Biotech Daily

Friday September 25, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 14%; TISSUE THERAPIES DOWN 11%**

*** ALCHEMIA SELLS LAST ASSET FONDAPARINUX TO DR REDDY'S FOR $24m**

*** OPTISCAN: 'EXTENDED CARL ZEISS DEAL WORTH $3m'**

*** CORRECTION: CLINUVEL**

*** UNILIFE, NOVARTIS EXPAND INJECTABLE DRUG DELIVERY DEAL**

*** QUEENSLAND, J&J INNOVATION $300k QUICK FIRE CHALLENGE**

*** INNATE ADDS 9 PATIENTS TO MIS416 COMPASSIONATE USE PROGRAM**

*** MEDIBIO SIGNS VITAL CONVERSATIONS FOR CARDIAC STRESS TEST**

*** CAPITAL GROUP BELOW 5% OF GI DYNAMICS**

MARKET REPORT

The Australian stock market fell 0.58 percent on Friday September 25, 2015 with the ASX200 down 29.6 points to 5,042.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and three were untraded.

Optiscan was the best, up 0.6 cents or 13.6 percent to five cents with 408,052 shares traded, followed by Orthocell up 11.6 percent to 72 cents with 560,648 shares traded.

Atcor and Living Cell climbed more than eight percent; Anteo was up 7.7 percent; Oncosil rose 6.7 percent; Actinogen was up 4.2 percent; Nanosonics and Resmed were up more than two percent; Acrux, Neuren and Prima were up more than one percent; with Cochlear and Impedimed up by less than one percent.

Tissue Therapies led the falls, down 0.5 cents or 10.6 percent to 4.2 cents with 292,166 shares traded.

Antisense lost 6.2 percent; Medical Developments was down 5.75 percent; Benitec and Pharmaxis fell more than four percent; Cellmid was down 3.3 percent; IDT and Starpharma shed more than two percent; Avita, Bionomics, Clinuvel, Compumedics, Mesoblast and Universal Biosensors were down one percent or more; with CSL, Sirtex and Viralytics down by less than one percent.

ALCHEMIA

Alchemia says it will sell the global rights to its fondaparinux generic heparin to distribution partner Dr Reddy's Laboratories for $US17.5 million ($A24.3 million).

In 2011, Alchemia jumped 40 percent to 86 cents on the US Food and Drug Administration approval of fondaparinux with then chief executive officer Dr Pete Smith saying the drug would deliver “tens of millions of dollars per year” to the company once the sales were “up to speed” (BD: Jul 13, 2011).

Shortly after fondaparinux was registered, Alchemia fell 44.55 percent to 28 cents on news that Canada’s Apotex had launched an authorized generic version of Glaxosmithkline’s Arixtra which was approved for the treatment of deep vein thrombosis and pulmonary embolism and the prevention of deep vein thrombosis after major surgery, such as knee and hip replacement (BD: Aug 9, 2011).

Alchemia was hit again last year when its hyaluronic acid version of irinotecan failed to meet the primary endpoint in its 415-patient phase III metastatic colorectal cancer trial (BD: Oct 10, 27, 2014).

In May, Alchemia fell to 3.5 cents on lower than expected revenue from fondaparinux sales and a dispute with Dr Reddy’s (BD: May 29, 2015).

Alchemia earned $9.6 million in profit share from Dr Reddy’s for the year to June 30, 2013, $8.01 million for the year to June 30, 2014 and $5.6 million for the 12 months to June 30, 2015 (BD: Aug 20, 2013; Aug 29, 2014; Aug 28, 2015).

In June, following an investment by the Sydney-based Sandon Capital, Alchemia said that chairman Santo Costa and director Dr Susan Kelley had resigned, with Tim Hughes appointed chairman and directors Dr Tracie Ramsdale and Nathan Drona continuing, with “significant pay cuts”, and all assets other than fondaparinux to be sold (BD: Jun 10, 2015).

In June, Sandon requested a meeting to replace directors Tim Hughes and Dr Tracie Ramsdale with Dinimus Capital principal Ken Poutakidis and Sandon Capital founder and managing director Gabriel Radzyminski and one week later the company appointed Mr Poutakidis as a director and in July Mr Poutakidis replaced Mr Hughes as the chairman (BD: Jun 18, 26; Jul 10, 2015).

In July, Alchemia said that Panther would buy its oncology assets including the Hyact platform for cash and stock worth more than $US16 million but by August that transaction was behind schedule in (BD: Jul 1, Aug 3, 2015).

Also in July, Vast Bioscience acquired Alchemia’s versatile assembly on stable templates (VAST) drug discovery platform for $100,000 upfront and royalties, and chairman Prof Peter Andrews told Biotech Daily that he was one of the VAST patent holders as well as a founder and former chairman of Alchemia (BD: Jul 3, 2015).

Today, Alchemia said it had a binding term sheet “for the sale of the worldwide exclusive intellectual property rights to fondaparinux sodium, its generic anti-coagulant drug” to Dr Reddy’s Laboratories, pending shareholder approval.

The company said that in 2007 it granted Dr Reddy’s non-exclusive rights to the manufacture of fondaparinux sodium in active pharmaceutical ingredient form and exclusive rights to market fondaparinux in the North America, in exchange for 50 percent of the net profit generated from sales.

Alchemia said that in 2012, it granted Dr Reddy’s exclusive rights to market fondaparinux in all territories, other than North America, in exchange for an agreed share of the net profits generated from sales in those territories.

The company said that fondaparinux was being sold in Canada and India, but sales “are yet to generate any profits” and fondaparinux was yet to be launched in any other territory.

Alchemia was up four cents or 114.3 percent to 7.5 cents with 32.4 million shares traded.

OPTISCAN

Optiscan says it has expanded its agreement with Carl Zeiss Meditec for endo-microscopy neurosurgery systems.
Optiscan said that collaboration was well-advanced and focused on addressing as regulatory clearance and design improvements.
In 2012, Carl Zeiss placed its first purchase for $800,000 of Optiscan's endo-microscopy neurosurgery systems (BD: Jun 21, 2012).
Today, Optiscan said Carl Zeiss agreed to new commercial terms, including payments for additional engineering works, joint ownership of the sterility barrier sheath, with Carl Zeiss taking responsibility for regulatory approval and Optiscan to supply further systems.
The company said that Carl Zeiss had agreed to a royalty model which would provide revenues over the lifetime of the product, with Optiscan retaining all sheath rights outside of the Carl Zeiss fields of application.
Optiscan said that Carl Zeiss would assume responsibilities that will relieve it of costs of about $750,000 relating to regulatory and legal issues.
The company said that the new arrangements were expected to generate cash flows for both the supply of services and instruments of more than $2.2 million by the end of 2016, which, when combined with the costs savings would result in a net cash benefit of $3 million over that period.
Optiscan said that a final licence payment of $160,000 would be paid later in the project, with the consequence that control of the timing of some of the remaining processes would pass to Carl Zeiss.
Optiscan executive director Peter Delaney said the company was "very pleased to have enhanced the collaboration agreement with our partner Carl Zeiss Meditec and see this as an important milestone, setting the course for possible commercial supply".
Optiscan was up 0.6 cents or 13.6 percent to five cents.

CORRECTION: CLINUVEL

Last night's edition incorrectly headlined that Clinuvel was up eight percent. The following Market Report was correct that Clinuvel was up 16.4 percent.
The sub-editor has departed and is looking for work in the Federal Electoral Division of North Sydney.

UNILIFE CORPORATION

Unilife says it has amended a supply agreement signed with Novartis in December 2013 to supply injectable drug delivery systems for use with an early-stage drug.
Unilife said it would supply Novartis with additional batches of its customized delivery device to enable administration of a novel investigational Novartis drug into a targeted organ during an on-going clinical drug trial.
The company said it had granted Novartis an option for exclusivity and it would generate revenue on the basis of the clinical product supplies.
Unilife said that both parties expected the collaboration would continue to support the clinical development and anticipated approval of the novel therapy, which was targeting a high prevalence disease where no pharmacological treatments were currently available.
Unilife chief medical officer Dr Rick Beckman said the Novartis collaboration "requires a high-precision delivery system to enable its accurate administration to the target organ".
The company said that the terms of the agreement were confidential.
Unilife was up 1.5 cents or seven percent to 23 cents with 2.1 million shares traded.

QUEENSLAND GOVERNMENT, JOHNSON & JOHNSON

The Queensland Government says with Johnson & Johnson Innovation it will provide $300,000 in prizes for “game-changing health innovations”.

Queensland Science and Innovation Minister Leeanne Enoch said her Government would provide $300,000 for the Advance Queensland Johnson & Johnson Innovation Quick Fire Challenge, to find projects to be developed and commercialized in Queensland.

“This is a global prize so we are looking for great ideas from across the world,” Ms Enoch said.

“It is part of the $180 million Advance Queensland initiative to create jobs now and for the future, drive productivity improvements, harness innovation and translate some of our great ideas into real economic outcomes for Queenslanders,” Ms Enoch said.

“We’re looking for exceptional innovations; ones with a real chance of being turned into investible products, with benefits for patients and that will create future jobs and business opportunities,” Ms Enoch said.

“There are three $100,000 prizes for innovations in the fields of pharmaceuticals, medical devices and diagnostics, and consumer healthcare,” Ms Enoch said.

A Queensland Department of Science and Innovation media release said that Johnson & Johnson Innovation and the Queensland Government would jointly assess the applications and the winners would be announced in 2016 at the opening of a new Johnson & Johnson Innovation Partnering Office at Queensland University of Technology.

“The winners will have to spend their prize money here in Queensland on direct research and commercialisation services, bringing direct benefits back to Queensland’s economy,” Ms Enoch said.

“Through this partnership, shortlisted applicants will also receive mentoring and coaching by Johnson & Johnson Innovation, which in itself is invaluable,” Ms Enoch said.

Johnson & Johnson Janssen-Cilag managing-director Chris Hourigan said that the challenge was “intended to inspire researchers and entrepreneurs globally to further develop transformational science to deliver novel healthcare solutions and to develop these innovations in Queensland”.

“By encouraging the progress of transformational science we can continue to advance cures for unmet medical needs across the world, a key mission of Johnson & Johnson,” Mr Hourigan said.

Johnson & Johnson Innovation director of new ventures Kathy Connell said the Asia Pacific Innovation Centre and Johnson & Johnson Innovation’s research organisations “look forward to collaborating with these researchers and entrepreneurs in our efforts to spur innovation through collaboration”.

The media release said that the Johnson & Johnson Innovation Partnering Office was the product of an agreement between Johnson & Johnson Innovation, Queensland university of Technology and the Queensland Government, to facilitate access by Queensland researchers and companies to the resources and expertise across Johnson & Johnson’s scientific research, investor and commercial business sectors with the aim of nurturing and accelerating Queensland’s life sciences ecosystem.

The Queensland Government said that the Advance Queensland Future Jobs Strategy would “build a culture of collaboration between research bodies and business to translate ideas and research into products, processes, service outcomes and jobs in Queensland”.

To enter the Advance Queensland Johnson & Johnson Innovation Quick Fire Challenge or for more information go to: www.advancequeensland.quickfirechallenge.com.

Applications close on November 30, 2015.

INNATE IMMUNOTHERAPEUTICS

Innate says it has 27 New Zealand patients using MIS416 for secondary progressive multiple sclerosis on a compassionate access scheme.

In May, Innate reported that it had 18 patients accessing the scheme (BD: May 20, 2015).

Today, Innate said that the first patient to be treated with MIS416 on compassionate grounds would “celebrate eight years of on-going treatment next month” having received the first dose of MIS416 in October 2008, was on continuous therapy and continuously reported apparent treatment-related benefits.

Innate said that in New Zealand compassionate use arose when a patient did not have effective treatment options and gave consent to their doctor to request access to, and treatment with, an unapproved experimental medicine.

The company said that of the 27 patients, 15 patients were continuing to receive MIS416 either once weekly or fortnightly, with six patients stopping treatment due to a lack of any apparent benefit and six stopping “for a variety of personal reasons”.

The company said the 21 patients who reported benefits while on MIS416 said they had reductions in pain, fatigue, mental confusion and improvements in bladder control, visual acuity, cognition and coordination.

Innate said that not all patients with secondary progressive multiple sclerosis had the same signs and symptoms and not all compassionate use patients reported the same benefits where benefits were reported.

Innate medical adviser Dr Michael Silverman said there was “significant value emerging from this compassionate treatment experience from the standpoint of longitudinal safety data … [and] based on the regular reports we are receiving from the patient's doctors, we are not detecting any novel or cumulative safety signals, which is reassuring from a clinical development standpoint”.

Innate chief executive officer Simon Wilkinson said that safety information was straightforward to collect, but information about treatment benefits was more challenging because the impact of the disease was variable from patient to patient.

Mr Wilkinson said that there were no simple blood tests or brain scans available to either diagnose secondary progressive multiple sclerosis or to monitor the effects of treatment on the disease and many of the worst effects of the disease from the patient's perspective, were effects that significantly interfered with the activities of daily living and were difficult to measure in a clinical or objective manner outside the context of a prospective, carefully structured clinical trial.

Innate said that compassionate use patients reported on treatment effect using a standard questionnaire, the ‘Brief Pain Inventory’ and the ‘Neurological Fatigue Index’.

The company said that 13 of the 15 patients regularly completing the questionnaire met or exceeded the clinically meaningful improvement threshold in three or more of the eight domains; data from the Inventory showed that all five on-going patients completing the Inventory reported a reduction in pain; three of the five on-going patients completing the Index reported a reduction in fatigue; and four of the five on-going patients demonstrated an improvement in two separate cognition assessments.

Innate said it was important to note that the above data sets were very small and had no statistical significance, there was no placebo control group and the analysis had not been subjected to peer review.

A 90-patient, phase IIb, placebo controlled, double blinded efficacy and safety trial was underway in Australia and New Zealand, with 56 patients enrolled or in late stage screening.

Innate was unchanged at 16.5 cents.

MEDIBIO

Medibio says it has launched its “corporate wellness partner program” with an agreement to provide its cardiac corporate stress product to Vital Conversations.
Medibio said that the Perth Western Australia-based Vital Conversations was “a large mental wellness provider …with a diverse client base”.
The Vital Conversations website describes its staff as psychologists and coaches and says it specializes in psychology, coaching, organisational development, profiling and leadership.
Medibio said that Vital Conversations provided “proactive psychological health services to some of the largest corporates in Western Australia as well as the public and not for profit sectors”.
Medibio said that its cardiac rhythm-based corporate stress product was “the first objective test to measure the level of stress and its impact on health and wellbeing” and included a series of mobile telephone application-based intervention or treatment modules “tailored specifically for the employee’s stress level”.
The company said that Vital Conversations would offer its corporate stress product to its executive and private customers and would seek to roll-out the product to corporate and public sector clients on a pilot basis.
Medibio said that Vital Conversations would be responsible for the acquisition of the electrocardiogram (ECG) monitors, any other hardware and the implementation of the test to its client base, with Medibio providing data analytics and reporting and to be paid on a per test basis.
The company said that the terms of the agreement were confidential, but the majority of the roll-out would begin in 2016 with some revenue this year.
Medibio chief executive officer Kris Knauer said the first partnership “with a corporate wellness provider … is our preferred route to market”.
Medibio was up one cent or 2.2 percent to 47 cents.

GI DYNAMICS

The Los Angeles, California-based Capital Group Companies says it has ceased its substantial holding in GI Dynamics.
Last year, the Capital Group became substantial in GI Dynamics with 43,140,000 Chess depositary interests (9.25%) buying the CDIs at an average price of 52 cents per CDI, the same price as the May placement (BD: May 2, 13, 2014).
The Capital Group provided no further information on the shareholding reduction.
GI Dynamics was up 0.4 cents or 12.9 percent to 3.5 cents with 6.1 million shares traded.