Biotech Daily

Thursday October 13, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VIRALYTICS UP 12%; PSIVIDA DOWN 7%**
- LBT UP 300% IN FOUR DAYS

*** CYCLOPHARM COMPLETES STAGE 1 OF TECHNEGAS FDA PROCESS**

*** STARPHARMA PHASE III VIVAGEL BV TRIALS ENROLLED**

*** RESONANCE MEASURES LIVER, PANCREATIC FAT IN DIABETES STUDY**

*** FDA SETS NOVEMBER 7 FOR CLINUVEL PRE-NDA MEETING**

*** CRESO PHARMA $5m IPO FOR MARIJUANA FOOD ADDITIVES**

*** USPTO GRANTS OBJ SKINCARE, ORAL CARE PATENTS**

*** INNOVATION AND SCIENCE AUSTRALIA BILL PASSES PARLIAMENT**

*** IMPEDIMED 2nd STRIKE, 635k 'PERFORMANCE' RIGHTS, 1.2m OPTIONS AGM**

*** MEMPHASYS RECEIVES $497k FEDERAL R&D TAX INCENTIVE**

*** ALLAN GRAY INCREASES, DILUTED TO 13% OF IMPEDIMED**

*** VINTAGE QUITS PROBIOTEC**

MARKET REPORT

The Australian stock market fell 0.71 percent on Thursday October 13, 2016 with the ASX200 down 39.1 points to 5,435.5 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and two were untraded. All three Big Caps fell.

Viralytics was the best for the second day in a row, up 13.5 cents or 12.05 percent to $1.255 with 1.8 million shares traded. Anteo climbed 5.9 percent; Impedimed and Neuren improved more than four percent; Living Cell and Polynovo were up more than three percent; Cyclopharm, Mesoblast and Orthocell rose more than two percent; Bionomics was up 1.2 percent; with Reva up 0.8 percent. Just outside the BDI-40, LBT was up 18 cents or 31.0 percent to 76 cents, a 300.0 percent rise since Monday's FDA approval.

Psivida led the falls, down 24 cents or 6.9 percent to $3.26, with 1,541 shares traded. Universal Biosensors lost 5.6 percent; Acrux, Avita and IDT fell more than four percent; Atcor shed 2.1 percent; Admedus, Clinuvel, Compumedics, CSL, Medical Developments, Osprey, Prana and Uscom were down one percent or more; with Airxpanders, Cochlear, Ellex, Nanosonics, Pro Medicus, Resmed and Sirtex down by less than one percent.

CYCLOPHARM

Cyclopharm says it has completed the first stage of its Technegas regulatory program to determine inter-reader and intra-reader variability for competitor Xenon-133.

Cyclopharm said that Xenon-133 was the only US Food and Drug Administration approved nuclear medicine ventilation imaging agent and the CYC-010 clinical trial program was “essential in establishing the number of patients required for the next stage in the clinical trial program”.

The company said that it would submit a phase III non-inferiority structural ventilation protocol to the FDA, comparing Xenon-133 with Cyclopharm’s Technegas in 240 patients by October 17, 2016 designated as CYC-009.

Cyclopharm said that the CYC-009 protocol had been completed and was being formatted for submission under a special protocol assessment (SPA) regime, with an FDA response expected within 45 days from lodgement and the CYC-009 trial to begin by July 2017.

The company said it expected to complete the clinical trial program by mid-2018 at a total cost of less than $US7 million ($A9.3 million).

Cyclopharm said that Technegas was sold in 55 countries, excluding the US, which had half the world’s nuclear medicine departments were located, so FDA approval would be “a significant opportunity … to materially expand its sales and profitability”.

The company said the International Atomic Energy Agency had reviewed emerging technologies in the production and supply of Molybdenum-99, the precursor to Technetium-99, which was used in more than 80 percent of nuclear medicine studies.

Cyclopharm said that its Ultralute technology was recognized for its optimization of the Technetium-99 isotope and the IAEA formally invited the company to collaborate in launching a multi-country, multi-centre evaluation of Ultralute in early 2017, which was a “significant recognition for the technology’s potential”.

The company said that Ultralute was scheduled for commercial launch by July 2017.

Cyclopharm said that with the University of Newcastle and through the Hunter Medical Research Institute and John Hunter Hospital it would conduct a pilot clinical trial to assess small airway dysfunction using Technegas functional lung ventilation imaging to identify treatable traits related to obstructive airway disease.

The company said the study would test two hypotheses: that there was ventilation heterogeneity among patients with severe obstructive airway diseases that could be assessed using Technegas functional lung ventilation imaging with quantification; and Technegas functional lung ventilation imaging with quantification was responsive to change following intervention in patients with severe obstructive airway diseases.

Cyclopharm said that the implication in advancing the hypotheses could expand the use of Technegas by improving the diagnosis and management of patients with chronic obstructive pulmonary disease, the fourth leading cause of death worldwide.

The company said that it expected the study’s protocol to be finished by mid-November 2016 with patient recruitment initiating in early 2017, taking two years to be completed and costing about $500,000.

Cyclopharm said that after 25 years of continuous operations at the Lucas Heights facility it would move to “a new state-of-the-art manufacturing facility” in Sydney’s south-west in the suburb of Kingsgrove in November 2016.

The company said that the new facility was designed for the growing demand for products and the expected US FDA Technegas approval in mid-2018, with the fit-out and relocation costing about $1.4 million, capitalised and amortised over 10 years.

Cyclopharm was up three cents or 2.65 percent to $1.16 with 850 shares traded.

STARPHARMA HOLDINGS

Starpharma says it has completed enrolment of about 1260 patients in its two pivotal phase III trials of Vivagel for prevention of recurrent bacterial vaginosis.

In 2014, Starpharma said the two 600-patient, phase III, double-blind, randomized, placebo-controlled trials would be identical in design comparing the rate of bacterial vaginosis recurrence in women using Vivagel to placebo gel over 16 weeks of treatment (BD: Jul 14, 2014).

In 2013, Starpharma said a phase II trial of Vivagel for the prevention of recurrence of bacterial vaginosis failed to meet its primary endpoint with a “clinically” but not statistically significant difference between Vivagel and placebo (BD: Apr 3,4, 2013).

In 2012, Vivagel failed to meet its phase III trial primary endpoint for a clinical cure of bacterial vaginosis (BD: Nov 28, 29, 2012).

Starpharma said that Vivagel, or SPL7013 astodrimer sodium, was a non-antibiotic vaginally-applied gel for prevention of bacterial vaginosis recurrence.

Today, Starpharma said the trials were being conducted in the US, Canada, Mexico, Europe and Asia with completion expected by April 2017 and top-line results by July 2017.

Starpharma said it had a “binding agreement” with the US Food and Drug Administration on the trial design including the primary endpoint, through a special protocol assessment.

The company said that the primary objective was “to demonstrate that the rate of [bacterial vaginosis] recurrence in women using Vivagel BV [was] lower than the rate of [bacterial vaginosis] recurrence in women using a placebo gel during the 16-week treatment period”.

Starpharma said that after treatment, there was a 12-week follow-up which would assess secondary endpoints including safety.

Starpharma chief executive officer Dr Jackie Fairley said the company was “delighted to have achieved full enrolment of our pivotal phase III trials for this indication and look forward to trial completion early next year”.

“There are no approved products for this indication, so we have an opportunity to be first in class with Vivagel BV for the prevention of [bacterial vaginosis] recurrence,” Dr Fairley said. “This important differentiating factor is a significant commercial advantage recognized by potential partners,” Dr Fairley said.

“There is significant unmet medical need for this chronic condition, where the global market is estimated to be worth around $1 billion annually,” Dr Fairley said.

Starpharma said it had developed Vivagel BV for bacterial vaginosis treatment separate to the prevention of recurrence indication and it was approved in Europe for the treatment of bacterial vaginosis, including relief of symptoms, and was well-advanced in regulatory review in other markets.

The company said that the US FDA recently issued a new draft clinical guidance for the development of products for bacterial vaginosis treatment.

Starpharma said that the new guidance recommended the assessment of the primary endpoint for efficacy in treatment studies be soon after cessation of treatment that is the end of treatment: day seven to 14 days post-randomization and not two to three weeks after treatment was ceased, which was the required timing previously.

The company said the FDA change was “particularly important as the … revised end of treatment time point is consistent with Starpharma’s 2012 phase III results for Vivagel BV for treatment of [bacterial vaginosis], which showed, in both studies, highly statistically significant clinical cure of [bacterial vaginosis] at the end of treatment time point”.

Starpharma said it had licenced Vivagel BV to Aspen Pharmacare for Australia and New Zealand and was in negotiations for other regions, including Europe.

Starpharma was unchanged at 61 cents.

RESONANCE HEALTH

Resonance says it will measure liver and pancreatic fat in a University of Leicester study on diabetic cardiomyopathy in young adults.
Resonance said that the UK National Health Service-funded 'Diastolic' was led by the University of Leicester's Prof Gerry McCann and expected to enrol 100 patients over 18-months to determine if diet and/or exercise could improve cardiovascular dysfunction in young adults under 40 years of age diagnosed with diabetes.
The company said it would provide quantitative fat measurements for both the liver and pancreas to monitor how fat changes in response to diet and exercise.
Resonance said that a number of patients had received their baseline magnetic resonance imaging (MRI) scans and this would provide further data for potential validation of Resonance Health's technologies.
The company said there had been a rapid rise in obesity-related type II diabetes, which affected about 380 million people and this had led to an increased prevalence of diabetic cardiomyopathy in younger people, a serious complication that is estimated to reduce life expectancy by about 15 years.
Resonance said that the University of Leicester Hospital had used its Ferriscan in routine clinical practice for a number of years and had established Hepafat-Scan recently for clinical use in addition to use for research in the Diastolic study.
Resonance general-manager Sander Bangma said that the inclusion of a validated technology such as Hepafat-Scan for quantitative measurement of volumetric liver fat with pancreatic fat assessment, "aims to provide further data to inform risk thresholds for these patients and monitor response to lifestyle changes or treatment".
Resonance said the study was expected to be completed in early 2018.
Resonance fell 0.1 cents or 3.6 percent to 2.7 cents.

CLINUVEL

Clinuvel says it will have a pre-new drug application meeting with the US Food and Drug Administration on November 7, 2016.
Clinuvel said the meeting with the FDA's Division of Dermatology and Dental Products would "focus on the contents of the scientific dossier for Scenesse (NDA) with the aim of gaining FDA approval to treat US patients diagnosed with the rare genetic disorder [erythropoietic protoporphyria]".
The company said that Scenesse had been granted fast track and orphan drug designation by the FDA and in 2014 it obtained marketing authorisation for the treatment of erythropoietic protoporphyria (EPP) for Scenesse from the European Medicines Agency and it was being prescribed in a number of European countries.
The company said that it expected the FDA meeting would agree on the timing of the new drug application filing and the establishment of risk evaluation and mitigation strategies to ensure the safety and long term follow up of US patients, as well as chemistry, manufacturing and controls, non-clinical, the clinical effectiveness and safety sections of the company's planned application for Scenesse.
Clinuvel said the FDA would host an October 24, 2016 workshop on EPP to obtain patients' and physicians' perspective on the disease, its impact on daily life, and their experiences with current treatment to assist the FDA during the review process.
The company said that under the fast track designation the FDA could review individual modules of a submission on a rolling basis and it expected to file the first part of its scientific dossier in 2017.
Clinuvel fell nine cents or 1.3 percent to $6.71.

CRESO PHARMA

Creso says it hopes to raise $5,000,000 at 20 cents a share to list on the ASX to develop marijuana-based food additive products for human and animal health.
The Perth, Western Australia-based Creso Pharma is the fourth company to list on the ASX to develop medical marijuana following MMJ Phytotech, Medlab Clinical and MGC (BD: Jan 22, Mar 4, May 12, Jul 13, 15, 2015).
Two other companies, Auscann and Zelda, have also said they intend to raise funds to develop medical marijuana (BD: May 9, Aug 24, 2016).
Creso company secretary Sarah Smith told Biotech Daily that the company hoped to list on the ASX under the code CPH "within the next week".
The company's website said that its strategy was "to develop, register, and commercialize pharmaceutical-grade cannabis- and hemp-based products and treatments, to the highest [good manufacturing practice] quality standards".
Creso said the global cannabis market would reach $US50 billion in the US and $US200 billion globally by 2018 and the "nutraceutical" or food additive market was estimated to reach $US204.80 billion between 2015 and 2020.
Creso said that the cannabis and nutraceutical market had experienced rapid growth in the past few years, with key catalysts the use of non-psychoactive and non-synthetic botanic full-plant derived therapeutics for a growing and aging human and pet population.
Creso said it was "focused on growing hemp and developing and producing [cannabinoid] extracts for use in its own products as well as other third-party owned products".
Creso's prospectus said that the executive chairman was Boaz Wachtel, Phytotech's chief executive officer prior to the merger with MMJ (BD: Jan 22, Aug 20, 2015).
The company said that the directors included managing-director Dr Miriam Halperin Wernli, Adam Blumenthal, Dr James Ellingford and Dr Simon Buckingham.
The prospectus said that the lead manager was Everblu Capital.

OBJ

OBJ says the US Patent and Trademark Office has granted two patents relating to its magnetic microarray technology for use in skincare and oral healthcare.
OBJ told Biotech Daily the two patents were entitled 'Delivery of oral care products' and 'Delivery of skin care products' and provided coverage until December 2031.
According to the USPTO website, OBJ executive director Jeffrey Edwards is the inventor of both patents.
The USPTO said that the patents were a method for the delivery of an oral care active and a skin care active agent "comprising the following step: applying an active agent(s) between a target oral biological [or dermal] barrier and a magnetic device comprising one or more pairs of displaced dipolar magnetic elements linked by a magnetic return wherein the magnetic return is orientated on the surfaces of the dipole pair distal to the biological [or dermal] barrier".
OBJ said that the granting of the patents in the US for the use of magnetic microarrays in skincare and oral healthcare applications provided the ability to offer patent protected market exclusivity in the world's largest market.
The company said it was prosecuting the same patent applications in Europe.
OBJ chairman Glyn Denison said that "for our major partners, protection in the world's largest, single skincare market is very important from a strategic perspective".
"It provides our partners with the ability to create unique products that they can confidently invest in," Mr Denison said.
OBJ fell half a cent or 6.5 percent to 7.2 cents with 8.4 million shares traded.

FEDERAL GOVERNMENT

Minister for Industry, Innovation and Science Greg Hunt says Parliament has passed the Industry Research and Development (Innovation and Science Australia) Bill 2016.
A Parliament of Australia official told Biotech Daily that the Bill would become an Act when it received Royal Assent from the Governor-General which was expected soon.
A media release from Mr Hunt said that the Bill would cement innovation and science "at the heart of our long-term plan to secure Australia's future economic prosperity".
The media release said that the Bill established in legislation the Innovation and Science Australia organization "charged with helping the Government complete the three waves of the National Innovation and Science Agenda".
The media release said that the organization was chaired by Bill Ferris, with chief scientist Dr Alan Finkel as deputy chair and the ISA board represented "innovators, scientists and entrepreneurs with track records of success".
The Federal Government said that Innovation and Science Australia would work across government, providing guidance "around our $10.1 billion investment in 2016-'17 in innovation, science and research … [and would] promote investment in industry, innovation, science and research in Australia, including showcasing successful innovators, entrepreneurs and researchers.
The media release said that Innovation and Science Australia would engage business and community sectors to improve the overall performance of the national innovation and science system.

IMPEDIMED

Impedimed says it will face a potential annual general meeting spill resolution, following more than 25 percent opposition to last year's remuneration reports.
Last year, Impedimed earned a remuneration report first strike with the annual general meeting voting 30,760,032 votes (25.1%) against the report and 91,846,039 votes (74.9%) in favor (BD: Oct 29, 2015).
The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.
Any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.
If the spill vote fails, the trigger is reset to no strikes.
The company said last year that 29,342,125 votes (25.9%) opposed the grant of 512,500 options to chief executive officer Richard Carreon with less than one percent of votes opposing the 33 percent increase in the non-executive directors' remuneration to $800,000.
Today, Impedimed said it proposed to issue Mr Carreon a further 470,000 'performance rights and 872,000 options, with 165,000 performance rights for former director, now executive, David Adams along with 335,000 options.
The company said that it would ask shareholders to remove 50 cent and 70 cent share price conditions from 7,252,561 options previously issued to Mr Carreon and vote on the election of directors Scott Ward, Elizabeth Gaines and Gary Goetzke.
The meeting will be held at the Four Seasons Hotel, 199 George Street, Sydney on November 14, 2016 at 10am (AEDT).
Impedimed was up 7.5 cents or five percent to $1.58 with one million shares traded.

MEMPHASYS (FORMERLY NUSEP)

Memphasys says it has received $497,355 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Memphasys said that the funds would be used “to further develop its Spermsep business and for working capital”.
Memphasys was untraded at 0.6 cents.

IMPEDIMED

Allan Gray Australia has further increased its substantial holding in Impedimed but has been diluted from 48,791,564 shares (14.44%) to 50,304,651 shares (13.44%).
Allan Gray said that it bought and sold shares between March 15 and October 10, 2016, with the single largest acquisition 1,305,882 shares for $1,227,445 or 94 cents a share and the single largest sale 1,083,926 shares for $1,831,943 or $1.69 a share.

PROBIOTEC

The Neutral Bay, Sydney-based Vintage Capital says it has sold all of its 4,500,000 shares in Probiotec.
In 2012, Vintage Capital said it acquired 1,452,519 shares between 2008 and 2012 at prices ranging from $2.49 to 24.5 cents a share (BD: Jun 22, 2012).
Today, Vintage said it bought a further 100,000 shares for $25,050 or 25 cents a share in July 2012 and December 2014, and sold all 4,500,000 shares between August 26 and October 12, 2016 for $3,503,240 or 77.8 cents a share.
Probiotec was up eight cents or 16.2 percent to 57.5 cents.