Biotech Daily

Thursday September 29, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 9%, ACTINOGEN DOWN 36%**

*** BIO-MELBOURNE: 'R&D TAX REVIEW - A HANDBRAKE ON INNOVATION'**

*** BIOTECH DAILY: $2m CAP WILL HIT THE BEST COMPANIES**

*** BDO: 'REVIEW WILL ADVERSELY IMPACT INNOVATION'**

*** ONEVENTURES $15m FOR MURDOCH CHILDREN'S PEANUT ALLERGY**

*** ACTINOGEN: 'FDA COULD DELAY XANAMEM ALZHEIMER'S TRIAL'**

*** AVITA APPOINTS TEB SANAAT LOTUS IRAN DISTRIBUTOR**

*** AUSTRALIAN ETHICAL REDUCES TO 5.6% OF ATCOR**

*** RESAPP REQUESTS 'STUDY RESULTS' TRADING HALT**

*** COCHLEAR CFO NEVILLE MITCHELL TO RETIRE**

*** FACTOR THERAPEUTICS: MELANIE FARRIS CO SEC, SASKIA JO FINANCE**

MARKET REPORT

The Australian stock market was up 1.09 percent on Thursday September 29, 2016, with the ASX200 up 58.9 points to 5,471.3 points. Eighteen of the Biotech Daily Top 40 companies were up, 15 fell, four traded unchanged and three were untraded.

Avita was the best, up 0.8 cents or 8.7 percent to 10 cents with 1.8 million shares traded. Universal Biosensors climbed 7.4 percent; Clinuvel was up 6.7 percent; Benitec rose 5.6 percent; Oncosil improved 4.35 percent; Cellmid was up 3.3 percent; Atcor, Compumedics, Medical Developments, Neuren, Orthocell and Osprey rose two percent or more; Nanosonics, Polynovo and Viralytics were up more than one percent; with Factor Therapeutics, Impedimed, Resmed and Sirtex up by less than one percent.

Yesterday's 8.5 percent best, Actinogen, led the falls, down 2.3 cents or 35.9 percent to 4.1 cents with 20.9 million shares traded. Dimerix lost 12.5 percent; Anteo and Opthea fell more than five percent; Admedus was down three percent; Genetic Signatures and Living Cell shed more than two percent; Airxpanders, CSL, Mesoblast and Pharmaxis were down one percent or more; with Cochlear, Cyclopharm, Ellex, Pro Medicus, Reva and Starpharma down less than one percent.

BIO-MELBOURNE NETWORK

Bio-Melbourne Network chief executive officer Dr Krystal Evans says the proposed changes to the 45 percent R&D Tax Incentive will “put a handbrake on innovation”.
Yesterday, the Federal Government called for consultation on its Research and Development Tax Incentive Review (BD: Sep 28, 2016).
In a posting to the social media website Linkedin, Dr Evans said that the R&D Tax Incentive Review recommended changes including a proposed $2 million cap on the annual cash refund payable under the R&D Tax Incentive.
“The proposed changes will need to be analysed to assess their full impact on the sector, but it is clear that [biotechnology and medical technology] companies will be affected by the proposed refundable cap which places a ceiling on the level of innovation support for high-growth potential companies,” Dr Evans said.
Dr Evans said that a preliminary analysis by her organization indicated that in the biotechnology sector the R&D Tax Incentive was “fulfilling policy objectives, in terms of driving additional and effective R&D activity and delivering strong economic outcomes in terms of jobs and growth”.
“Of the small data set we have complied to date more than 40 percent of biotech companies will be impacted by this proposed $2 million R&D Tax Incentive cap,” DR Evans said.
Dr Evans said that a recent R&D Tax Incentive survey showed that faced with changes to the R&D Tax Incentive companies might not undertake additional research and development activity, or might move their research and development activity overseas and reduce their overall spend in Australia.
“These are the consequences of the proposed changes - putting a handbrake on innovation,” Dr Evans said.
Dr Evans said that less research and development activity in Australia would lead to less translation of medical research into medical products and less opportunity to extend and expand the pipeline of discoveries that are being developed into the cures and therapies of the future.
“Considering the broader policy focus of the Turnbull Government's National Science and Innovation Agenda is to drive entrepreneurship and translate good ideas into great businesses, it is perplexing to see proposed changes that limit the support for our most innovative companies,” Dr Evans said.
“But it’s not over yet,” Dr Evans said.
“The uncertainty around [the] future of the R&D Tax Incentive will continue, with a new round of consultations open ‘till October 28, followed by round tables and a further six months until the Turnbull Government will officially respond in March, 2017,” Dr Evans said.
“What this does is create an opportunity to mount the case outlining why proposed changes [to the] R&D Tax Incentive are unnecessary and damaging to the [biotechnology and medical technology] sector,” Dr Evans said.
“The Bio-Melbourne Network will use this time to continue to build the evidence and provide the case studies needed to demonstrate that, for our sector, the R&D Tax Incentive is working, is effective, is achieving outcomes and is vital to developing the drugs, diagnostics and devices that will transform the future of health and our economy,” Dr Evans said.
“Your voices are more important than ever and we will look to work in collaboration with our members and the wider sector to ensure that your views are heard,” Dr Evans said.
The Review and more information are at: https://www.business.gov.au/rd-review.

BIOTECH DAILY

Biotech Daily has reported 15 companies receiving R&D Tax Incentives of more than the proposed $2 million cap in the 12 months to September 13, 2016.
A further 23 companies received less than $2 million.
Since the 2011 start of the R&D Tax Incentive under the Labor-Greens Government, 39 payments were greater than $2 million and 72 payments were less than $2 million.
What is clear from the reported data is that the majority of companies receiving more than $2 million were at the time among the Biotech Daily Top 40 Index (BDI-40) companies, including Alchemia ($6m, $9m), Bionomics ($4.2m, $7m), Circadian ($2.2m, $3m), Mesoblast ($4.3m, $5m, $6m), Prana ($2.5m, $7m, $6.5m), Starpharma ($6m, $4.2m, $3.4m), Universal Biosensors ($8m, $8.2m) and Viralytics ($2.5m $2.9m).
Some of the companies receiving less than $2 million were also in the BDI-40 group.
Biotech Daily has previously commented on the counterproductive penny-pinching Budget measures that inhibit innovation and we are astounded that the Review was completed and delivered to Prime Minister Malcolm Turnbull on April 4, 2016, released yesterday with a one month deadline on submissions until October 28, 2016.
The six recommendations include raising the maximum expenditure to $200 million from the existing $100 million “so that large R&D-intensive companies retain an incentive to increase R&D in Australia” but nowhere does the Review recommend cutting the rate by 1.5 percent to 43.5 percent as agreed by the Government and the Labor Opposition.
There are other recommendations that require consideration but missing from the recommendations was increasing the revenue threshold from the current low $20 million, which affects companies including Acrux, Ellex, Cogstate, Compumedics, ITL, Mesoblast, Nanosonics, Pro Medicus, Sirtex, Somnomed and Universal Biosensors, not to mention Cochlear, CSL and Resmed and companies with large one-off payments like Bionomics.

BDO (BINDER DIJKER OTTE) AUSTRALIA

Accountancy firm BDO says that Australian innovation and start-ups “will be adversely impacted by [the] Review of the R&D Tax Incentive scheme”.
BDO said that “set against the backdrop of the recent reduction of 1.5 percent to the [research and development] offsets … industries that are expensive to enter such as biotech and mining start-ups are most likely to be adversely affected by the proposed $2 million cap on the annual cash refund”.
BDO Australia research and development tax partner Nicola Purser said that BDO generally agreed with the recommendations contained in the report, but “the constant tinkering to the R&D tax incentive program was not helpful for research and development programs which are generally long-term undertakings by a company”.
Ms Purser said that incentives for businesses to hire doctoral graduates and collaborate with research institutions was good but “the fact that they’re proposing to limit the introduction of a collaboration premium of up to 20 percent for the non-refundable tax offset so as to provide additional support for the collaborative element of expenditure undertaken with publicly funded research organisations … plays to the strengths of the larger end of town with turnovers of over $20 million”.
“We believe it should be opened to all, including [small and medium sized enterprizes]”.
BDO said it welcomed increasing the research and development intensity threshold to $200 million but did not believe it should be linked to a threshold of one to two percent.
BDO said it did not agree with publishing company lists and refund amounts saying that “the increased administration would outweigh the transparency benefits”.

ONEVENTURES , MURDOCH CHILDREN'S RESEARCH INSTITUTE

Oneventures says it has led an investment round raising $15 million for Melbourne's Murdoch Children's Research Institute to develop a treatment for peanut allergy.

In a media release Oneventures said that unlike other peanut allergy treatments in development the Murdoch Children's Research Institute's therapy, known as probiotic therapies for allergy or Prota, would allow children with peanut allergy to incorporate peanut and peanut products as a regular part of their diet.

The venture capital firm said that the novel action of the treatment, discovered and developed by the Institute's Prof Mimi Tang was in the combination of the two components of peanut allergen with a probiotic which had been shown in clinical trials to induce tolerance to peanut.

Oneventures said the approach had the potential to be used to treat other common food allergies, such as allergies to milk, egg, shellfish and other nuts.

The media release said that Oneventures would invest $8 million through its Innovation and Growth Fund II and "late stage negotiations [were] underway to secure an additional $7 million from strategic investors and partners".

Oneventures managing partner Dr Paul Kelly said that Australian research was "leading the way with a much needed cure for peanut and other food allergies".

"This deal embodies exactly what the [Federal] Government's Innovation Agenda is about, providing the capital, skills and international expertise to help translate promising Australian developments into commercial products, that address large global needs," Dr Kelly said.

"Oneventures will play an active role in bringing Prota's treatment to market and assist with the management of clinical development and navigating the regulatory pathway, and bringing international partners to the table, as it has done with previous investments, including Hatchtech," Dr Kelly said.

Oneventures said that food allergy was a significant and growing problem affecting about 250 million people worldwide and had increased 350 percent over the past 20 years, with peanut allergy increasing at the greatest rate.

The company said that about six million people across US and Europe were allergic to peanuts and hospital admissions due to food anaphylaxis continued to increase.

MCRI business development and strategy general manager Dr James Dromey said that the investment would "play an important role in progressing development of this promising new treatment for peanut allergy and is a strong indication of the quality of research at Murdoch Children's".

The media release said that Murdoch Children's Research Institute study tested 62 peanut-allergic children given a dose of the probiotic Lactobacillus rhamnosus with peanut protein in increasing amounts, or a placebo, over 18 months to assess whether children would become tolerant to peanut.

Oneventures said that 82 percent of children who received the probiotic-peanut therapy were able to tolerate up to 16 peanuts after the treatment had finished compared with four percent of children who received placebo.

The company said that a further multi-centre study was underway, across three Australian sites, to see if the therapy could produce a longer term tolerance of up to 12 weeks.

"Based on the results we have seen to date, if nine children were given probiotic and peanut therapy, seven would benefit," Prof Tang said.

"This is a very promising result and we look forward to seeing further evidence from the current trial and progressing the development of this approach so that all children with peanut allergy can access this treatment," Prof Tang said.

Oneventures is a private company.

ACTINOGEN MEDICAL

Actinogen says the US Food and Drug Administration has asked further questions about the potential safety surveillance of Xanamem before it can treat US patients.

Actinogen said that if the questions could not be resolved “in a reasonable time [it] will not be able to recruit patients in the phase II Alzheimer's disease clinical trial by the end of 2016”.

In June, Actinogen said that safety discussions with the FDA had led to an “enhanced protocol” for its 200-patient ‘Xanadu’ phase II trial of Xanamem for Alzheimer’s disease and the enhanced protocol would be harmonized with both Australian and UK regulators and hospital sites, with patients expected to be enrolled by the end of 2016 (BD: Jun 8, 2016).

Last year, Actinogen said that its 24-volunteer, dose-ranging, phase I trial of Xanamem confirmed safety and tolerability up to 35mg twice daily, the drug crossed the blood-brain barrier and was effectively delivered to the brain (BD: May 12, Sep 29, 2015).

Actinogen fell 2.3 cents or 35.9 percent to 4.1 cents with 20.9 million shares traded.

AVITA MEDICAL

Avita says it has appointed Teb Sanaat Lotus as its exclusive Iran distributor and a dedicated clinic for its wound treatment devices will open in Tehran.

Avita said that the Tehran clinic would initially treat patients for re-pigmentation and scar reconstruction.

The company said that Teb Sanaat Lotus would distribute its products through Zikad International Aesthetics Supplier, its Iranian partner company, which had four aesthetics clinics and supplied aesthetic products.

Avita said that Zikad’s Renovacell Clinic would act as a training centre, partnering with other private clinics and planned to expand to treating burns and chronic wounds.

The company said that about 16 million people had aesthetic procedures in Iran every year, making it the tenth biggest market in the world and the second largest in the Middle East.

Avita chief executive officer Adam Kelliher said that “using a dedicated clinic is a new approach for Avita and we believe it will give us real focus to reach this important market”.

“The dedicated Renovacell clinic and training centre should support the rapid adoption of our skin renewal technology … and when this platform is further rolled out to burns and chronic wounds, we anticipate Iran will become a significant market for Avita,” Mr Kelliher said.

Avita said that the distribution agreement was “a significant step for [its] growth strategy in the Middle East”.

Avita was up 0.8 cents or 8.7 percent to 10 cents with 1.8 million shares traded.

ATCOR MEDICAL

Australian Ethical Investment has reduced its substantial holding in Atcor from 13,802,534 shares (6.94%) to 11,302,239 shares (5.56%).

Australian Ethical said it bought and sold shares between October 14, 2015 and September 23, 2016, buying 600,000 shares on November 2, 2015 for $126,000 or 21 cents a share and selling 1,042,485 shares on September 23, 2016 for 96,218 or 9.2 cents share.

Atcor was up 0.2 cents or 2.1 percent to 9.6 cents.

RESAPP HEALTH

Resapp has requested a trading halt “pending the release of an announcement regarding updated results from its adult clinical study”.
Trading will resume on October 3, 2016 or on an earlier announcement.
Resapp fell 1.75 cents or 3.5 percent to 48.75 cents with 3.3 million shares traded, prior to the trading halt.

COCHLEAR

Cochlear says that chief financial officer and company secretary Neville Mitchell will retire by June 30, 2017.
Cochlear chairman, Rick Holliday-Smith said that “in his 26 years as CFO, Neville has made a significant and lasting contribution to building Cochlear”.
“He was part of the team that floated Cochlear in 1995 with a market capitalisation of $125 million and has been an integral part of building Cochlear into a global market leader with a market cap of over $8 billion today,” Mr Holliday-Smith said.
Mr Holliday-Smith thanked Mr Mitchell “for his valuable service over the past 26 years and … wish him well for the future”.
Cochlear said it would begin the search for the new chief financial officer.
Cochlear fell 50 cents or 0.35 percent to $141.35 with 186,188 shares traded.

FACTOR THERAPEUTICS

Factor Therapeutics says it has Melanie Farris as its company secretary replacing Saskia Jo who continues as finance director, effective from September 29, 2016.
Factor Therapeutics said that Ms Farris had experience in governance, company and board administration, operations and communications in the life sciences, investment and not-for-profit sectors.
The company said that Ms Farris was currently Invion’s company secretary and previously had worked in the Prince of Wales’ Office, Global Asset Management, Imperial Cancer Research Fund and The Prince’s Foundation.
Ms Farris’ Linkedin page said she held a Bachelor of Communication from Griffith University and a Master of Business Administration from the Australian Institute of Business.
The company said it was experience “significantly increased operational activity” and Ms Jo previously held both the role of company secretary and finance director and her increased responsibly and activity, particularly during the initiation of the US phase II trial, warranted the changes.
Factor Therapeutics was up 0.05 cents or 0.9 percent to 5.45 cents.