Biotech Daily

Friday April 1, 2016

Daily news on ASX-listed biotechnology companies

*** MARCH BDI-40 UP 4%, ASX200 UP 4%, BIG CAPS DOWN 2%**

- MESOBLAST UP 34%, OSPREY 29%; ANTISENSE DOWN 30%, PRANA 28%

*** TODAY: ASX, BIOTECH DOWN: AVITA UP 10%, UNIVERSAL BIO DOWN 7%**

*** UK ALLOWS SIRTEX SIR-SPHERES MONOTHERAPY ALTERNATIVE**

*** MESOBLAST STEM CELL TRIAL 'IMPROVES KNEE PAIN, FUNCTION'**

*** UNIVERSAL BIOSENSORS REVIEW, FDA, TAX HALT COAGULATION TEST**

*** ANATARA EARNS MILESTONE FOR ZOETIS DETACH SHIPMENT**

*** BIODIEM CHINA LICENCEE STARTS LAIV PHASE I SAFETY STUDY**

*** MEDIBIO 'PLEASED' WITH FDA DEPRESSION TEST MEETING**

*** NUSEP ADVISER PROF JOHN AITKEN WINS $2k CARL HARTMAN GONG**

MARKET REPORT

The Australian stock market lost 1.64 percent on Friday April 1, 2016 with the ASX200 down 83.4 points to 4,999.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and seven were untraded.

Avita was the best, up one cent or 9.5 percent to 11.5 cents with two million shares traded.

Cellmid and Compumedics climbed more than five percent; Benitec and Neuren were up more than four percent; Atcor, Orthocell and Starpharma rose more than two percent; Anteo, Impedimed and Viralytics were up more than one percent; with Cochlear, Pro Medicus and Resmed up by less than one percent.

Universal Biosensors led the falls, down 2.5 cents or 6.85 percent to 34 cents with 112,607 shares traded.

Tissue Therapies lost 5.3 percent; Biotron, Mesoblast and Prana fell more than four percent; Acrux, Admedus, Living Cell, Pharmaxis and Polynovo were down more than three percent; Clinuvel shed 2.1 percent; Opthea was down 1.2 percent; with CSL, Nanosonics and Sirtex down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) rose 3.7 percent in March to a collective market capitalization of $7,102 million, while the S&P ASX200 was up 4.1 percent for the month.

For the year to March 31, 2016, the BDI-40 (which does not include the three Big Caps of Cochlear, CSL and Resmed) climbed 30.3 percent, while the ASX200 fell 13.7 percent.

The Big Caps stellar run appears to have petered-out, with a fall of 2.3 percent for the month of March, but a small 2.7 percent rise for the year to March 31, 2016. CSL fell a further 1.2 percent to $46,962 million, Cochlear slipped 0.15 percent to $5,852 million, while Resmed fell 8.2 percent to $10,402 million.

Twenty two of the BDI-40 companies were up, 15 fell and three were unchanged. Twelve companies were up more than 10 percent and four fell more than 10 percent.

Mesoblast recovered $251 million or 34.4 percent to $981 million, the best for two months in a row, but still a long way from its high of $2,299 million in November 2011. Osprey recovered 28.6 percent to $45 million, followed by Actinogen (25.7%), IDT (25.5%), Uscom (25.0%), Clinuvel (20.0%), Pro Medicus (18.1%), Biotron and Tissue Therapies (16.7%), Opthea (12.3%), Medical Developments (12.2%) and Impedimed (10.9%).

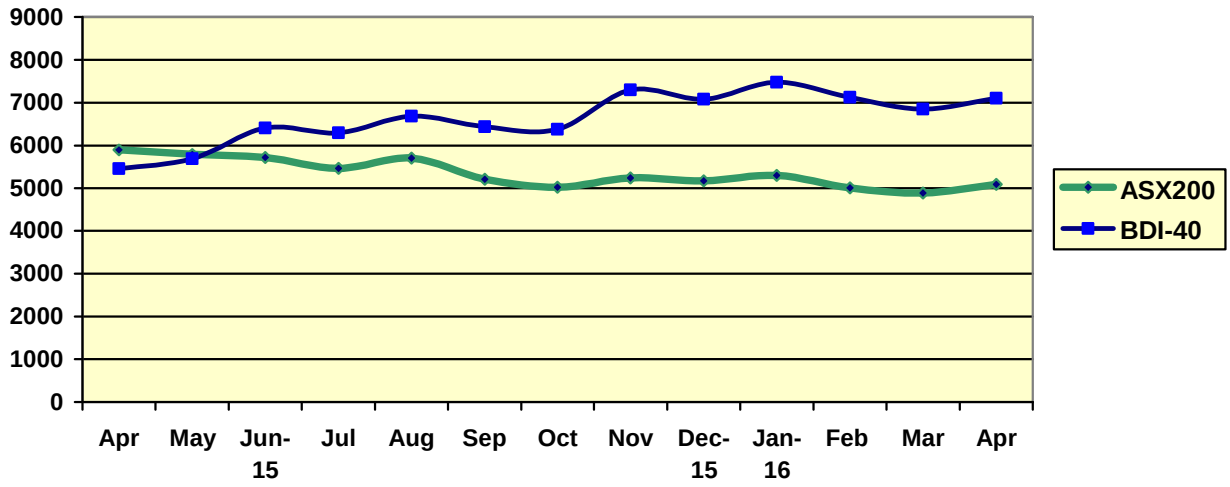
From a low base, Antisense lost a further 30 percent to $7 million, Prana was down 27.7 percent to $34 million - its lowest value since February 2011 and some distance from $518 million in March 2014, followed by Cellmid (15.8%), Anteo (12.7%) and both Psivida and Sirtex down 9.7 percent.

The Nasdaq Biotech Index was up 2.5 percent in March, but of the former Australian companies, Heartware was down 7.2 percent to $719 million, Biota lost 8.4 percent to $76 million, while Sunshine Heart recovered $1 million or 5.3 percent to $20 million.

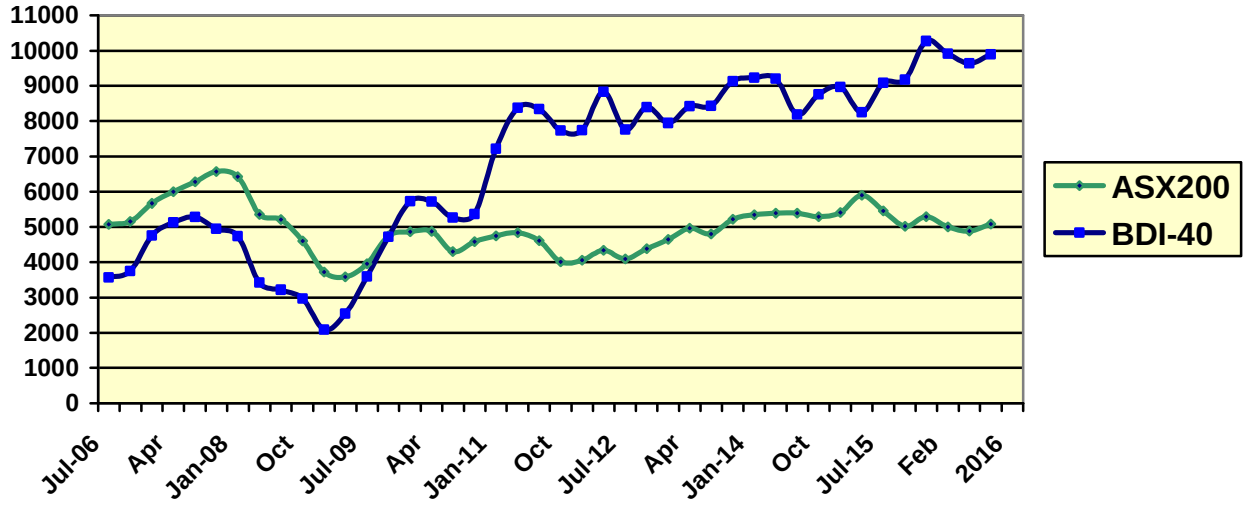
Outside the BDI-40, Resapp climbed 91.8 percent to $117 million in March and 2,240 percent for the nine months since it back-doored into Narhex. Airxpanders, Anatara, Cogstate and Dorsavi more than doubled their values over 12 months.

Airxpanders has been promoted into the Second 20, replacing 10-year BDI-40 veteran Optiscan which is in a suspension for funding.

BDI-40 ($m) v S&P ASX 200 – Mar 31, 2015 – Mar 31, 2016



BDI-40 v ASX200 Jun 30, 2006 to Mar 31, 2016 - Adjusted



SIRTEX MEDICAL

Sirtex says the UK National Institute for Health and Care Excellence has approved SIR-Spheres as an alternative to standard therapy for inoperable primary liver cancer.

Sirtex said that the Institute had issued a new medical technologies innovation briefing stating that Nation Health Service doctors and commissioners might consider SIR-Spheres Y-90 resin microspheres as an alternative to standard therapy with trans-arterial chemoembolization or sorafenib in the treatment of patients with inoperable primary liver cancer, or hepatocellular carcinoma.

The company said that the Institute briefing stated that patients with inoperable hepatocellular carcinoma had a poor prognosis and limited effective treatment options, and existing clinical evidence suggested that SIR-Spheres microspheres were as effective as both trans-arterial chemoembolization and sorafenib.

British Liver Trust chief executive Andrew Langford said that patients with inoperable hepatocellular carcinoma had access only to two effective therapy options and would have the third option of SIR-Spheres.

“This form of local radiotherapy is well tolerated and convenient for the patient,” Mr Langford said.

Sirtex chief executive officer Gilman Wong said the Institute briefing supporting the treatment of inoperable primary liver cancer with SIR-Spheres microspheres was “an important step forward to enable [hepatocellular carcinoma] patients to receive our therapy”.

“The UK is an important market for Sirtex where funding of our product is currently available in specialist centres via the commissioning through evaluation process for those patients with previously treated inoperable, liver predominant metastatic colorectal cancer and intrahepatic cholangio-carcinoma,” Mr Wong said.

UK investigator on the 420-patient combination SIR-Spheres and sorafenib (Soramic) trial Prof Daniel Palmer said the briefing was “welcomed, as it opens the door for UK [hepatocellular carcinoma] patients to have access to SIR-Spheres Y-90 resin microspheres as a well-tolerated alternative to other standard therapies”.

Sirtex fell one cent or 0.03 percent to $28.91 with 374,188 shares traded.

MESOBLAST

Mesoblast says its trial of MPC-75-IA for knee injuries found that a single injection resulted in improvement in pain, function, cartilage thickness and joint structure.

Mesoblast said that the 17-patient, phase IIa, double-blind, placebo-controlled trial randomized patients aged 18 to 40 years old who had undergone anterior cruciate ligament knee reconstruction surgery four to six weeks earlier to receive either a single intra-articular injection of 75 million allogeneic mesenchymal precursor cells plus hyaluronic acid or hyaluronic acid alone.

The company said that the trial met its primary safety and secondary efficacy endpoints with no cell-related serious adverse events.

Mesoblast said that the stem cell group showed greater improvement in knee injury and osteoarthritis outcomes scores (KOOS) scores for symptoms and pain relative to the control group at week 78 ($p = 0.034$; $p = 0.026$) and week 104 ($p = 0.041$; $p = 0.018$), respectively, with the short form health survey (SF-36) pain score demonstrating greater pain reduction for the stem cell group than the control group at weeks 26 ($p = 0.019$), 52 ($p = 0.050$) and 104 ($p = 0.032$), respectively.

The company showed that by x-ray, the control group had reduced joint space width at weeks 78 and 104 compared with the stem cell group ($p = 0.027$ and $p = 0.069$, respectively) consistent with reduced cartilage thickness.

Mesoblast said that magnetic resonance imaging showed that the stem cell group showed less tibial bone expansion over 26 weeks than the control group of 0.5 percent compared to 4.0 percent ($p = 0.02$) and a trend towards less tibial bone expansion over 52 and 104 weeks, with the stem cell group showing a trend towards less medial tibial volume loss over 26 weeks.

The company said that the results were presented at the Osteoarthritis Research Society International meeting in Amsterdam on March 31, 2016 by at Monash University Preventative Medicine's Prof Flavia Cicuttini, who said the results "suggest that Mesoblast's cells may be disease modifying and potentially slow or halt the natural history of osteoarthritis".

Mesoblast said the results were consistent with the protective and pro-regenerative effects of its allogeneic mesenchymal precursor cells on joint cartilage seen previously in sheep models of both post-traumatic knee injury and established osteoarthritis and suggested that the cells might have disease-modifying effects on osteoarthritis, potentially halting the adverse structural changes in this common condition.

The company said that the results supported further study of the effects of allogeneic mesenchymal precursor cells on cartilage preservation and longer-term osteoarthritis outcomes in patients at high risk of disease progression or with established disease.

"These results are remarkable in that we were able to demonstrate significant improvements in patient symptoms and joint structure," Prof Cicuttini said.

"We look forward to conducting a larger phase II/III trial to confirm the observed significant long-term benefits in pain, function, and quality of life," Prof Cicuttini said.

Mesoblast said that post-traumatic osteoarthritis was a common and debilitating disease that affected about 27 million people in the US, resulting in annual medical care expenditures of $US185.5 billion.

The company said that post-traumatic osteoarthritis of the knee, hip and ankle accounted for about 5.6 million cases of osteoarthritis in the US, with about 200,000 anterior cruciate ligament reconstruction procedures performed each year and while knee reconstruction was cost-effective, a cost of $US2.78 billion was attributable to the long-term development of osteoarthritis and a therapy that could modify the disease could save $US1.1 billion.

Mesoblast fell 11 cents or 4.3 percent to $2.46 with 1.4 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says that several factors have led to it putting its blood coagulation self-testing device on hold.

Universal Biosensors said that a prioritizing review of its projects, the $20 million maximum revenue criterion for the Federal Government's R&D Tax Incentive and the US Food and Drug Administration flagging increased scrutiny on point-of-care diagnostics had led to the decision.

The company said that it made "very little sense … to chase short term small revenue increases that will take our revenue above this limit".

Universal Biosensors said it had attended an FDA workshop on point-of-care diagnostics for monitoring warfarin medication therapy, where the US regulator "flagged increased scrutiny on these [point-of-care] tests, which may lead to changes in regulatory requirements for future FDA submissions".

The company said it had put the development of its own pro-thrombin time, international normalized ratio (PT-INR) device on hold and would "enhance the product features to address the opportunity associated with the changes foreshadowed by the FDA".

Universal Biosensors said the enhanced product features would potentially improve its position in the marketplace and maximize value for shareholders.

The company said that the changes would not have any significant impact on revenues in 2016 except to help keep revenue within the eligibility limits prescribed by the R&D Tax Incentive legislation, but would allow it to reduce spend and improve its cash flow.

Universal Biosensors executive chairman and acting chief executive officer Andrew Denver said that "research and development of new best in class healthcare products is a lengthy process … however, the rewards are significant".

"Our product platform is capable of being best in this field and we are determined to deliver the best [point-of-care] blood testing products we can, to provide a real benefit for patients," Mr Denver said.

Universal Biosensors fell 2.5 cents or 6.85 percent to 34 cents.

ANATARA LIFESCIENCES

Anatara says it will earn a milestone payment for shipping its Detach non-antibiotic treatment for diarrhoea in farm animals to licencee Zoetis Inc (BD: Jan 27, 2016).

Anatara said it would invoice the Florham Park, New Jersey-based Zoetis for the first upfront payment under the licence agreement.

Anatara chief executive officer Dr Paul Schober told Biotech Daily the amount of the milestone payment was confidential.

The company said that Zoetis would begin "an aggressive and comprehensive evaluation program using Detach in multifaceted trials across a range of livestock species".

Dr Schober said the Detach consignment was manufactured under strict good manufacturing practice compliance and labelled to conform to US standards.

"We now have in place the ability to manufacture and supply large quantities of Detach which are sufficient to meet global demand," Dr Schober said.

"The shipment of product to the US marks a significant milestone for the company," Dr Schober said.

Anatara said it would conduct a full good laboratory practice target animal safety study in piglets in compliance with international guidelines.

Anatara has previously said that it would develop the pineapple stem bromelain-based Detach for human use (BD: Oct 16, 2014).

Anatara was up 1.5 cents or 1.1 percent to $1.375.

BIODIEM

Biodiem says its China licencee Changchun BCHT Biotechnology Co has begun a phase I safety study of its live attenuated influence virus vaccine.

Biodiem said that Changchun BCHT had made progress in the development of the vaccine since licensing the technology three years ago.

The company said that Changchun BCHT had developed the manufacturing process for the vaccine, received investigational new drug approval from the Chinese Food and Drug Administration and had now started the clinical trials required for approval.

Changchun BCHT research and development director Dr Jinchang Wu said that the trial of the intranasal vaccine would enrol children from three years of age and adults over the next three months.

Biodiem chief executive officer Julie Phillips said Changchun BCHT had “moved quickly down the commercialization path for their influenza vaccine”.

“An intranasal ’flu vaccine presents many advantages, especially for children and for those who dislike needles,” Ms Phillips said.

“Royalties will flow to Biodiem from sales of the product into the private market in China,” Ms Phillips said.

Biodiem is a public unlisted company.

MEDIBIO

Medibio says a pre-submission meeting with the US Food and Drug Administration has confirmed a regulatory pathway for its proposed diagnostic for depression.

Medibio said that the FDA confirmed its proposed indications for use, clinical study protocols and data requirements for the cardiac rhythm test for depression.

The company said that the FDA confirmed that depression algorithm was eligible for the de novo regulatory pathway and “expressed no significant concerns with the proposed indications for use”.

Medibio said that its proposed level of concern for its depression algorithm was acceptable to the FDA.

The company said that the level of concern was based on how the operation of the software associated with device function affected the patient or operator.

Medibio said that the extent of the documentation required in an FDA premarket submission depended on the device’s level of concern.

Medibio chief medical officer Dr Matt Mesnik said that the company was “pleased with the high level of engagement from the FDA and the collaborative nature of the meeting”.

“The confirmation of our regulatory pathway is an important milestone for the company,” Dr Mesnik said.

Medibio fell half a cent or 2.2 percent to 22 cents.

NUSEP

The Society for the Study of Reproduction has awarded Nusep’s Scientific Advisory Board chairman Professor John Aitken its $US1,500 ($A1,956) Carl G. Hartman Award.

The Madison, Wisconsin-based Society said that the award was sponsored by the Bloomington, Indiana-based Cook Medical.

Nusep said that the award was “one of the most internationally prestigious awards in reproductive biology … [recognizing] a researcher’s outstanding career in the field”. Nusep said that Prof Aitken was the second researcher working outside the US to win the award.

Nusep was untraded at 1.3 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT MAR 31, 2016

Company $Am	**Apr-15**	**Mar-16**	**Apr-16**
Cochlear	5,168	5,861	5,852
CSL	43,302	47,545	46,962
Resmed	13,056	11,326	10,402
BDI-20			
Acrux	143	110	101
Admedus	116	90	97
Benitec	92	18	17
Bionomics	194	159	154
Biotron	42	18	21
Clinuvel	134	165	198
Impedimed	249	294	326
Medical Developments	133	271	304
Mesoblast	1,178	730	981
Nanosonics	531	527	567
Neuren	151	206	189
Opthea	23	57	64
Osprey	92	35	45
Pharmaxis	39	79	86
Prima	42	82	85
Psivida	149	134	121
Reva	191	485	468
Sirtex	1,176	1,833	1,656
Universal Biosensors	44	70	64
Viralytics	79	159	154
Second 20			
Actinogen	41	35	44
Airxpanders	77	229	236
Anteo	79	63	55
Antisense	15	10	7
Atcor	31	32	35
Avita	26	56	56
Cellmid	18	19	16
Compumedics	22	63	61
Ellex	35	79	84
Genetic Technologies	79	33	33
IDT	41	55	69
Living Cell	25	25	26
Oncosil	31	68	72
Orthocell	21	25	23
Polynovo	30	161	155
Prana	76	47	34
Pro Medicus	158	293	346
Starpharma	140	228	250
Tissue Therapies	32	12	14
Uscom	17	16	20

* Biotech Daily editor, David Langsam, owns shares in Acrux, 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.

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