Biotech Daily

Monday September 28, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 15%; OPTISCAN DOWN 10%**

*** VIRALYTICS: '5 OF 12 PFS IN CAVATAK MELANOMA EXTENSION TRIAL'**

*** VIRALYTICS BEGINS CAVATAK KEYTRUDA MELANOMA TRIAL**

*** MUNDIPHARMA PAYS MEDICAL DEVELOPMENTS $10m**

*** GI DYNAMICS: 'GERMAN DIABETES SOCIETY BACKS ENDOBARRIER'**

*** PHOSPHAGENICS BEGINS TPM PIGLET NUTRITION TRIAL**

*** ANALYTICA HIRES SALESFORCE4HIRE FOR US SALES, 52m OPTIONS**

*** SIRTEX AGM FOR $1.5m, 46k CEO 'PERFORMANCE RIGHTS'**

*** UBS AG TAKES 9% OF GI DYNAMICS AT ½¢ A SHARE**

*** PROBIOTEC SELLS PROTEIN PLANT TO BESTON PURE DAIRIES FOR $7m**

*** POLYNOVO REQUESTS 'TRIAL FUNDING CONTRACT' TRADING HALT**

*** ACTINOGEN REQUESTS 'CSF STUDY RESULTS' TRADING HALT**

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

MARKET REPORT

The Australian stock market climbed 1.42 percent on Monday September 28, 2015 with the ASX200 up 71.4 points to 5,113.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and four were untraded.

Prima was the best, up 0.8 cents or 14.6 percent to 6.3 cents with 7.2 million shares traded, followed by Cellmid up 10.3 percent to 3.2 cents with 2.3 million shares traded. Starpharma climbed 9.3 percent; Biotron was up 8.25 percent; Benitec was up 7.3 percent; Avita and Viralytics rose more than six percent; Ellex was up 5.3 percent; Medical Developments, Osprey and Reva were up more than three percent; Tissue Therapies rose 2.4 percent; with Antisense and Mesoblast up more than one percent.

Friday's best, Optiscan led the falls, down 0.5 cents or 10 percent to 4.5 cents with 453,721 shares traded. Admedus, Prana and Uscom lost more than seven percent; IDT was down 6.25 percent; Anteo fell 5.1 percent; Orthocell fell 4.9 percent; Bionomics and Oncosil were down more than three percent; with Living Cell, Resmed and Universal Biosensors shedding more than two percent.

VIRALYTICS

Viralytics says that four or 13 advanced melanoma (Calm) extension trial patients achieved an objective response to Cavatak (BD: Apr 21, 2015).

Viralytics said that data was presented by lead investigator and Utah-based Huntsman Cancer Institute Prof Robert Andtbacka at the European Cancer Congress in Vienna, September 25 to 29, 2015, and showed that five of 12 patients treated with Cavatak, or Coxsackievirus A21, achieved immune-related progression free survival at six months.

The company said that biopsies were taken from melanoma lesions of the 13 advanced melanoma patients prior to and after Cavatak administration and along with the objective response, there were “tumor responses in patients that had failed prior immunotherapies including the checkpoint inhibitors, ipilimumab and pembrolizumab”.

The company said that Cavatak treatment “mediated positive changes within the tumor micro-environment by inducing increases in immune response genes, immune cell infiltrates and expression of PD-L1” or programmed death ligand-1.

“The observation of Cavatak-induced immune cell infiltration within the tumour, combined with the encouraging results seen in the Calm trial, point to Cavatak as an investigational agent with real promise in combination with checkpoint inhibitors such as anti-CTLA-4 ipilimumab and/or anti-PD-1 pembrolizumab,” Prof Andtbacka said. “Cavatak treatment may have potential application in a rescue strategy to reconstitute the immune cells within the tumor microenvironment of lesions resistant to immune checkpoint inhibitors.”

Viralytics climbed 3.5 cents or 6.2 percent to 60 cents.

VIRALYTICS

Viralytics says it has begun a 30 patient phase Ib trial of Cavatak with the checkpoint inhibitor Keytruda, or pembrolizumab, in late-stage melanoma patients.

Viralytics said the open-label study would evaluate the safety and tolerability of Cavatak in combination with Keytruda, as well as evidence of anticancer activity, including response rates and bio-markers of anti-tumor immunity.

The company said that the lead investigator was Rutgers Cancer Institute of New Jersey’s Dr Howard Kaufman who was also an investigator in the phase II Calm trial assessing Cavatak as a monotherapy in late-stage melanoma patients.

“Based on the positive results of the Calm trial, including data from the Calm extension study showing Cavatak’s ability to increase the number of cancer-fighting immune cells present in tumor tissue, I am eager to explore the combination of Cavatak and Keytruda in human trials,” Dr Kaufman said.

“Although Keytruda and other checkpoint inhibitors represent a major advance in the treatment of melanoma, there is great interest in the potential of oncolytic viruses such as Cavatak to improve upon these outcomes in patients with melanoma,” Dr Kaufman said.

Viralytics managing-director Dr Malcolm McColl said that preclinical studies provided “encouragement that this combination may produce superior efficacy outcomes”.

“Along with our [melanoma intra-tumoral Cavatak and ipilimumab] clinical trial, initiated earlier this year to assess Cavatak given along with ipilimumab, this study will provide valuable data about Cavatak’s potential as part of an immunotherapy combination strategy against major cancers,” Dr McColl said.

Viralytics said the cavatak and pembrolizumab in advanced melanoma (Capra) study would use Cavatak administered intra-tumorally in combination with Keytruda, with Cavatak be injected on days one, three, five and eight, and then at three-weekly intervals, up to a maximum of 19 total injections, with intravenous pembrolizumab (2mg/kg) starting on day eight and continuing every three weeks for up to two years.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it received about $10 million from Mundipharma under the European distribution deal for its Penthrox inhaled methoxyflurane analgesic.
Earlier this month, Medical Developments said that the Cambridge, UK-based Mundipharma would pay up to $US54.5 million ($A76.9 million) for the exclusive rights to Penthrox in 39 European countries, with a $US7 million ($A9.8 million) payment on signing and $US10 million ($A14.1 million) for marketing approvals and first re-imbursed sales of Penthrox for the emergency treatment of pain (BD: Sep 14, 2015).
Medical Developments chief executive officer John Sharman said the company was “debt free and expects to generate strong cash flow from operations this financial year”.
Medical Developments was up 11 cents or 3.35 percent to $3.39.

GI DYNAMICS

GI Dynamics says that the German Diabetes Society has published a statement on the termination of the Endo US pivotal study, supporting the use of Endobarrier.
GI Dynamics said that the statement balanced background for the termination of the US Food and Drug Administration study of the Endobarrier for obesity and type 2 diabetes and the preliminary results with the experiences and data observed in Germany.
The company said that based on a review of Endo study data at August 1, 2015, a significant ($p = 0.008$) reduction in HbA1c by 1.11 percentage points from a baseline of 8.8 percent was observed in the intervention group after 12 months.
GI Dynamics said the HbA1c reduction recorded in the German national register was 1.72 percentage points from a baseline of 8.6 percent HbA1c.
The company said that the German Diabetes Society statement maintained support for hospitals and physicians to offer Endobarrier therapy as a beneficial treatment option to obese patients who have uncontrolled type 2 diabetes.
In July, GI Dynamics closed its 500-patient US trial of the Endobarrier for obesity and type 2 diabetes, due to the higher than expected rate of hepatic abscess, a bacterial infection of the liver (BD: Jul 30, 31, 2015).
GI Dynamics was unchanged at 3.5 cents with 3.0 million shares traded.

PHOSPHAGENICS

Phosphagenics says the start of the first trial of its tocopheryl phosphate mixture (TPM) for piglet nutrition is “a key milestone” for its animal health and nutrition business.
Phosphagenics said the trial would assess the phosphorylated vitamin E feed additive for weaner pigs, measuring weight gain, feed efficiency and other production endpoints.
Phosphagenics chief executive officer Dr Ross Murdoch said it was “very pleasing … to announce the start of this significant trial so soon after the creation of the business unit”.
“This is a significant milestone for Phosphagenics and emphasises our commitment to unlock shareholder value in the short term,” Dr Murdoch said.
“This is the first of a number of near-term trials we are planning to initiate in the animal health and animal nutrition space over the next 12 months,” Dr Murdoch said.
Phosphagenics explored the use of the then Phospha-E with Nestle for the prevention and treatment of “metabolic syndrome” before moving to a phase I trial of TPM-insulin for diabetes (BD: Dec 14, 2006; Dec 17, 2009).
The company later explored the use of TPM for the transdermal delivery of diclofenac (Voltaren) and opioids, as well as with vitamin A for acne.
Phosphagenics was unchanged at 1.4 cents.

ANALYTICA

Analytica says it has a services agreement with Salesforce4hire LLC to increase US sales of its Pericoach intra-vaginal stress urinary incontinence diagnostic system.
Analytica said that the Raleigh, North Carolina-based Salesforce4hire was a wholly owned subsidiary of the private family wealth fund McGeever LLC and would receive a portion of its compensation in performance-based Analytica share options.
The company said that Salesforce4hire provided commercialization assistance for the medical device, diagnostic and healthcare information technology industries and specialized in product launches in the US.
Analytica said that Salesforce4hire would be responsible for sales and marketing of Pericoach in the US, allowing it to focus on market awareness and adoption of the system.
The company said that the agreement would "help drive sales and revenue growth of Pericoach while minimising Analytica's business and financial risk".
Analytica said that in March the US Food and Drug Administration granted 510(k) clearance for Pericoach (BD: Mar 19, 2015).
Analytica chief executive officer Geoff Daly said that with "a solid sales team behind us, Analytica will have the capacity to focus on driving market awareness and adoption of the Pericoach system".
Analytic said that it would issue 52,083,334 unlisted options exercisable at 1.9 cents each by February 28, 2020 in three tranches pending performance hurdles and as "consideration for sales and marketing services".
Analytica was unchanged at 0.6 cents.

SIRTEX MEDICAL

Sirtex will vote to grant chief executive officer Gilman Wong 45,930 'performance rights' worth about $1.5 million and re-elect directors.
Sirtex said it would ask shareholders to approve the issue of the performance rights at no cost and exercisable at no cost to Mr Wong, pending targets based on the ASX300 accumulation index and a 20 percent increase in its compound annual growth rate.
The Sirtex share price has increased from $2.00 when Mr Wong was appointed in May 2005 to $11.98 on June 28, 2013, $16.88 on June 30, 2014.
The Sirtex notice of meeting said shareholders would vote on the remuneration report and the re-election of directors Dr Katherine Woodthorpe and Grant Boyce.
The meeting will be held at the Royal Automobile Club of Australia, Macquarie Room, Level 4, 89 Macquarie Street Sydney, on October 27, 2015 at 10am (AEDT).
Sirtex was up three cents or 0.1 percent to $33.40 with 161,319 shares traded.

GI DYNAMICS

The Singapore-based UBS AG and related bodies corporate say they have become substantial shareholders in GI Dynamics with 44,304,916 shares (9.32%).
UBS AG has been buying, selling, borrowing and returning Australian biotechnology shares as a "prime broker" for several years (BD: Nov 21, 2013)
Today, UBS AG said that it bought and sold GI Dynamics shares on behalf of unnamed custodians between June 1 and September 23, 2015 with the largest and most recent acquisition 43,140,000 shares for $215,700 or 0.5 cents a share.
On Friday, Capital Group said it had ceased its substantial shareholding in GI Dynamics, in which it previously held 43,140,000 shares (BD: Sep 25, 2015).
The trade is believed to be an "off-market crossing" not involving a trading platform.

PROBIOTEC

Probiotec says its subsidiary Australian Dairy Proteins Pty Ltd has sold its Jervois, South Australia protein plant to Beston Pure Dairies for $7.0 million.
Probiotec said that about $6.2 million would repay several existing debt facilities with the balance to fund working capital requirements.
Probiotec managing-director Wes Stringer said the sale of assets continued the objectives of reducing debt and streamlining the business model.
Probiotec was up half a cent or 2.3 percent to 22.5 cents.

POLYNOVO

Polynovo has requested a trading halt “pending the release of an announcement of a contract to fund a clinical trial”.
Trading will resume on September 30, 2015 or on an earlier announcement.
Polynovo last traded at 12 cents.

ACTINOGEN

Actinogen has requested a trading halt ““pending an announcement regarding the results of the [cerebro-spinal fluid] clinical data”
Trading will resume on September 30, 2015 or on an earlier announcement.
In June, Actinogen said it had begun the third and final of its phase I studies of Xanamem for Alzheimer’s disease with four patients undergoing lumbar puncture to confirm central nervous system pharmaco-kinetics as well as plasma and cerebro-spinal fluid levels (BD: Mar 31, Apr 14, Jun 11, 2015).
Actinogen last traded at five cents.

RESAPP

Resapp has requested a trading halt “pending the release of an announcement regarding the company’s clinical study results”.
Trading will resume on September 30, 2015 or on an earlier announcement.
Resapp last traded at 3.5 cents.