

Biotech Daily

Tuesday November 1, 2011

Daily news on ASX-listed biotechnology companies

- * OCTOBER GOOD FOR BIOTECH; BDI-40 UP 6%; ASX200 UP 7% - PHARMAXIS UP 80%, ALCHEMIA DOWN 21.7%
- * TODAY: ASX, BIOTECH DOWN: NEUREN UP 18%; LIVING CELL DOWN 8%
- * US FDA 'BIOLOGIC CLASS' FOR TISSUE THERAPIES' VITROGRO
- * BIO-MELBOURNE: PROF YARON ILAN ON COMMERCIALIZING RESEARCH
- * CBIO LOSES STEPHEN JONES, PROF JOHN FUNDER, JASON YEATES
- * CBIO PLACES \$2.3m
- * QBF CHANGES NAME TO QIC BIOVENTURES
- * PHYLOGICA HAS LESS THAN TWO QUARTERS CASH; DEAL EXPECTED
- * BONE AGM FOR 4.3m DIRECTOR SHARES, 2m OPTIONS FOR FEES
- * SOLAGRAN SAYS IT HAS ONE QUARTER CASH, MORE COMING
- * FEDERAL GOVERNMENT ANNOUNCES \$310m ARC GRANTS

MARKET REPORT

The Australian stock market fell 1.52 percent on Tuesday November 1, 2011 with the S&P ASX 200 down 65.2 points to 4232.9 points. Six of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and 10 were untraded. All three Big Caps fell.

Neuren was the best on its first day back in the BDI-40 (see below), up 17.9 percent to 3.3 cents with 25.6 million shares traded; followed by Sunshine Heart up 12.5 percent to 4.5 cents with 100,000 shares traded; Compumedics and Psivida up more than two percent; with Bionomics and Optiscan up more than one percent.

Living Cell led the falls, down 0.5 cents or 7.7 percent to six cents, with 660,873 shares traded, followed by Mesoblast down 7.2 percent to \$7.61 with 1.2 million shares traded.

Benitec, Impedimed, Patrys, Phosphagenics and Prima lost five percent or more; Allied Health fell 4.9 percent; QRX was down 3.1 percent; Cochlear and Sirtex shed more than two percent; Acrux, Alchemia, Anteo, Clinuvel, Pharmaxis and Resmed were down more than one percent; with Biota, CSL and Starpharma down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) climbed 6.0 percent in October with the S&P ASX200 up 7.2 percent for the month.

The BDI-40 (which does not include the Big Caps of Cochlear, CSL and Resmed) remained well ahead of the benchmark index for the year to October 31, 2011, up 31.7 percent compared to the ASX200 falling 7.8 percent.

And October was a surprisingly good month for the BDI-40, with 22 companies up, 11 down and seven unchanged.

Pharmaxis led the recovery following European approval of Bronchitol, up 79.5 percent to a market capitalization of \$298 million, followed by Allied Health recovering from its 2.8 cent a share placement, up 44.4 percent to \$26 million.

More impressively, Phosphagenics was up 43.5 percent to \$178 million, followed by QRX (35.9%), Impedimed (32.9%), Tissue Therapies (28.2%), Prima (15.7%) and Living Cell (13.6%).

The biggest fall was Alchemia's 21.7 percent drop to \$54 million, followed by Optiscan (16.7%), Sunshine Heart (15.8%), Genetic Technologies (14.9%), and Bionomics (13.3%).

Cochlear saved the three Big Caps falling more than a collective 0.4 percent for the month, recovering 26.3 Percent to \$3,333 million, while CSL fell 2.8 percent to \$15,151 million and Resmed lost 7.8 percent to \$4,217 million.

There are significant changes to both the BDI-20 and Second 20 this month, with QRX replacing Patrys in the BDI-20, while Avita and Neuren return to the Second 20 - proving that what goes down, can come up - and replacing Advanced Surgical and LBT Innovations.



BDI-40 v ASX200 JUN 30, 2006 TO OCT 31, 2011

TISSUE THERAPIES

Tissue Therapies says the US Food and Drug Administration has formally classified its Vitrogro synthetic protein as a biologic product.

Tissue Therapies lead US regulatory consultant Dr Patsy Trisler said that synthetic proteins were "now usually classified as biologic products and the Tissue Therapies preparation for US FDA clinical trials, approval for sale and reimbursement have been designed to satisfy or exceed all of the requirements of this classification".

Tissue Therapies chief executive officer Dr Steven Mercer said the company "understood that a biologic classification was possible and planned our US FDA clinical trials to satisfy either the device or biologic classification".

"We did this because we recognized that some wound healing products produced from purified animal proteins are currently regulated by the FDA as devices, compared to Vitrogro which uses a synthetic manufacturing process that avoids the use of human or animal derived materials," Dr Mercer said.

"A biologic classification is much simpler, quicker and cheaper than the approval process required for a product classified as a pharmaceutical," Dr Mercer said.

The company said that on October 28, 2011 the European Union notified body, the British Standards Institute (BSI), completed an audit of the quality management systems of Tissue Therapies and "found no non-conformances".

Tissue Therapies said it would receive the certificates of compliance necessary for the sale of Vitrogro wound healing products in the EU and Canada, soon.

"The FDA classification and successful BSI audit are two more critical milestones we have now achieved that are essential for the commencement of sales, initially in the EU in the second quarter of 2012 and later in the United States, Canada and globally," Dr Mercer said.

"The company is now in a strong position for the start of key market sales in 2012," Dr Mercer said.

Tissue Therapies was unchanged at 59 cents.

BIO-MELBOURNE NETWORK

Hadassah Medical Center Department of Medicine director Prof Yaron Ilan will discuss commercialization of clinical research at the November Bio-Melbourne Bio-Briefing. The Bio-Melbourne Network said that Prof Ilan was also Immuron's chief medical officer and on a visit from Israel would address the November 29, 2011 Bio-Briefing at the Royal Melbourne Hospital.

Hadassah's technology transfer company Hadasit owns 18 percent of Immuron. The Network said Prof Ilan was "well known for his successful commercialization of health technologies including being a founder of several start-up companies in Israel".

The Network said that Prof Ilan was acknowledged for his work in internal medicine, immunology and liver disease with more than 230 peer-reviewed publications to his name and more than 30 patents, including drugs being developed by pharmaceutical companies.

Bio-Melbourne chief executive officer Michelle Gallaher said that Prof Yaron would "provide valuable insights and first-hand experience of [commercializing] promising clinical research".

The November 29, 2001 Bio-Briefing will be held at the Charles La Trobe Theatre, Ground Floor North, Royal Melbourne Hospital, Grattan St, Parkville.

Registration is from 3:45pm for a 4pm presentation followed by networking drinks. To register online go to: <u>http://www.biomelbourne.org/events/view/209</u>.

<u>CBIO</u>

CBio says founder and chairman Stephen Jones as well as former chief executive officer and director Jason Yeates and director Prof John Funder have resigned.

CBio said Mr Jones was appointed chairman in 2000, Mr Yeates joined the company in 2004 and Prof Funder was appointed a director in 2007.

Last month CBio said that if any one of three shareholder action group proposed directors were elected, "each and every existing non-executive director will resign with immediate effect" (BD: Oct 21, 2011).

The action group proposed replacing chairman Stephen Jones and directors Prof John Funder and James Greig with former Amrad director Helen Cameron, Ergon Energy chairman Dr Ralph Craven and Warren Brown (BD: Sep 5, 7, 2011).

Mr Greig resigned on October 26 followed by company secretary Ben Graham on October 28, 2011.

The action group criticized the phase II trial of XToll for rheumatoid arthritis, which failed to meet its primary endpoint (BD: Aug 1, 2011) and a related media announcement.

The election of the three action group proposed directors will be considered at the company's extraordinary general meeting on November 4, 2011.

CBio was up two cents or 10 percent to 22 cents.

<u>CBIO</u>

CBio says it has raised about \$2.3 million through the issue of 12.7 million shares at 18 cents a share to clients of Zheng He Securities.

The company said the funds would be applied to drug formulation studies and increased drug manufacturing capacity for "a larger Lupus trial than originally contemplated", as well as working capital.

QIC BIOVENTURES

The Queensland Bio-Capital Fund, known as QBF, will change its trading name to QIC Bioventures, effective from yesterday October 31, 2011.

QBF said that as a subsidiary of the State Government-owned Queensland investment Corporation it had invested in biotechnology companies since 2002 and in recent years, increasingly used QIC services from a shared base in Brisbane.

QBF said that it would be recognized as one of QIC's "investment boutiques" and the QIC House of Boutiques combined the specialist skills of its sector-specific investment management teams with the backing of an investment manager.

QBF said that QIC Bioventures would continue to invest in and actively manage companies in the biotechnology and life sciences sector.

QIC Bioventures will remain at Central Plaza 2, 66 Eagle Street, Brisbane.

PHYLOGICA

Phylogica says its net operating cash burn for the three months to September 30, 2011 was \$1,961,000, with cash at the end of the quarter of \$3,258,000.

Phylogica was expecting to close a further licencing or partnering deal with an unnamed major pharmaceutical company prior to the end of September 2011, but has not yet completed the deal.

Phylogica was untraded at 6.2 cents.

BONE MEDICAL

Bone shareholders will vote to issue about 4,301,840 shares and about 2,150,920 options to directors, former directors and a related company as payment for fees.

Bone's notice of annual general meeting asked shareholders to approve the issue of the shares and options to chairman Dr Roger new, chief executive officer Peter Young, directors Prof Peter Brooks, Leon Ivory, Ivory & Co and former directors Lief Jensen and Dr Barry Walker.

The company said the shares would be issued at five cents each and the attaching options would be exercisable at 10 cents within three years of issue.

The company said shareholders would also vote on the re-election of Mr Ivory.

The meeting will be held at Ledger Corp, Level 3, 46 Ord Street, West Perth, on November 30, 2011 at 4.30pm (AWST).

Bone was unchanged at one cent.

SOLAGRAN

Solagran says its net operating cash burn for the three months to September 30, 2011 was \$2,050,000 with cash at the end of the quarter of \$498,000.

Solagran said it received \$300,000 in October as part of a \$2,900,000 "financing facility with an overseas party".

The company said that its pine needle extract, cure-all Ropren had been included in a Russian program allocated 15,000,000 Rubles (\$A470,510), but the announcement was not clear on whether the funds were for Ropren or the entire program. Solagran was up 0.3 cents or 4.4 percent to 7.1 cents.

FEDERAL GOVERNMENT AUSTRALIAN RESEARCH COUNCIL

Innovation Minister Senator Kim Carr says the \$310 million for 1,000 Australian Research Council major grants was an investment in quality research.

A media release from the Department of Innovation, Industry, Science and Research said that \$236 million was awarded to 778 projects under the Discovery Projects scheme, \$42 million for 151 Linkage Projects, \$28 million for 77 Linkage Equipment, Infrastructure and Facilities projects and \$3.8 million for 10 indigenous researchers under the Discovery Indigenous scheme.

The Department said that the research projects would begin in 2012 and be administered over a period of up to five years.

Senator Carr said that the funding, particularly under the Linkage schemes, would help secure partnerships among researchers, industry and other organizations outside the higher education sector "to find tangible, workable solutions to real issues".

"The Australian research institutions being awarded Linkage funding have partnered with 338 national and international organizations, who will top-up the Government's investment with almost \$166 million in cash and in-kind support," Senator Carr said.

"University of Queensland researchers will receive a \$405,000 grant to produce a novel image-guidance system to better target cancer tumors during radiotherapy, for more effective cancer treatments," Senator Carr said.

"Researchers at the University of Technology, Sydney, will use a \$170,000 grant to examine experiences of patients and doctors to improve reporting of medical incidents to save lives," Senator Carr said.

The Department media release said that the summaries of funding outcomes and information on the schemes were at: <u>www.arc.gov.au/media/major_announce.htm</u>.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Nov-10	Oct-11	Nov-11
Cochlear	4,022	2,639	3,333
CSL	18,060	15,582	5,555 15,151
Resmed	5,170	4,575	4,217
BDI-20	5,170	4,575	4,217
	490	533	563
Acrux Alchemia	490 100	69	54
Bionomics	88	165	54 143
Biota	175	146	145
Clinuvel	55	46	46
	11	48 74	40 63
Genetic Technologies Heartware	976	893	922
	115	893 70	
Impedimed	43	70 19	93 22
Living Cell Mesoblast			
	402	2,269	2,299
Nanosonics	204	120	128
Pharmaxis	637	166	298
Phylogica	14	23	25
Prima	96	166	192
QRX Pharma	99	170	231
Sirtex	337	240	262
Starpharma	168	265	278
Sunshine Heart	15	57	48
Tissue Therapies	61	78	100
Universal Biosensors	252	147	143
Second 20	0	40	
Allied	6	18	26
Anteo	38	45	47
Antisense	8	9	10
Avita	12	23	24
Benitec	15	19	19
Bioniche	153	80	80
Cathrx	37	21	20
Cellmid	7	8	7
Circadian	28	22	23
Compumedics	19	12	13
Genera	30	9	10
Neuren	7	17	32
Optiscan	5	12	10
Patrys	18	13	14
Phosphagenics	89	124	178
Prana	30	43	43
Psivida	115	91	85
Reva	275	183	177
Uscom	17	8	8
Viralytics	19	29	27

* Biotech Daily editor, David Langsam, owns shares in Alchemia, Allied Health, Biota, Neuren, Optiscan, Pharmaxis, Sunshine Heart and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Atcor, Circadian, Pharmaxis, QRX and Tissue Therapies. These holdings are liable to change.

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