Biotech Daily

Tuesday September 13, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OPTHEA UP 18%, BIONOMICS DOWN 7%**

*** AUSBIOTECH CALLS ON GOVERNMENT, ALP TO KEEP 45% TAX INCENTIVE**

*** BIOTECH DAILY: 'PENNY-PINCHING CUT A DISGRACE'**

*** MELBOURNE UNI: 'PEPTIDE POLYMERS KILL RESISTANT BACTERIA'**

*** REDHILL, STANDFORD UNI YELIVA HEAD, NECK CANCER MOUSE STUDY**

*** WEHI: 'CONE SNAIL VENOM INSULIN COULD AID HUMAN INSULIN'**

*** CANADA APPROVES STARPHARMA VIVAGEL DUAL PROTECT CONDOM**

*** TGA DEVICE BRANCH: 'CANCEL GI DYNAMICS ENDOBARRIER'**

*** PSIVIDA REVENUE DOWN 94% TO $2m, PROFIT TO $29m LOSS**

*** REGAL FUNDS RE-TAKES 5% OF IMPEDIMED**

*** SG HISCOCK TAKES 5% OF RESONANCE**

*** AUSBIOTECH, JOHNSON & JOHNSON AWARDS OPEN**

MARKET REPORT

The Australian stock market fell 0.23 percent on Tuesday September 13, 2016 with the ASX200 down 11.8 points to 5,207.8 points. Twenty-two of the Biotech Daily Top 40 companies were up, seven fell and 11 traded unchanged.

Opthea was the best, up 13 cents or 18.3 percent to 84 cents with 423,593 shares traded, followed by Orthocell up 10.1 percent to 38 cents with 411,921 shares traded. Neuren climbed 7.7 percent; Dimerix rose 6.7 percent; Ellex and Impedimed improved more than five percent; Acrux, IDT and Nanosonics were up four percent or more; Cochlear, Genetic Signatures, Prima and Pro Medicus rose more than two percent; Anteo, Clinuvel, Compumedics, Osprey, Polynovo and Sirtex were up more than one percent; with Airxpanders, Mesoblast, Resmed, Reva and Viralytics up by less than one percent.

Bionomics led the falls, down two cents or 6.8 percent to 27.5 cents with 397,469 shares traded. Benitec and Medical Developments fell more than four percent; Cyclopharm and Living Cell were down more than three percent; Psivida was down one percent; with CSL and Starpharma down by less than one percent.

AUSBIOTECH

Ausbiotech has called on the Federal Government to remove, and the Labor Opposition to oppose, the 1.5 percent cut to the R&D Tax Incentive in the Omnibus Savings Bill.
Ausbiotech chief executive officer Glenn Cross said that he noted the Labor Party's negotiations for significant amendments to the Omnibus Bill, but it was "disappointing that the opportunity was not taken to save the Research and Development Tax Incentive intact".
"While defending the R&D Tax Incentive and opposing the Coalition's plan to cut the Incentive by 1.5 percent, right up until the nonsensical turnaround in the election campaign, this was Labor's chance to right this wrong step," Mr Cross said.
"In supporting the Omnibus Bill with amendments, the R&D Tax Incentive is to be compromised," Mr Cross said.
"The Opposition has – as has the Government - contradicted its clear statements of support regarding innovation and entrepreneurship," Mr Cross said.
"Both parties' rhetoric has been supportive of optimising the environment for start-up enterprises, which make up the bulk of the Australian life science sector," Mr Cross said.
"Reducing the benefit of the R&D Tax Incentive will have a direct impact on an area of national competitive advantage, which has responded recently with growth, in large part due the effect of the R&D Tax Incentive."
"The desire for jobs and growth can only be undermined by cutting the most significant programme to promote innovation in this country," he said.
"It also sends a negative message to our international partners and collaborators, which undermines economic activity in the sector," Mr Cross said.
"Ausbiotech calls for the Government to remove the R&D Tax Incentive cut from the Omnibus Savings Bill," Mr Cross said.

BIOTECH DAILY EDITORIAL

Biotech Daily is extremely disappointed that Labor innovation spokesman Senator Kim Carr has reneged on a promise made to this publication just three months ago.
In May, Senator Carr told Biotech Daily unequivocally that Labor would reverse the intended 1.5 percent cut to the Research and Development Tax Incentive, which was before Parliament (BD: May 23, 2016).
The Federal Greens also promised to block the 1.5 percent cut and they continue to oppose the measure.
Biotech Daily is concerned about the cut for three main reasons.
1. The business community frequently calls any change it doesn't like "uncertainty" and this penny-pinching tinkering with the 45 percent R&D Tax Incentive is the clearest method of creating uncertainty for investors, whether they are venture capital or retail.
2. The Federal Government claim that the reduction is off-set by a small business tax cut is simply nonsense as many start-up companies aren't liable for tax and some may never be. And if it is offset, then it saves no money for the Budget anyway.
3. The cut sends all the wrong signals to global researchers, scientists and investors on the seriousness of Prime Minister Malcolm Turnbull's claims to be the "innovation prime minister" when he is cutting the single most important measure for innovation.
That the Labor Party supports this cut – having promised the opposite just three months ago - is an equal disgrace.

David Langsam
Editor

THE UNIVERSITY OF MELBOURNE

The University of Melbourne says its staff have developed “star-shaped peptide polymers” that can kill antibiotic resistant bacteria, in-vitro and in rats.

The University said that the star-shaped, short chains of peptide polymers, formally described as ‘structurally nano-engineered antimicrobial peptide polymers’ were developed by the Department of Chemical and Biomolecular Engineering’s Prof Greg Qiao and doctoral student Shu Lam, with the Faculty of Medicine’s Prof Neil O’Brien-Simpson and Prof Eric Reynolds.

The University of Melbourne media release said that the star-shaped peptide polymer “was extremely effective at killing Gram-negative bacteria, a major class of bacteria known to be highly prone to antibiotic resistance, while being non-toxic to the body … [and was] effective in killing superbugs when tested in animal models”.

The research article, entitled ‘Combating multidrug-resistant Gram-negative bacteria with structurally nano-engineered antimicrobial peptide polymers’ was published in Nature Microbiology and said the ‘superbug’ tested in unspecified animals was Acinetobacter baumannii.

An abstract is available at: http://www.nature.com/articles/nmicrobiol2016162.

The University said that tests on red blood cells showed that the star-shaped polymer dose rate would need to be increased more than 100 times to become toxic and the resistant bacteria showed no signs of resistance against these peptide polymers.

The media release said that the peptide polymers could kill bacteria with multiple pathways, including destroying the bacteria cell wall, unlike most antibiotics which killed with a single pathway, which could account for the superior performance of the peptide polymers over antibiotics.

Prof Qiao said that currently the only treatment for infections caused by bacteria was antibiotics, but over time bacteria mutated to protect themselves against antibiotics, making treatment no longer effective.

“It is estimated that the rise of superbugs will cause up to 10 million deaths a year by 2050,” Prof Qiao said. “In addition, there have only been one or two new antibiotics developed in the last 30 years.”

REDHILL BIOPHARMA

Redhill says it has begun a collaboration with Stanford University to evaluate Yeliva as a radio-protectant for prevention of mucositis in head and neck cancer patients.

Last week, Redhill said it had begun a 77-patient, open-label, dose-escalation, phase Ib/II study of Yeliva (ABC294640) in patients with refractory or relapsed multiple myeloma at Duke University Medical Centre (BD: Sep 9, 2016).

The company said ABC294640 was licenced from the Hummelstown, Pennsylvania-based Apogee Biotechnology in 2015, and in 2010, its bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney’s Giaconda (BD: Aug 17, 2010).

Today, Redhill said the California-based Stanford University School of Medicine collaboration was intended to complement its planned phase Ib study to evaluate Yeliva as a radio-protectant for prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy.

The company said that Stanford would evaluate the effect of Yeliva on mucositis reduction and tumor control in a mouse model of head and neck cancer, with results expected in mid-2017.

On the Nasdaq, Redhill was up 36 US cents or 2.46 percent to $US15.02 ($A19.90) with 23,261 shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that venom from a species of marine cone snail could lead to 'ultra-fast-acting' insulins, for more efficient diabetes management.

The Institute said its staff had determined the three-dimensional structure of insulin found in cone snail venom, showing how the Conus geographus G1 (Con-Ins G1) protein could operate faster than human insulin to take up glucose from the blood.

WEHI said that the researchers discovered that Con-Ins G1 was able bind to human insulin receptors, signifying the potential for its translation into a human therapeutic.

The research article, entitled 'A minimized human insulin-receptor-binding motif revealed in a Conus geographus venom insulin' has been published in the journal Nature Structural and Molecular Biology, and an abstract is available at: http://www.nature.com/nsmb/journal/vaop/ncurrent/full/nsmb.3292.html.

The abstract said that "insulins in the venom of certain fish-hunting cone snails facilitate prey capture by rapidly inducing hypoglycemic shock".

"One such insulin, Conus geographus G1 (Con-Ins G1), is the smallest known insulin found in nature and lacks the C-terminal segment of the B chain that, in human insulin, mediates engagement of the insulin receptor and assembly of the hormone's hexameric storage form," the abstract said.

"Removal of this segment … in human insulin results in substantial loss of receptor affinity," the abstract said. "These findings may facilitate efforts to design ultra-rapid-acting therapeutic insulins".

WEHI said that Prof Mike Lawrence led the study with the University of Utah, the Monash Institute of Pharmaceutical Sciences, La Trobe University and Flinders University.

Prof Lawrence said the teams used the Australian Synchrotron to create and analyze the three-dimensional structure of the cone snail venom insulin protein.

"We found that cone snail venom insulins work faster than human insulins by avoiding the structural changes that human insulins undergo in order to function," Prof Lawrence said. "They are essentially primed and ready to bind to their receptors."

Prof Lawrence said human insulins could be considered clunky by comparison.

"The structure of human insulins contain an extra hinge component that has to open before any molecular handshake or connection between insulin and receptor can take place," Prof Lawrence said.

"By studying the three-dimensional structure of this snail venom insulin we've found how to dispense with this hinge entirely, which may accelerate the cell signalling process and thus the speed with which the insulin takes effect," Prof Lawrence said.

WEHI said that the University of Utah reported that the marine cone snail Conus geographus used an insulin-based venom to trap its prey and fish that swam into the invisible trap immediately became immobilised in a state of hypoglycaemic shock induced by the venom.

The University of Utah's Dr Helena Safavi-Hemami said it was "fascinating to uncover how the cone snail insulin was able to have such a rapid effect on its prey and, furthermore, that the peptide had therapeutic potential in humans".

"We were thrilled to find that the principles of cone snail venom insulins could be applied to a human setting," Dr Safavi-Hemami said.

"Our Flinders University colleagues have shown that the cone snail insulin can switch on human insulin cell signalling pathways, meaning the cone snail insulin is able to successfully bind to human receptors," Dr Safavi-Hemami said.

"The next step in our research … is to apply these findings to the design of new and better treatments for diabetes, giving patients access to faster-acting insulins," Dr Safavi-Hemami said.

STARPHARMA HOLDINGS

Starpharma says Health Canada approved its Vivagel condom, which marketing partner Ansell would launch under the Lifestyles Dual Protect brand.
The company said the Vivagel condom was “a world-first product based on innovative Australian technology … the only condom of its type, providing barrier protection and incorporating the proprietary compound, astodrimer sodium (SPL7013, Vivagel) in the condom lubricant”.
Starpharma chief executive officer Dr Jackie Fairley said the Health Canada approval “marks a further key commercial milestone for the Vivagel condom product and is very significant as the first North American approval for the product”.
Starpharma fell half a cent or 0.8 percent to 65.5 cents.

GI DYNAMICS

GI Dynamics says the Australian Therapeutic Goods Administration medical device branch has “recommended that Endobarrier’s inclusion on the [Register] be cancelled”.
GI Dynamics said that it had received an email from the TGA “indicating” the potential removal of the Endobarrier, for obesity and type 2 diabetes, from the Australian Register of Therapeutic Goods.
The Endobarrier has faced regulatory issues in Europe and the US including an association with liver abscesses (BD: Oct 6,7, Dec 1, 2014; Jul 30, 31, 2015).
Today, the company said that the Endobarrier had been on the Register since 2011, allowing it to be sold commercially in Australia.
GI Dynamics said that in May it announced an on-going communication with the TGA regarding compliance-related matters (BD: May 20, 2016).
The company said that it had provided all the information requested by the TGA and had received an email advising that the TGA’s medical device branch had “recommended that Endobarrier’s inclusion on the [Register] be cancelled”.
GI Dynamics said that the notice of the TGA’s decision on the recommendation was “expected to be received by the company later this week”.
The company said that should the Endobarrier be suspended or cancelled by the TGA it would not be permitted to supply the device in Australia.
GI Dynamics said it was “continuing to discuss this matter with the TGA”.
GI Dynamics fell 1.3 cents or 43.3 percent to 1.7 cents with 2.9 million shares traded.

PSIVIDA

Psivida says revenue for the year to June 30, 2016, fell 93.9 percent to $US1,620,000 ($A2,155,060) turning the previous net profit after tax to a $US21,547,000 ($A28,663,910) loss.
In September 2014, Psivida said that the US Food and Drug Administration approval of Iluvien for diabetic macular oedema had triggered a $US25 million payment from licencee Alimera Sciences (BD: Sep 29, 2014).
Psivida said that research and development expenses increased by $US2.3 million, or 19 percent to $US14.4 million compared to $US12.1 million in the previous year.
The company said that the previous net earnings per share of 21 US cents had turned to a diluted loss per share of 68 US cents per share.
Psivida said it had $US28,992,000 in cash and cash equivalents at June 30, 2016, compared to $ US28,535,000 at June 30, 2015.
Psivida fell five cents or one percent to $4.80.

IMPEDIMED

Regal Funds Management has become a substantial shareholder in Impedimed, again, with 18,720,001 shares or 5.00 percent of the company.

The Sydney-based Regal Funds previously became a substantial shareholder in Impedimed on July 1 with 18,682,335 shares or 5.00 percent of the company but on July 5, said it had been diluted below five percent through the issue of shares under the employee share option plan (BD: Jul 1, 2016).

Today, Regal Funds said that it acquired the shares between May 16 and September 8, 2016 at prices ranging from 88 cents to $1.76 a share and the registered holders were UBS Nominees, Credit Suisse Securities Europe, Merrill Lynch (Australia) Nominees and HSBC Custody Nominees (Australia).

Impedimed was up eight cents or 5.8 percent to $1.45 with 1.2 million shares traded.

RESONANCE HEALTH

SG Hiscock and Co says it has become a substantial shareholder in Resonance with the acquisition of 21,016,635 shares (5.022%).

The Collins Street Melbourne-based SG Hiscock said the shares were held by HSBC Custody Nominees and gave its address as HSBC in Sydney.

The company said that it acquired 1,200,000 shares at 2.5 cents a share on September 12, 2016 but failed to disclose the cost of the other 19,816,635 shares as required under the Corporations Act.

Resonance was unchanged at 2.5 cents with 1.5 million shares traded.

AUSBIOTECH, JOHNSON & JOHNSON INNOVATION

Ausbiotech says that nominations have opened for the Johnson & Johnson Innovation Industry Excellence Awards to be announced at its October national conference.

Ausbiotech said that Johnson & Johnson Innovation sponsored the three awards, the industry leadership award, company of the year and emerging company of the year “to recognise the highest achievers in the Australian life sciences”.

Nominations close Friday 30 September 2016

The Ausbiotech conference will be held at the Melbourne Convention Centre, October 24 to 26, 2016.

Nominations can be forwarded to: Ausbiotech national conference and events manager Kirsty Grimwade: kgrimwade@ausbiotech.org.