Biotech Daily

Tuesday May 9, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYCLOPHARM UP 7%, DIMERIX DOWN 7%**

*** PSIVIDA PRESENTS 12-MONTH MEDIDUR/DURASERT UVEITIS DATA**

*** RESAPP COLLABORATES WITH MÉDECINS SAN FRONTIÈRES**

*** PROTEOMICS: 'WORLD'S MOST ACCREDITED PROTEIN TESTING LAB'**

*** ANI LAUNCHES IDT'S 1st ACQUIRED GENERIC PINDOLOL**

*** CYCLOPHARM FACES 19% DISSENT OVER BUY-BACK**

*** IMMURON HOPES TO RAISE $12m FOR NASDAQ IPO**

*** ADMEDUS TELLS ASX: 'FDA CARDIOCEL 3D GRANT NOT MATERIAL'**

*** MMJ IMPORTS MEDICAL MARIJUANA CAPSULES**

*** LUCERNE SERVICES TAKES 6% OF VISIONEERING**

MARKET REPORT

The Australian stock market fell 0.53 percent on Tuesday May 9, 2017 with the ASX200 down 31.0 points to 5,839.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and two were untraded.

Cyclopharm was the best, up five cents or 6.7 percent to 80 cents, with 5,000 shares traded.

ITL climbed 4.1 percent; Medical Developments, Prima and Psivida were up more than three percent; Actinogen, Bionomics, Polynovo and Reva rose more than two percent; Admedus, Ellex and Starpharma were up more than one percent; with Clinuvel, Cochlear and Sirtex up by less than one percent.

Dimerix led the falls, down 0.05 cents or 7.1 percent to 0.65 cents with 933,333 shares traded.

Acrux lost 5.6 percent; Impedimed, Living Cell, Neuren and Oncosil fell more than four percent; Compumedics and Factor Therapeutics were down more than three percent; Opthea shed 2.7 percent; Airxpanders, Avita, Mesoblast, Orthocell and Osprey were down more than one percent; with CSL, Nanosonics, Pro Medicus, Resmed and Viralytics down by less than one percent.

PSIVIDA

Psivida says that 12-month follow up data shows that three-year Durasert treatment "significantly reduces recurrences" of posterior segment uveitis through 12 months
Last year Psivida said its first 129-patient, phase III trial of Medidur for posterior uveitis met its primary endpoint of prevention of recurrence of disease with high statistical significance of $p < 0.00000001$ at 12 months follow-up (BD: Jul 28, 2016).
Previously, Psivida has referred to the technology as Medidur and had described the delivery system Durasert.
Today's announcement appeared to refer to the same trial but with the technology name changed from Medidur to Durasert.
Psivida said that the 12-month follow-up data from its first phase III trial was presented at the Association for Research in Vision and Ophthalmology meeting in Baltimore, Maryland from May 7 to 11, 2017.
The company said that the Durasert three-year uveitis implant demonstrated a significant reduction in the recurrence of posterior segment uveitis through 12 months with 27.6 percent of Durasert treated patients having a recurrence compared to 85.7 percent of patients in the control group ($p < 0.001$).
Psivida said that best corrected visual acuity gain of 15 letters or more at six and 12 months was 23 percent and 22.4 percent, respectively, for Durasert and 7.3 percent and 10.3 percent, respectively, for the sham procedure, demonstrating a sustained effect over 12 months.
Psivida chief executive officer Nancy Lurker said that the results "both at six and 12 months, demonstrated a significant reduction in the prevention of recurrence of posterior segment uveitis, a devastating disease and the third leading cause of blindness".
Ms Lurker said that she expect the first read-out from the second phase III trial of Durasert and submission of the European market authorization application by the end of June and the company was on-track to file a new drug application with the US Food and Drug Administration by the end of 2017.
Psivida was up nine cents or 3.5 percent to $2.69.

RESAPP HEALTH

Resapp says its Resappdx has been evaluated by Médecins San Frontières (doctors without borders), which study the respiratory diagnostic in a lower income rural setting.
Resapp said that pneumonia killed more than 950,000 children under five every year, with many deaths caused by delays in diagnosis due to the lack of high-quality medical care.
The company said that Médecins San Frontières was an international, independent, medical humanitarian organization delivering emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural disasters.
Resapp said that Médecins San Frontières expressed an interest in Resappdx and both parties were willing to collaborate to ensure that those children who would benefit most from the technology were not left behind and Médecins San Frontières had been providing input into ensuring its suitability in humanitarian settings and lower and middle income countries.
Resapp chief executive officer Dr Tony Keating said the company had used the feedback from Médecins San Frontières "to refine Resappdx even further for the difficult environments in which [Médecins San Frontières] operates".
"We are looking forward to evaluating the clinical performance of Resappdx in some of the most challenging conditions that doctors encounter," Dr Keating said.
Resapp fell half a cent or 1.6 percent to 30 cents with 1.3 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it is the “world’s most accredited protein testing laboratory” and has launched pharmacokinetic and companion diagnostic testing for clinical trials.

Proteomics said it became “the most accredited protein testing company in the world with the award of ISO 17025 research and development certification”, which included compliance with the Paris-based Organisation for Economic Co-operation and Development principles of good laboratory practice.

The company said that the research and development certification extended its existing certification for ISO 17025 for chemical testing and the accreditation guaranteed the “highest quality of data for clinical trials, biomarker discovery, biologics and biosimilars testing”.

Proteomics said it would launch a suite of pre-clinical and clinical testing capabilities including pharmaco-kinetic, pharmaco-dynamic and companion diagnostic services.

Proteomics managing-director Dr Richard Lipscombe said that Asia was the preferred destination for clinical trials, but there was a shortage of analytical laboratories servicing the large number of clinical trial centres.

Dr Lipscombe said there were more than 1,500 clinical trials registered in Australia and New Zealand in 2016, most commonly phase I safety trials.

“Clinical trials are an area of great Australian strength and we’re proud to become one of only three companies based in the country to offer clinical trial [pharmaco-kinetic] testing services,” Dr Lipscombe said.

“Approximately 10 percent of clinical trial costs are related to analytical testing and consequently these new services are expected to add significantly to our analytical business”, Dr Lipscombe said.

Proteomics was unchanged at 16 cents.

IDT AUSTRALIA

IDT says that Baudette, Minnesota-based distribution partner ANI Pharmaceuticals has launched 5mg and 10mg pindolol beta-blocker tablets for hypertension in the US.

Last month, IDT said the US Food and Drug Administration affirmed the technology transfer of pindolol, clearing the path for a US launch (BD: Apr 27, 2017).

IDT said the US market for pindolol was about $US10 million a year and the ANI Pharmaceuticals launch signalled the culmination of its efforts to re-launch the first of its acquired generic drug products (BD: Nov 3, Dec 18, 2014).

IDT was unchanged at 14 cents.

CYCLOPHARM

Cyclopharm says that 7,655,702 votes (18.7%) were cast against a potential share buy-back with 33,229,371 shares (81.3%) in support.

The company said that all other resolutions were passed easily with 9,583 votes against the remuneration report and the 12.5 percent increase in the remuneration of non-executive directors from $200,000 to $225,000, with 40,875,490 votes in favor.

Cyclopharm said that directors David Heaney and Tom McDonald were elected unopposed.

According to the Cyclopharm buy-back of up to 25 percent of its shares, it had 59,951,733 shares on issue, meaning the vote against the buy-back amounted to 12.7 percent of the company, sufficient to requisition extraordinary general meetings.

Cyclopharm was up five cents or 6.7 percent to 80 cents.

IMMURON

Immuron says it hopes to raise $US8,750,007 ($A11,918,262), through the issue of 416,667 American depository shares (ADSs) at $US21 each, to list on the Nasdaq.
Immuron said it would also offer warrants or options to buy 208,334 ADSs at one US cent each exercisable at about 125 percent of the ADS price ($US26.25) within five years.
The company said that shares and warrants would be listed on the Nasdaq under the symbols IMRN and IMRNW, respectively.
Immuron said the funds raised would be used for the clinical development of IMM-124E for fatty liver disease, IMM-529 for Clostridium difficile and general corporate purposes.
The company said it expected to list on the Nasdaq by July 2017 and the joint book-runners were Joseph Gunnar & Co, Rodman & Renshaw and a unit of HC Wainwright & Co, with Wallachbeth Capital a co-manager.
Immuron said that each ADS would represent 40 Australian shares.
Immuron fell three cents or 5.3 percent to 53.5 cents.

ADMEDUS

Admedus has responded to an ASX ‘aware’ query that its Cardiocel 3D grant by the US Food and Drug Administration is not material.
The ASX noted a four cent or 12.3 percent share price rise from 32.5 cents on April 28 to 36.5 cents on May 1, 2017 and that the FDA had granted Cardiocel 3D 510(k) pre-market approval on April 28, but the company did not announce the approval until May 2, 2017.
The ASX said that companies were required to make material announcements immediately.
Admedus told the ASX that in its Appendix 4C quarterly report of April 26 it noted that it had lodged its FDA submission for Cardiocel 3D and expected that would be approved later in the year.
The company said that the FDA grant process was administrative as opposed to a technical approval for the FDA clearance process and was “essentially an extension of the company's existing FDA clearance” with the grant process typically taking up to 30 days, compared to a clearance taking about six months.
“The company does not consider that the FDA grant of Cardiocel 3D itself, as opposed to the previous Cardiocel FDA clearance, is information that a reasonable person would expect to have a material effect on the price or value of its securities, particularly given that the market was already aware that the company was applying, and expected to receive, that grant within the timeframe that it was in fact received and that key expected timings and deliverables remained consistent with earlier company announcements on February 28 and April 26, 2017,” Admedus said.
The company said that on May 1 it lodged an unrelated announcement entitled ‘Admedus HSV-2 Phase IIa Results Webinar’ and said “it is not unusual for the share price of bio-companies to increase in anticipation of results being released”.
Admedus said there was speculation about the results and an analysis of the trades on May 1 showed a large volume of relatively small individual trades, consistent with speculative trading ahead of results.
The company said that the share p[rice rose a further two cents to 38 cents on May 2, but following the release of the results on May 4 “the company's share price had dropped 18.4 percent to approximately 31 cents … consistent with speculative traders selling shares in the company following the HSV-2 program results not being as positive as they had anticipated”.
Admedus was up half a cent or 1.7 percent to 30.5 cents.

MMJ PHYTOTECH

MMJ says that Melbourne distribution partner HL Pharma Pty Ltd has imported its first shipment of medicinal cannabis products from its Swiss-subsidiary Satipharm AG.
MMJ said the imported products included two strengths of Satipharm's Gelpell CBD cannabidiol capsules, which could be used for a variety of medical conditions as approved by prescribing physicians under Australian law.
The company said that the CBD capsules were "one of the first medicinal cannabis products available to approved prescribers in Australia, further strengthening [its] position as a first-mover in the evolving Australian market".
MMJ said the capsules had passed a phase I safety and bioavailability trial and were produced under good manufacturing practice protocols in Switzerland and would be available in a 10mg and a 50mg doses containing no detectable levels of tetrahydrocannabinol (THC).
MMJ managing-director Andreas Gedeon said that completing the initial shipment "it solidifies our position as one of the first providers of world-class medicinal cannabis products to Australian prescribers".
"The company views the evolving Australian market as a significant near-term growth opportunity and we are fully supportive of the Australian Government's decision to facilitate easier access to medicinal cannabis products for all approved prescribers," Mr Gedeon said.
MMJ was unchanged at 39 cents with seven million shares traded.

VISIONEERING TECHNOLOGIES

The Melbourne-based Lucerne Services says it has become a substantial shareholder in Visioneering with 12,285,426 shares or 6.24 percent.
Lucerne said that the registered holders were Principis Master Fund PC, Lucerne Composite Master Fund and Citicorp Nominees.
Lucerne did not disclose how much it paid for the shares as required under the Corporations Act, but said it became substantial on March 23, 2017, prior to the company listing on the ASX, following its initial public offer at 42 cents a share.
Visioneering's top 20 holders list said that JP Morgan Nominees held 12,285,426 shares or 6.24 percent.
Visioneering was untraded at 39 cents.