Biotech Daily

Monday November 26, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: FACTOR UP 50%; COMPUMEDICS DOWN 8%**

*** TELIX BUYS PARTNER ANMI FOR $9.3m CASH, SCRIP**

*** BTC LICENCES EPISIL ORAL PAIN RELIEF FROM CAMURUS**

*** LBT 1st APAS INDEPENDENCE IN THE US; LOCAL SALES DELAYED**

*** PROTEOMICS, JANSSEN WORK ON DIABETIC KIDNEY, HEART FUNCTION**

*** ALCIDION: MKM $12m QUEENSLAND REFERRAL CONTRACT**

*** OPTHEA ENROLS LAST OF 366 PATIENTS IN OPT-302 WET AMD TRIAL**

*** ACTINOGEN ENROLS LAST PATIENT IN XANAMEM ALZHEIMER'S TRIAL**

*** ZELDA, ST VINCENT'S TRIAL MARIJUANA FOR PAIN**

*** MESOBLAST, TASLY MEET FOR STEM CELL HEART DRUG PATHWAY**

*** DIMERIX WINS $100k FEDERAL GRANT TO IDENTIFY TARGETS**

*** BLUECHIIP LOSES DIRECTOR BLAIR HEALY**

*** SIMAVITA TO LOSE DIRECTOR WARREN BINGHAM, DAMIEN HAAKMAN IN**

*** PETER GRIFFITHS REPLACES NEUROTECH CEO, M-D WOLFGANG STORF**

*** ADMEDUS APPOINTS MATTHEW MCDONNELL INTERIM CFO**

MARKET REPORT

The Australian stock market fell 0.78 percent on Monday November 26, 2018 with the ASX200 down 44.6 points to 5,671.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and two were untraded.

Factor was the best, up 0.1 cents or 50 percent to 0.3 cents, with 13.1 million shares traded. Paradigm climbed 21.05 percent; Ellex was up 6.8 percent; Pharmaxis and Prana were up more than five percent; Genetic Signatures improved 4.6 percent; Cyclopharm, Opthea, Starpharma and Uscom were up more than three percent; Actinogen and Immutep rose more than two percent; Avita, Clinuvel, Mesoblast and Neuren were up more than one percent; with Resmed up 0.9 percent.

Compumedics led the falls, down 3.5 cents or 8.2 percent to 39 cents with 31,642 shares traded. LBT lost 6.7 percent; Cynata, Dimerix and Universal Biosensors fell more than four percent; Bionomics, Prescient, Telix and Volpara lost more than three percent; Oncosil shed 2.9 percent; CSL, Impedimed, Medical Developments, Nanosonics, Optiscan and Pro Medicus were down more than one percent; with Cochlear down 0.4 percent.

TELIX PHARMACEUTICALS

Telix says it will pay $9.3 million in cash, scrip and debt for Advanced Nuclear Medicine Ingredients SA for its Illumet prostate imaging kit, currently marketed in the US.

In October, Telix said it had expanded its partnership with the Liege, Belgium-based Advanced Nuclear Medicine Ingredients SA (ANMI) for the 68 gallium-labelled prostate-specific membrane antigen 11 (68Ga-PSMA) cold kit for detecting prostate cancer, developed by ANMI and commercialized by Telix for the US where it was marketed as Illumet (BD: Oct 15, 2018)

Today, the company said it would acquire ANMI for EUR3.15 million ($A4.94 million) in shares at 83 cents a share, EUR2 million ($A3.13 million) in cash and assume non-recourse debt of EUR800,000 ($A1.25 million).

Telix said the projected cash impact of the transaction was neutral as ANMI revenues covered the basic operating costs of the business and a portion of Telix's budgeted product development costs could be redirected ANMI in lieu of third-party providers.

The company said that 46.5 percent of the shares were for management and were escrowed for two years, with the remainder investor shares, with 25 percent escrowed for three months and 75 percent escrowed for 12 months, and the shares would be issued to 20 new shareholders, with none above five percent.

Telix said that of the EUR2 million in cash, EUR1.7 million was to ANMI shareholders and EUR300,000 was to repay a convertible loan to ANMI from an investor with a commercial conflict-of-interest with Telix.

The company said that a five-year "performance-based deferred cash payment" would be based on sales following first marketing authorization in the US or European Union.

Telix said that there was a "rapidly growing demand" outside the US for prostate imaging and an opportunity to increase group revenue for Illumet test, building on the existing commercial and manufacturing relationships between it and ANMI.

The company said that combining the resources, data and human capital of the two companies would "accelerate the process of preparing a new drug application in the US and Europe for prostate imaging subject to regulator engagement" and by aligning the European and US activities more closely, they would achieve time and cost efficiencies.

Telix said that ANMI had "a highly capable radiochemistry product development team with the requisite expertize and technologies" to develop kit-based implementations of [its] … diagnostic and therapeutic product pipeline for rapid and streamlined deployment into US and international radio-pharmacy networks".

The company said that ANMI had "several other relevant and synergistic products" in its pipeline which it could bring to market by July 2020.

Telix chief executive officer Dr Christian Behrenbruch said the companies "already work very closely together and this transaction is the logical progression that creates a significantly more capable company with the ability to act strategically on a global basis, rather than in a territorially-segmented manner".

ANMI co-founder and chief executive officer Ludovic Wouters said that "with the growing importance of the role of nuclear medicine, particularly in prostate cancer care, our respective companies can benefit from establishing a more integrated approach to combining our diagnostic and therapeutic strengths".

"We see a clear way for ANMI to contribute to Telix's product development by packaging their therapeutic products in way that makes them fast and easy to prepare in the radio-pharmacy setting," Mr Wouters said.

Telix said ANMI would operate as a subsidiary company within the Telix Group, headquartered in Liège and reporting to Telix Europe chief operating officer Odile Jaume.

Telix fell 2.5 cents or 3.6 percent to 67.5 cents.

BTC HEALTH

BTC Health says that wholly-owned subsidiary Bioimpact has licenced Episil for oral pain relief from the Lund, Sweden-based Camurus AB, but did not disclose terms.
BTC Health said that Episil was indicated for “the relief of oral pain caused by inflammatory conditions of the mouth such as oral mucositis and stomatitis”.
The company said that mucositis was a side effect of radiation and chemotherapy, casing redness, mouth sores and ulcers that could be painful, making it difficult to eat, drink and speak and according to Mosby’s Medical Dictionary a stomatitis is any inflammatory condition of the mouth.
BTC said that “when in contact the buccal membrane, Episil transforms into a thin protective layer of gel, offering effective pain relief for up to eight hours” and was registered as a medical device in Europe, the US and Japan.
The company said that Bioimpact would submit a marketing application in Australia and New Zealand in early 2019 and expected to launch the product by July 2019.
The company said that Episil had been launched in 12 countries with additional market approvals pending.
BTC chair Dr Richard Treagus said the company looked forward to making Episil available through cancer treatment centres in Australia and New Zealand.
BTC was untraded at 15 cents.

LBT INNOVATIONS

LBT says it has placed its first automated plate assessment system (APAS) Independence in a US medical centre, with four Australian sales taking longer than expected.
LBT said that the installation of the APAS Independence at the Minneapolis, Minnesota-based Hennepin Healthcare System, which included the Hennepin Healthcare Research Institute and Hennepin County Medical Centre.
The company said that the Hennepin County Medical Centre was a level I adult trauma centre and level I paediatric trauma centre and acute care hospital, and its microbiology laboratory provided diagnoses of bacterial, viral, mycotic, and parasitic infections, including extensive testing and reporting or anti-microbial susceptibility results.
LBT said that through its Clever Culture Systems joint venture a memorandum of understanding had been signed, with training and commissioning of the APAS Independence expected in coming weeks and integration into the Hennepin Healthcare Research Institute workflow in early 2019.
Institute microbiology director Dr Glen Hansen said the collaboration would “further benefit our customers and their patients by bringing together our clinical expertise and with the artificial intelligence of APAS Independence, further enable the microbiology laboratory in its delivery of accurate and timely diagnosis”.
LBT said that the US was the world’s single largest pathology market and the APAS technology was the only US Food and Drug Administration-cleared instrument, indicated for use as a class II medical device, following the clearance for the manual version, APAS Compact in October 2016.
The company said that a 510(k) authorization was required for the APAS Independence with a submission expected before the end of 2018.
Separately, the company said that the expected sale of four APAS instruments in Australia by the end of this year had been delayed.
LBT chief financial officer Ray Ridge told Biotech Daily the company expected the sales to be completed in the new year.
LBT fell 0.7 cents or 6.7 percent to 9.8 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has a research collaboration agreement with Johnson & Johnson's Janssen Research and Development for diabetic kidney disease research.

Proteomics managing-director Dr Richard Lipscombe said that "using Promarkerd predictive technology to accelerate drug discovery is an exciting development with significant applications globally".

"We are pleased to be working with one of the largest [pharmaceutical] companies to support rapid treatment development for diabetic kidney disease," Dr Lipscombe said.

Proteomics said that Janssen would provide samples from its clinical trials of a gliflozin, or SGLT-2 inhibitor, class that helped lower blood sugar in adults with diabetes, and Proteomics would perform sample testing, with joint analysis of the study results.

The company said that each party would bear their own costs and the analysis was expected to take six to 12 months at which point the results would be published.

Proteomics said the study would use Promarkerd as an early predictor of kidney function in patients who took part in Janssen's clinical trials and assess how the score correlated with drug response in patients with diabetic kidney disease.

The company said the collaboration would also evaluate how Promarkerd performed in predicting heart disease, another major complication of diabetes, with cardio-vascular risk diagnosis a new application for Promarkerd.

"Gliflozin drugs could be hugely beneficial in improving patient outcomes from diabetes complications and we look forward to determining whether Promarkerd can help in assessing responses to this treatment", said Dr Lipscombe.

Proteomics was up five cents or 12.2 percent to 46 cents with 1.85 million shares traded.

ALCIDION GROUP

Alcidion says that subsidiary MKM Health has contract worth about $12 million over six years with Queensland Health to establish a State-wide referral service directory.

Alcidion said that MKM would use a local service as a software system managed by partner Nextgate Solutions Inc.

The company said the referral directory was a component of the integrated referral management program of Queensland Health's specialist outpatient strategy launched in September 2016 to tackle outpatient waiting lists.

Alcidion said the system provided general practitioners online access to their patients' hospital records.

The company said that the contract covered the supply of the referral service directory until mid-2024 and a second contract with Metro South Hospital and Health Service covered the initial implementation and configuration of the integration with the general practitioners' referrals platform, allowing doctors to submit electronic referrals from existing practice software.

Alcidion chief executive officer Kate Quirke said it was MKM's second major Nextgate contract, following its authorization as a Nextgate reseller, earlier this year.

"The reseller agreement with Nextgate gives us access to a market-leading, and highly complementary product set, and importantly puts us at the forefront of a major public healthcare [information technology] project set to benefit many patients and [doctors] across Queensland," Ms Quirke said.

"This contract will allow us to establish a stronger presence in Queensland, working closely with Queensland Health and in partnership with Queensland Health agencies to deliver on a high value project," Ms Quirke said.

Alcidion was up 0.6 cents or 13.95 percent to 4.9 cents with 2.25 million shares traded.

OPTHEA

Opthea says it has enrolled the last of 366 patients in its phase IIb trial of OPT-302 for wet age-related macular degeneration (BD: Dec 19, 2017).
Opthea said it was focused on the completion of all patient dosing and data collection and expected to report top-line primary outcome results by the end of 2019, “significantly ahead of the original projected timelines”.
Opthea chief executive officer Dr Megan Baldwin said the company was “very pleased to have completed this patient enrolment clinical milestone ahead of schedule and are looking forward to completing the six-month treatment phase of this study”.
Opthea was up two cents or 3.45 percent to 60 cents.

ACTINOGEN MEDICAL

Actinogen says it has enrolled the last of 186 patients in its Xanadu phase II trial of Xanamem for mild Alzheimer’s disease (BD: Sep 7, 2017).
Actinogen said the final patient would complete the randomized, placebo-controlled trial in four months, following three months on treatment a one-month follow-up period, with results expected by July 2019.
Actinogen chief executive officer Dr Bill Ketelbey said that enrolment of the final patient was “a major milestone for Actinogen, as we now have certainty on the timeline to completion of the trial and to the reporting out of the results”.
Actinogen was up 0.1 cents or 2.4 percent to 4.3 cents.

ZELDA THERAPEUTICS

Zelda says that with Melbourne’s St Vincent’s Hospital, it will study the potential of marijuana-based medicine in patients on chronic, high-dose, pain management.
Zelda said opioids for chronic pain could have side-effects including physical dependence.
The company said it would conduct an initial pharmaco-kinetic study to “inform a small scale 20 patient double-blinded, randomized, placebo-controlled study, with the potential to expand into a larger trial depending on results”.
Zelda said the marijuana drugs would be supplied by the Dortmund, Germany-based Hapa Medical and pending ethics approval the trial was expected to begin in early 2019.
Zelda managing-director Dr Richard Hopkins said that “while similar studies have been conducted in other countries with promising results, we believe that local medical community participation in these studies will accelerate acceptance of the potential of cannabinoid-based medicines”.
Zelda was up 0.1 cents or 2.2 percent to 4.7 cents.

MESOBLAST

Mesoblast says that China partner Tasly plans to meet the regulator to discuss the approval pathway for its heart failure stem cell candidate MPC-150-IM.
Mesoblast said that Tasly Pharmaceutical Group would meet with the National Medical Products Administration of the People’s Republic of China, formerly known as the China Food and Drug Administration, by April 2019.
The company said that the first joint steering committee of the two companies was chaired by Tasly Biopharma chief medical officer Dr Gloria Wang and comprised equal representation from the two companies.
Mesoblast was up 2.5 cents or 1.9 percent to $1.36 with 1.2 million shares traded.

DIMERIX

Dimerix says it has been awarded a $50,000 Federal grant, to work with the Harry Perkins Institute and University of Western Australia on targets of interest.
Dimerix said that it would match the Federal Innovation Connections Grant through the Department of Industry, Innovation and Science.
The company said the Harry Perkins Institute of Medical Research head of molecular endocrinology and pharmacology Prof Kevin Pfleger would lead the 10-month program.
Dimerix said the profiling of molecular biology targets under the grant was aligned with its receptor-heteromer investigation technology (Receptor-HIT) which developed DMX-200, currently in phase II trials for diabetic kidney disease and for focal segmental glomerulo-sclerosis.
Dimerix fell 0.4 cents or 4.2 percent to 9.2 cents.

BLUECHIIP

Bluechiip says non-executive director Blair Healy will retire at the close of today's annual general meeting.
Bluechiip said that Mr Healy would be "spending an increasing amount of time in Europe due to his involvement in a new technology start-up venture".
Bluechiip was untraded at 5.6 cents.

SIMAVITA

Simavita says that director Warren Bingham will not seek re-election and will resign, effective from the close of the meeting on December 11, 2018.
Simavita said it thanked Mr Bingham for his contributions over the past three and a half years, "particularly … through the transition period in 2016".
The company currently has three directors, but did not refer to a replacement for Mr Bingham.
Biotech Daily was referred to the materials for the annual general meeting and extraordinary general meeting filed to the ASX on November 14, 2018 which said on page nine of 36 that the company proposed to elect former director Damien Haakman as a director.
Simavita was untraded at 2.9 cents.

NEUROTECH INTERNATIONAL

Neurotech says director and investor Peter Griffiths will replace Wolfgang Storf as chief executive officer and managing-director, effective immediately, starting on $250,690.
The Malta-based Neurotech said that following the change the resolution for the re-election of Mr Storf as a director had been withdrawn from the annual general meeting to be held on November 30, 2018.
The company said that Mr Griffiths would have a base salary of EUR160,000 ($A250,690) with short and long-term incentives "to be determined".
Neurotech company said that Mr Griffiths had been an investor since 2015 and a director since May 2016.
The company said Mr Griffiths previously was an executive with Cognos, IBM and CA Technologies and held a Bachelor of Science from England's Brighton University.
Neurotech was up 0.9 cents or 16.1 percent to 6.5 cents.

ADMEDUS

Admedus says it has appointed former KPMG partner Matthew McDonnell as its interim chief financial officer, effective from November 23, 2018.

Last week, Admedus said that chief financial officer and former company secretary and director Catherine Costello resigned on November 16, 2018 (BD: Nov 19, 2018).

The company said Ms Costello was appointed interim executive director on May 23, 2018 and company secretary on March 15, 2018, following the resignation of then director Mathew Ratty, fulfilling the requirement to have two resident Australian directors and it had begun a search for an Australian director (BD: May 21, 23, Oct 29, 2018).

In October, Admedus said that Star Bright Holding nominee Dr Wenyi Gu would replace retiring director Dr Simon Buckingham (BD: May 21, Oct 4, 29, 2018).

In September, Admedus said that Hong Kong interests had taken a 19.99 percent stake in the company (BD: Apr 27, Aug 2, 6, 8, 20, Sep 3, 17, 29, 2018).

Today, the company said that Mr McDonnell worked for KPMG for 24 years, including 10 years as a partner.

Admedus said that Mr McDonnell was involved in Queensland Government restructures and privatizations, the Linc Energy re-listing on the Singapore Exchange and Virgin Australia's purchase of Skywest.

The company said that Mr McDonnell held a Bachelor of Economics from Macquarie University in New South Wales.

Admedus was in an extended suspension and last traded at 13.5 cents.