and difficult injury to treat with more than 50 percent of adults over 50 years of age affected.

The company said that rotator cuff disease led to disability, reduced quality of life, absenteeism from work and was a burden on healthcare resources.

Orthocell said that patients would have failed previous conservative treatment options, including physiotherapy and other injection therapies.

Orthocell managing-director Paul Anderson said that "demonstrating the efficacy of Ortho-ATI for rotator cuff tendinopathy is an important element of our product development strategy".

"We expect results to show Ortho-ATI is a durable, curative and cost effective treatment for degenerate shoulder injuries," Mr Anderson said.

"Our collaboration with DePuy Synthes enables global development of the technology," Mr Anderson said.

Orthocell said that in studies it had conducted, Ortho-ATI had been shown to be a cost effective long-term and durable, non-surgical solution for difficult to treat tendon pathology.

The company said that Ortho-ATI was available in Australia, New Zealand, and Hong Kong for patients who have failed conservative treatment options such as corticosteroid injections and exercise programs and had on-going symptoms.

Orthocell was up 1.5 cents or 3.6 percent to 43 cents.

ANALYTICA

Analytica says it has released the first production units of its “next generation” Pericoach version 3 intra-vaginal pelvic floor strengthening monitor and training device.

Analytica said the version 3 device was an integral part of the Pericoach system which included a mobile telephone application and data management system.

The company said that the Pericoach 3 implemented “significant improvements in processing capability, wireless connectivity and power management, over-the-air firmware update capability, as well as enhanced user experience”.

Analytica said that one of the changes was the inclusion of an accelerometer and gyroscope micro-chip to sense the motion of the device during pelvic floor exercise.

The company said it had patents registered and pending on the movement technology and force sensor arrangement.

Analytica said that the new hardware, combined with the force sensors that directly measured pelvic floor muscle squeeze force, would allow the system to make an assessment about exercise technique by comparing the sensor signals against a database of correct and incorrect technique signatures.

Analytica chief executive officer Geoff Daly said that key opinion leaders had reported that correct technique was “critical to the efficacy of pelvic floor exercise”.

“Their message is that poor technique leads to poor results and that causes women to simply give up,” Mr Daly said.

“When half of all women don’t do their exercises correctly to start with, the dropout rate has a big impact on clinician’s faith in pelvic floor exercise and many time-poor clinicians simply hand their patients a pamphlet,” Mr Daly said.

“The v3 has the potential to break this circle, helping more women to do their exercises correctly, getting better outcomes, and restoring conservative treatments as the first step before jumping to surgery,” Mr Daly said.

Analytica was unchanged at 0.55 cents with 3.9 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has new cosmetics sales agreements in Europe, with additional contracts expected to follow by July 2017.

MGC said it had signed “multiple wholesale reseller agreements” for its MGC Derma cosmetics product lines with retail outlets including dispensaries and cannabis lifestyle retailers in Spain, Italy and Romania and the “anti-ageing and essentials products” would be available this month.

The company said it owned 51 percent of the Ljubljana, Slovenia-based MGC Derma, with the remainder owned by Dr Burstein Ltd.

MGC said the agreements were with Italy’s Tail-Ma SRL hydroponic growing shops and cannabis lifestyle vendors, Spain’s Organic Oz, which operated dispensaries and distributes cannabis-related products throughout Spain and Romania’s Coplex Distribution SRL a spa industry distributor, as well as an unnamed Italian cannabis group working through retail pharmacies.

Separately, MGC requested a trading halt “pending the execution of a material strategic agreement with [Melbourne’s] Royal Melbourne Institute of Technology”.

The company said that the trading halt related to its “Australian-based medical cannabis operations, licensing and strategy”.

MGC said its shares would remain in a trading halt until May 3, 2017 or until the announcement was made.

MGC last traded up 0.2 cents or 3.3 percent to 6.2 cents with 13.5 million shares traded.

OVENTUS MEDICAL

Oventus says it has made progress with its O2Vent with a positive airway pressure connection and enrolled the first patient in a trial of the system.

Oventus said the hybrid O2Vent anti-snoring mouth-guard with a positive airway pressure system was designed to address the effectiveness of oral appliances for moderate to severe sleep apnoea and the non-compliance of positive airway pressure patients.

The company said that the system was designed to bridge the gap between oral appliances delivered by dentists and positive airway pressure therapy, delivered by sleep clinicians or specialist sleep centres.

Oventus said that following its initial pilot study which showed the O2Vent reduced pressure swings and collapsibility, as well as the reduced pressure requirements when used in combination with positive airway pressure and as a mask-free interface, it had completed optimization for an expanded positive airway pressure connection study, with the first patient recruited to the hybrid arm of the study.

Oventus founder and clinical director Dr Chris Hart said the clinical evidence would be used to engage with sleep clinicians which was "critical for the acceptance of oral appliances by sleep specialists and critical for the many patients".

The company said the trial was expected to be completed by the end of 2017, but the US Food and Drug Administration FDA 510k submission for the initial combination system with nasal positive airway pressure was planned to be lodged by July 2017.

Oventus fell two cents or 4.35 percent to 44 cents.

PRESCIENT THERAPEUTICS

Prescient says the US Food and Drug Administration has granted orphan drug designation for PTX-200 for acute myeloid leukaemia.

Prescient said that the designation was provided to drugs for the treatment, diagnosis or prevention of diseases that affect fewer than 200,000 people in the US and was designed to provide benefits and incentives for drug development including seven-year market exclusivity, the potential for accelerated review and 50 percent tax credit on US trials.

Prescient was up 0.3 cents or 3.3 percent to 9.3 cents with 1.1 million shares traded.

LIFESPOT HEALTH

Lifespot says that with Germany's Seng Vital it will form Seng Vital Australia to integrate the medical marijuana Cannamed vaporizer into its Bodytel platform.

Lifespot said that under the memorandum of understanding it would hold 50 percent to the Seng Vital Australia joint venture.

The company said that it provided internet-based digital health medical monitoring.

Lifespot fell 5.5 cents or 18.6 percent to 24 cents.

STEMCELL UNITED

Stemcell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 83.3 percent from 12 cents on April 28 to 22 cents today, May 1, 2017 and noted an increase in trading volume.

Stemcell said that it was mentioned in an article on marijuana companies in the Fairfax media over the weekend.

Stemcell was up eight cents or 66.7 percent to 20 cents with 9.4 million shares traded.

SIMAVITA

Simavita says its net operating cash burn for the three months to March 31, 2017 was \$1,808,000 with cash at the end of the quarter of \$1,527,000.

Simavita provided no further information, but this morning requested a trading halt “pending an announcement regarding a proposed capital raising”.

The company said trading would resume on May 3, 2017 or on an earlier announcement. Simavita last traded at six cents.

COCHLEAR

Baillie Gifford & Co and associates have increased their substantial holding in Cochlear from 5,976,169 shares (10.45%) to 5,423,215 shares (9.44%).

The Edinburgh-based Baillie Gifford said it bought and sold shares between September 16, 2015 and April 27, 2017 in more than 500 separate trades.

Cochlear climbed 47 cents or 0.3 percent to \$140.35 with 152,238 shares traded.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 221,810,862 shares (39.76%) to 227,544,113 shares (40.79%).

The London and Guernsey Island-based Crystal Amber Fund said that between March 13 and April 28, 2017 it acquired 5,733,251 shares for \$339,387 or 5.9 cents a share.

GI Dynamics was up 0.1 cents or 1.5 percent to 6.7 cents with 1.3 million shares traded.

DIMERIX

Dimerix says it has appointed Hatchtech chief executive officer Hugh Alsop as a non-executive director, effective from today, May 1, 2017.

Dimerix said Mr Alsop had more than 20 years' experience in business development, partnering, drug development and leadership of scientific teams and was responsible for several drug development programs including phase III programs, two significant transactions and the filing of US Food and Drug Administration new drug applications.

Dimerix said Mr Alsop helped secure a \$200 million commercialization agreement for Hatchtech's head-lice and egg treatment with India's Dr Reddy's Laboratory and at Acrux was part of the team that secured the Axiron licence to Eli Lilly.

The company said that Mr Alsop previously worked at Phosphagenics, Sigma and Faulding in business development and manufacturing related roles.

Dimerix said that Mr Alsop held a Bachelor of Science from the University of Melbourne and a Masters of Business Administration from the Melbourne Business School.

Dimerix fell 0.1 cents or 14.3 percent to 0.6 cents.

USCOM

Uscom says it has appointed Damien Linnett as its sales and marketing manager.

Uscom said Mr Linnett had more than 20 years' medical device sales and marketing experience and had worked for Datex Ohmeda, Spacelabs and Kinetic Concepts.

Mr Linnett's LinkedIn page said he held a Bachelor of Arts from the Armidale, New South Wales-based University of New England and a Masters of Business Administration from the University of Queensland.

Uscom was up 0.5 cents or 2.5 percent to 20.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT APR 30, 2017

Company \$Am	May-16	Apr-17	May-17
Cochlear	6,180	7,767	8,033
CSL	48,163	56,989	60,232
Resmed	10,444	13,156	12,972
BDI-20			
Admedus	77	83	83
Airxpanders	184	245	242
Bionomics	152	181	166
Clinuvel	205	328	325
Compumedics	68	96	83
Ellex	92	133	129
Impedimed	330	270	272
Medical Developments	362	297	292
Mesoblast	835	976	1,348
Nanosonics	630	923	941
Neuren	137	125	124
Opthea	71	123	183
Pharmaxis	82	93	88
Polynovo	162	152	135
Prima	91	64	67
Pro Medicus	440	595	559
Psivida	140	86	93
Reva	462	406	426
Sirtex	1,703	1,033	897
Viralytics	177	288	255
Second 20			
Acrux	102	48	46
Actinogen	51	38	55
Atcor	33	13	13
Avita	72	62	56
Benitec	16	35	37
Cellmid	19	40	31
Cyclopharm	38	48	46
Dimerix	10	12	13
Factor Therapeutics	22	51	45
Genetic Signatures	35	44	37
IDT	77	35	35
ITL Ltd	19	45	56
Living Cell	26	74	77
Oncosil	63	45	59
Orthocell	27	29	31
Osprey	41	111	117
Prana	45	38	34
Starpharma	244	247	273
Universal Biosensors	52	72	79
Uscom	19	22	22

* Biotech Daily editor, David Langsam, owns shares in Acrux, Admedus, Benitec, Mesoblast, Nanosonics, Volpara 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.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au; www.biotechdaily.com.au; twitter: @biotech_daily