Biotech Daily

Wednesday July 25, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: BENITEC UP 5%; MEDICAL DEV DOWN 19.5%**

*** TELIX: FDA APPROVES DRUG FILE, PROSTATE CANCER IMAGING TRIALS**

*** FDA: MEDICAL DEVELOPMENTS PENTHROX TRIAL 'ON HOLD'**

*** SOMNOMED RECEIPTS UP 26% TO $60.5m**

*** IMMURON SALES REVENUE UP 29% TO $2m**

*** MEDADVISOR OPERATING REVENUE UP 56% TO $6.6m**

*** MEDLAB STARTS PHASE IIa NRGBIOTIC FOR DEPRESSION TRIAL**

*** NUHEARA, MELBOURNE UNI TO STUDY IQBUDS FOR AUTISM**

*** REDHILL RECRUITS 400 PATIENTS FOR RHB-105 HELICOBACTER STUDY**

*** IDT DISCUSSES REMEDIATION PLAN WITH FDA, PRODUCTS ON-MARKET**

*** DAVID PHILLIPS REPLACES SUDA BDM NICK WOOLF**

MARKET REPORT

The Australian stock market fell 0.29 percent on Wednesday July 25, 2018 with the ASX200 down 18.2 points to 6,247.6 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell and eight traded unchanged. All three Big Caps fell.

Benitec was the best, up one cent or 5.3 percent to 20 cents with 856,480 shares traded. Dimerix, Optiscan, Prana and Prescient climbed more than four percent; Airxpanders, Clinuvel, Starpharma and Telix improved more than three percent; Avita, ITL, Opthea and Volpara rose more than two percent; with Compumedics, Cyclopharm, Nanosonics, Neuren and Pro Medicus up one percent or more.

Medical Developments led the falls, down $1.14 or 19.5 percent to $4.71 with 463,897 shares traded. Immutep fell 5.9 percent; Reva lost 3.3 percent; Admedus, Cochlear, Cynata, Osprey and Resmed shed more than two percent; Bionomics, CSL, Impedimed, Pharmaxis and Polynovo were down one percent or more; with Ellex, Mesoblast, Sirtex and Universal Biosensors down by less than one percent.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has reviewed and allowed the Memorial Sloan Kettering Cancer Centre and Endocyte Inc use of its prostate cancer imaging kits.

In a complicated media release, Telix said that on July 10, the FDA had requested more information on its sterile kit for the preparation of the prostate cancer imaging agent 68 Gallium-labeled prostate-specific membrane antigen 11 (68Ga-PSMA-11).

The company said that the "further information request" followed the first referencing of the drug master file by the New York-based Sloan Kettering Cancer Centre.

Telix said that a complete response to the information request was submitted on July 13 and today said it had been informed by Sloan Kettering investigators that they were authorized to proceed with the first US clinical trial referencing the drug master file.

The company said that the master file was "to establish a comprehensive manufacturing dossier with the FDA for the kit as part of preparing for pivotal clinical studies and an eventual marketing authorization of the imaging agent, subject to FDA approval".

Telix said that the drug master file and subsequent FDA review enabled "two commercially important developments … [enabling Telix] to provide the kit to suitably equipped commercial and clinical radio-pharmacies as an investigational product under an approved investigational new drug application … [and] to grant access to a confidential regulatory package for both academic and commercial clinical trials in the US in a highly streamlined way".

The company said that with ANMI it had validated the use of the kit with the three leading manufacturers of the portable 68Ga radioactive source generators.

Telix said that a letter of authorization had been filed with the FDA for Sloan Kettering and the West Lafayette, Indiana-based Endocyte Inc to reference the drug master file for their clinical trials.

The company said that with Sloan Kettering it had opened the master file by amending an investigational new drug application for a prostate imaging clinical trial.

Telix said that Sloan Kettering's clinical trial was a 500-patient, expanded access trial that would take about one year to recruit and it was supporting the trial by providing access to kits for investigational use.

The company said that Endocyte had been authorized to reference the drug master file to screen patients for its planned phase III Vision US trial for up to 750 patients and it had agreed to provide access to kits in exchange for access to the imaging-related patient data obtained from the clinical trial (BD: April 10, 2018).

In March, Telix said it had submitted the drug master file for the 68Ga-PSMA-11 sterile kit for prostate imaging to the FDA (BD: Mar 26, 2018).

The company said at that time that the kit had been validated for use with all major vendors of 68Ga generators and was expected to be commercially available by mid-2018, subject to FDA review of the manufacturing package.

Telix said that the drug master file was held by Kyzeo Imaging LLC, a joint-venture company between Telix and the Liege, Belgium-based Advanced Nuclear Medicine Ingredients (ANMI) SA.

Telix US president Dr Bernard Lambert said in March that the drug master file submission was "an important step" towards a commercial prostate-specific membrane antigen prostate imaging product for the US "and we are the first to have achieved this accomplishment in collaboration with our partner ANMI"

Last year, the company said its TX591 antibody was in a phase IIa trial for imaging and therapy of metastatic prostate cancer and was developed at New York's Cornell University and licenced from the Cambridge, UK-based Abzena (BD: Sep 18, 2017).

Telix was up 2.5 cents or 3.8 percent to 68 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its US clinical program to approve its Penthrox inhaled methoxyflurane is on hold pending a letter from the US Food and Drug Administration.
Medical Developments said the letter would outline outstanding issues and concerns and was expected within two months.
Medical Developments chief executive officer John Sharman told Biotech Daily that the company filed its investigational new drug application to the FDA along with preclinical data five weeks ago.
Mr Sharman said that the company had been discussing protocols for a phase I trial with the regulator.
Medical Developments fell $1.14 or 19.5 percent to $4.71 with 463,897 shares traded.

SOMNOMED

Somnomed says that unaudited revenue for the year to June 30, 2018 was up 30.2 percent to $64,200,000 compared to the previous corresponding period.
Somnomed's Appendix 4C quarterly report said that receipts from customers for the year to June 30, 2018 rose 26.2 percent to $60,487,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $13,383,000 at June 30, 2018, with an expected outflow of $18,300,000 for the three months to September 30, 2018, with revenue for the three months to June 30 2018 of $17,008,000.
Somnomed was up 29 cents or 13.6 percent to $2.42.

IMMURON

Immuron says that sales revenue for the year to June 30, 2018 was up 29 percent to $2 million compared to the previous corresponding period.
Immuron said that US sales of its "over-the-counter gastrointestinal and digestive health supplement" Travelan for travellers' diarrhoea were up 114 percent to $765,000 for the year to June 30, 2018 compared to the previous corresponding period, $265,000 of which was from the last three months alone.
The company said Australian sales were up 19 percent for the year to June 30, 2018 compared to the previous corresponding period.
Immuron fell half a cent or 1.3 percent to 38 cents.

MEDADVISOR

Medadvisor said that operating revenue for the year to June 30, 2018 was up 55.67 percent to $6.6 million compared to the previous corresponding period.
Medadvisor said that receipts from customers for the year to June 30, 2018 rose 28.55 percent to $6,452,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $10,591,000 at June 30, 2018, with an expected outflow of $3,204,000 for the three months to September 30, 2018.
Medadvisor fell 0.2 cents or 4.3 percent to 4.5 cents with 1.8 million shares traded.

MEDLAB CLINICAL

Medlab says the Queensland University of Technology has begun recruitment for its 150-patient, phase IIa trial of probiotic NRGBiotic and anti-depressants for depression.

In 2016, Medlab said it would begin a double-blind, placebo-controlled, phase IIa trial of its bacteria-based NRGBiotic anti-depression therapy to target the gut-brain axis, that was due to begin in October 2016, after a phase I trial of NRGBiotic in patients who had been prescribed anti-depressants for an average of 2.5 years showed improvement of 80 and 90 percent in two cohorts (BD: Aug 30, 2016).

Last year, the company said it had ethics approval for the phase IIa trial with the University of Queensland, and later said it had been granted a patent for NRGBiotic as an adjunct treatment for depression (BD: Mar, 27, Sep 18, 2017).

Today, Medlab said it had received approval for a Federal Government grant for the cost of the trial and the study was designed to meet requirements for an expedited drug approval mechanism being developed by the Therapeutic Goods Administration.

The company said the trial was led by Brisbane's Queensland University of Technology, with psychology and counselling lecturer Dr Esben Strodl as principal investigator and Dr Matthew Bambling, who supervised the phase I trial, as a co-investigator.

Medlab said that the trail was based on research on the connection between gut health and inflammation and its subsequent effect on mental health.

Medlab director of medical research Prof Luis Vietta said there was increasing evidence of the association between poor gut health and depression and that NGRBiotic, which targeted the gut-brain axis, had shown in phase I trials that "its positive effect on gut health also boosted the body's ability to absorb a standard anti-depressant".

Medlab was up half a cent or one percent to 49.5 cents.

NUHEARA

Nuheara says it has partnered with the University of Melbourne to investigate whether its Iqbuds improve sensory experience in children with autism.

Nuheara said the University's Centre For Auditory Neuroscience would conduct a study that built on research from the Perth, West Australia-based Ear Science Institute of Australia into children with auditory processing disorder, which the company commissioned earlier this year (BD: May 2, 2018).

Nuheara chief executive officer Justin Miller said the company had "anecdotal evidence which demonstrates the immediate responsive change in some children who have autism when they are wearing Iqbuds".

Nuheara fell 0.1 cents or 1.1 percent to 8.9 cents with 1.9 million shares traded.

REDHILL BIOPHARMA

Redhill says it has enrolled 400 of the planned 444 patients in its phase III US study of RHB-105, formerly named Heliconda and now Talicia, for helicobacter pylori.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

In May, the company said it had enrolled 300 patients and expected top-line results for the confirmatory second trial of RHB-105 by the end of 2018 (BD: May 7, 2018).

Today, Redhill said it planned to file a new drug application to the US Food and Drug Administration in early 2019, which meant RHB-105 could be approved by July 2019.

On the Nasdaq, Redhill was up nine US cents or 0.9 percent to $US9.99 ($A13.49) with 201,971 shares traded.

IDT AUSTRALIA

IDT says it has discussed remediation for a warning about its facilities in a meeting with the US Food and Drug Administration.

Last month, IDT said it had changed its quality and operational personnel, as well as its internal processes and systems, following a US Food and Drug Administration warning it received in May, regarding a December 2017 inspection of its facilities by the US regulator (BD: May 29, Jun 8, 2018).

Today, the company said it had met with representatives from the FDA's office of manufacturing quality in Silver Spring, Maryland and discussed the progress it had made regarding its remediation commitments to date and provided an update on its longer-term commitments.

IDT said it was allowed to market products in the US and the FDA encouraged it to continue with its remediation plans.

The company said it would provide the FDA with bi-monthly updates on its progress and would prepare its facility for re-inspection.

IDT fell 0.4 cents or five percent to 7.6 cents.

SUDA PHARMACEUTICALS

Suda says director David Phillips will lead the company's business development replacing Nick Woolf, "as the company moves into a new growth phase".

Suda said Mr Phillips, who was appointed as an advisor to the board in November 2017 before being appointed a director in April 2018, would take over discussions with potential partners interested in present and future products, including cannabinoids, and would appoint a representative to promote products in the US (BD: Nov 29, 2017, Apr 9, 2018).

The company said its chief business officer Nick Woolf had retired, having led business development activities for the last five years.

Suda was unchanged at 0.5 cents with 2.95 million shares traded.