Biotech Daily

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Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH UP: CLINUVEL UP 13%, LIVING CELL DOWN 8%**

*** IMMURON DETAILS PHASE IIb IMM-124E NASH TRIAL**

*** GRANDLODGE, ANASTASIOU REDUCE TO 15% OF IMMURON**

*** DAVID PLUSH, TEXAS WOODS BELOW 5% IN IMMURON**

*** FDA OKAYS INVION RE-START OF INV102 SMOKING CESSATION TRIAL**

*** BONE RAISES $4m, ROB TOWNER CHAIRMAN, LEON IVORY GOES**

*** USCOM, DELTEX DOPPLER MONITOR DISTRIBUTION COLLABORATION**

*** FIL (FORMERLY FIDELITY) REDUCES BELOW 5% IN ACRUX**

*** ALLAN GRAY TAKES 11% OF ACRUX**

*** CELLMID SIGNS HUANA LIKANG AS CHINA DISTRIBUTOR**

*** NUSEP APPOINTS ANDREW GOODALL TO PRIME BOARD**

MARKET REPORT

The Australian stock market climbed 1.04 percent on Wednesday January 29, 2014 with the S&P ASX 200 up 53.9 points to 5,229.0 points. Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and five were untraded.

Clinuvel was the best, up 17 cents or 13.1 percent to $1.47, with 14,485 million shares traded, followed by Anteo up 11.8 percent to 19 cents with 7.4 million shares traded, with Cellmid up 10.3 percent to 3.2 cents with 23.0 million shares traded.

Psivida climbed 8.7 percent; Admedus rose 6.7 percent; Starpharma was up 5.3 percent; Pharmaxis was up 4.2 percent; Alchemia, Ellex, Nanosonics, Patrys and Prana rose more than two percent; Acrux, Cochlear, CSL and Medical Developments were up more than one percent; with Mesoblast and Sirtex up by less than one percent.

Living Cell led the falls, down 0.7 cents or 7.8 percent to 8.3 cents with 40,000 shares traded. QRX lost 6.45 percent; Circadian fell 4.3 percent; Oncosil was down 3.45 percent; Reva shed 2.3 percent; Benitec, Genetic Technologies, Prima, Resmed and Universal Biosensors were down one percent or more; with Bionomics down 0.7 percent.

IMMURON

Immuron hopes to begin its 120-patient, phase IIb trial of IMM-124E for non-alcoholic steato-hepatitis by October 2014, pending a successful $9.66 million rights issue.
Presenting at Macquarie Bank in Melbourne, Immuron chief executive officer Amos Meltzer said he hoped the rights issue, underwritten by Patersons, with BBY as lead broker, would be finalized by the end of February and provide funding for more than two years, including the non-alcoholic steato-hepatitis (NASH) trial (BD: Jan 22, 2014).
Mr Meltzer said that the trial of the bovine colostrum-based IMM-124E had an open investigational new drug application with the US Food and Drug Administration and the principal investigation would be Virginia Commonwealth University Medical Center professor of medicine Prof Arun Sanyal.
Mr Meltzer said the trial would be conducted at centres in the US, Australia and Israel.
In 2013, Immuron said that its bovine colostrum-based oral IMM-124E alleviated liver damage and fibrosis in mice, quoting in-vivo pre-clinical data from the Jerusalem, Israel-based Hadassah-Hebrew University Medical Center (BD: Nov 8, 2013).
Mr Meltzer said the company expected a US National Institutes of Health-funded phase II trial of IMM-124E for alcoholic steato-hepatitis to begin within the next three months.
Mr Meltzer said that the company had been through a complete change of board and management and had also parted company with Takeda, the distributor of its over-the-counter Travelan for travellers' diarrhoea, in Australia.
Mr Meltzer said that selling Travelan directly with Immuron's own sales force had led to greater margins for the company and revenue expected to be about $1 million in 2013-'14 and "substantially more" in 2014-'15.
He said that Travelan was approved in Canada and as a dietary supplement in the US.
Mr Meltzer said that to gain US approval with the claim that it was beneficial for travellers' diarrhoea would require a further clinical trial.
He said he hoped two or three more countries in Asia would approve Travelan sales this year.
Mr Meltzer said the company had a pipeline of potential treatments for indications including clostridium difficile, as well as other liver-related projects.
Immuron was up 0.1 cents or 20 percent to 0.6 cents with 1.0 million shares traded.

IMMURON

Grandlodge and the Anastasiou Superannuation Fund have reduced their substantial holding in Immuron from 168,326,929 shares (16.56%) to 155,276,929 shares (14.74).
The substantial shareholder notices said that the Chirnside Park, Victoria-based companies acquired 8,750,000 for no consideration as the result of an issue approved at the annual general meeting and sold 21,800,000 shares for $136,932 or 0.63 cents a share on January 23, 2014.
The notice was filed by Grandlodge director Peter Anastasiou, whose brother Stephen Anastasiou is a director of Immuron.
Separately, David Plush and Texas Woods said they had ceased their substantial holding in Immuron "as a result of the issue of additional shares by Grandlodge".
In July 2013, Mr Plush and Texas Woods became substantial holders with the acquisition of 146,576,329 shares or 14.42 percent of the company (BD: Jul 8, 2013).
The Melbourne-based entities said at that time that Mr Plush was a director of Texas Woods, which held more than 20 percent of Grandlodge.
Today, Mr Plush and Texas Woods said the ownership of the shares was no longer combined with Grandlodge and 101,626,929 shares were affected by the change.

INVION

Invion says the US Food and Drug Administration has removed the “clinical hold” on its phase II smoking cessation trial of INV102.

Last month, Invion said the FDA requested changes to the trial protocol that resulted in a halt to enrolment of the patients with pre-existing chronic obstructive pulmonary disease (BD: Dec 20, 2013).

Today, Invion said that following its response to FDA requests, the Division of Anesthesia, Analgesia and Addiction Products accepted its amendments and lifted the clinical hold.

Invion said that the changes “were sufficient to require a re-launch of [the] study” but it had expanded the number of sites to minimize the impact on timing and reporting.

Invion did not disclose how many of the planned 136 patients had been enrolled in the original trial when the clinical hold was applied, but confirmed to Biotech Daily that the trial had to be restarted.

The company said it began enrolment in July 2013 and later said it hoped to start the trial by the end of November (BD: Jul 22, Nov 11, 2013).

The company said that new sites had been selected for their expertise in smoking cessation, chronic obstructive pulmonary disease and analysis capabilities of biochemical markers of inflammation and healing.

Invion chief medical officer Dr Mitchell Glass said that the FDA “took the unusual step of changing our reviewing division to DAAAP after study initiation, which then placed us on clinical hold”.

“Questions raised by the DAAAP were resolved by aligning titration criteria and dosing with our asthma study,” Dr Glass said.

“These changes will enable sites to recruit and treat our targeted … patient population which is in dire need of successfully quitting smoking,” Dr Glass said.

In December, Invion said that “the rationale for the clinical hold appears to be to align the titration and termination criteria for the study in [chronic obstructive pulmonary disease] patients with the criteria established in Invion’s ongoing study of nadolol in mild asthma patients ongoing under Invion’s [investigational new drug application] with the Division of Pulmonary, Allergy, and Rheumatology Products”.

“While the two study populations are quite different, aligning the titration criteria will enable Invion to integrate the safety data from the two trials seamlessly, providing us with a more robust titration schedule for future studies whether in [chronic obstructive pulmonary disease] or more severely asthmatic patients,” Dr Glass said.

Invion was up 0.3 cents or 3.3 percent to 9.3 cents.

BONE MEDICAL

Bone says it has raised $3,821,500 through the placement of 9,553,750,000 shares at 0.04 cents a share.

Last year, Cornerstone Corporate said it hoped to recapitalize Bone and pay off its La Jolla Cove draw-down equity facility (BD: Nov 28, 2013).

Today, Bone said that Cornerstone was the lead manager to the placement and managing director Robert Towner had been appointed non-executive chairman replacing Dr Roger New who continued as a director.

The company said that John Hannaford had been appointed a director replacing Leon Ivory and Prof Peter Brooks.

Bone said the funds would be applied to advancing the pipeline, seeking new strategic growth opportunities, rebuilding market value and general working capital purposes.

Bone was in a suspension.

USCOM

Uscom says it has a three-year distribution and marketing collaboration with Deltex Medical Group, for its Uscom 1A cardiac monitor, primarily in the US, UK and Middle East.
Uscom said Deltex was appointed as a nonexclusive distributor for the ultra-sonic cardiac output monitor, establishing “the foundations for further collaboration in the delivery of Doppler technologies to the global cardiovascular monitoring market”.
Uscom executive chairman Robert Phillips told Biotech Daily that the company had opted for non-exclusive distribution deals, including four in the US, four in Europe, two in Canada as well as China and Mexico.
Uscom’s media release said that Deltex manufactured and marketed the Cardioq-ODM oesophageal doppler monitor and had “excellent representation in the UK [National Health Service] system, as a leading proponent and adopter of Doppler haemodynamic monitoring”.
The company said that the Cardioq-ODM was marketed for peri-operative and intra-operative surgical monitoring with the Deltex business model based on sales of single patient disposable probes.
Uscom said its monitor was noninvasive with widespread application in sepsis, heart failure and hypertension in neonates, children, adults and the elderly and was marketed as a single capital sale.
The company said that the devices were complementary and had practice-leading clinical evidence, with both companies committed to growing the cardiac output monitoring market aggressively, by expansion into routine clinical practice in addition to replacement of invasive and less accurate technologies with safe and accurate Doppler ultrasound technologies.
Uscom said its monitor would be introduced into the Deltex distribution channels and the Cardioq-ODM would be introduced into the existing Uscom distribution channels over the next 12 months.
The company said the agreement was “a collaboration between the two major Doppler cardiac monitoring companies to better exploit growing market opportunities and is in response to the increasing recognition by clinicians of the clinical importance of Doppler cardiac monitoring”.
Uscom said the agreement aimed to generate $582,000 in revenue in the first year.
Mr Phillips said “this Doppler partnership shifts the cardiac monitoring landscape”.
“Doppler is now a clear lead technology in the sophisticated cardiovascular monitoring market, and Uscom and Deltex lead this field,” Mr Phillips said.
“This partnership will generate immediate revenue for both companies, provide for market growth and market consolidation, and establish a foundation for longer term strategic opportunities,” Mr Phillips said.
Uscom was untraded at 14 cents.

ACRUX

The Singapore-based FIL Limited (formerly Fidelity Investments) says it has reduced its substantial holding in Acrux from 8,936,097 shares (5.37%) to 8,112,578 shares (4.87%).
In December 2013, Fidelity Investments Singapore increased its substantial holding in Acrux from 8,636,252 shares (5.19%) to 8,936,097 shares (5.37%) and said that associated company FMR no longer had a substantial holding in Acrux (BD: Dec 5, 2013).
Today FIL said that between December 9, 2013 and January 24, 2014 it bought 17,711 shares and sold 841,230 shares at prices ranging between $2.21 and $2.63.
Acrux was up three cents or 1.3 percent to $2.38.

ACRUX

Allan Gray Australia has increased its substantial holding in Acrux from 17,120,068 (10.28%) to 18,955,022 shares (11.38%).
Allan Gray said that between December 11, 2013 and January 24, 2014 it bought 1,834,954 shares for $4,225,305 or an average price of $2.30 a share.

CELLMID

Cellmid says wholly-owned subsidiary Advangen has signed a Chinese distribution agreement for its hair loss products with Beijing Huana Likang Biotechnology.
Cellmid said the three year agreement could be automatically extended if minimum sales of Lexilis Black for men and Jo-Ju for women were met.
The company said that Huana Likang was “a fast growing direct marketing company with primary channels through television shopping networks and web-based sales”.
Cellmid said that companies importing healthcare and cosmetic goods to China faced significant hurdles and often took several years to be issued sales permits but the Advangen acquisition in May 2013 included Chinese import permits for Lexilis and Jo-Ju.
The company said there had been “intense interest in [its] FGF-5 inhibitor hair growth products”.
Cellmid said that costs associated with marketing and sales would be met by Huana Likang, but it would provide assistance by supplying its marketing information and materials and product designs to the distributor.
The company said that the premium Chinese hair growth market was more than $3 billion, assuming that about five million people, or 0.37% of the total population, were or would be using hair growth enhancing lotions and shampoos.
Cellmid said that other, Australian manufactured hair growth product brands, were planned to expand the market reach of the FGF-5 inhibitor technology in China.
Cellmid was up 0.3 cents or 10.3 percent to 3.2 cents with 23.0 million shares traded,

NUSEP HOLDINGS

Nusep says that non-executive director Andrew Goodall has been appointed a non-executive director of subsidiary Prime Biologics.
Nusep said it was in the process of spinning-out Prime Biologics and Mr Goodall would join former chief executive officer Dr Hari Nair and former executive chairman John Manusu on the Prime board.
The company said that it expected the Xeraya investment group to invest in Prime and two representatives of Xeraya would be appointed to the Prime board.
Nusep was untraded at eight cents.