Biotech Daily

Monday December 12, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: ATCOR UP 9%, OSPREY DOWN 5%**

*** SIENNA REGISTERS CE-MARKED IVD PRODUCT IN EU**

*** ZELDA PREPARES MEDICAL MARIJUANA SLEEP TRIAL**

*** PHOSPHAGENICS, TESA LABTEC TPM-OXYMORPHONE PATCHES**

*** MEMPHASYS RAISING UP TO $1m FOR WORKING CAPITAL, LITIGATION**

*** CELLMID EXPECTS RISING PACIFIC EDGE CXBLADDER TEST ROYALTIES**

*** GI DYNAMICS REQUESTS CAPITAL RAISING TRADING HALT**

*** BIONOMICS ISSUES 'LESS DILUTIVE' WARRANTS OVER 16m SHARES**

*** RACE APPOINTS PROF MARTIN TALLMAN FOR AML ADVISORY BOARD**

MARKET REPORT

The Australian stock market edged up 0.04 percent on Monday December 12, 2016 with the ASX200 up 2.2 points to 5,562.8 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and three were untraded.

Atcor was the best, up 0.6 cents or 9.4 percent to seven cents with 1.8 million shares traded.

Acrux and Living Cell climbed more than eight percent; Cellmid and Mesoblast improved more than seven percent; Avita rose four percent; Neuren, Pharmaxis and Sirtex were up more than three percent; IDT and Prana rose two percent or more; Oncosil, Orthocell, Polynovo and Resmed were up more than one percent; with Viralytics up 0.8 percent.

Osprey led the falls, down 2.5 cents or 5.4 percent to 44 cents with 99,123 shares traded.

Benitec and Pro Medicus fell more than four percent; Airxpanders, CSL, Ellex, Impedimed and Universal Biosensors lost more than three percent; Anteo shed 2.3 percent; Bionomics, Clinuvel, Cyclopharm, Factor Therapeutics, Medical Developments and Reva were down one percent or more; with Cochlear and Nanosonics down by less than one percent.

SIENNA CANCER DIAGNOSTICS

Sienna said the European Medicines and Healthcare Products Regulatory Agency has approved its telomerase-based adjunct in-vitro diagnostic, initially for bladder cancer.
Last month, Sienna said the US Food and Drug Administration had approved the in-vitro diagnostic (BD: Nov 15, 2016).
Sienna has previously said that 90 percent of cancers up-regulated telomerase and the detection of telomerase in cytology samples would be an important adjunct test for the diagnosis of cancer and about 1.5 million urine cytology tests were performed every year in the US (BD: October 6, 14, 2016).
Today, Sienna said the Conformité Européenne (CE) marked in-vitro diagnostic, to detect the presence of the hTERT component of telomerase, was registered in all EU countries.
The company said that it was working to secure distribution partner agreements throughout the EU, with Histocyte Laboratories and Biosystems Switzerland already appointed for the UK and Switzerland, respectively.
Sienna chief operating officer Matthew Hoskin said the European registration, along with the FDA listing meant the company had access to the two biggest markets in the world.
“With all countries in the EU subject to a single regulatory process, this was a high priority for Sienna as it opens a large market with a single registration,” Mr Hoskin said.
“Additional regulatory filings will follow for countries outside of the USA and EU.”
Sienna is a public unlisted company.

ZELDA THERAPEUTICS

Zelda says it is progressing discussions for multiple sites for a trial of its medical marijuana-based formulation for sleep disorders, including the US and Australia.
Zelda said it was progressing discussions with potential partner clinical research organizations and submissions for ethics committees approvals were in progress.
The company said it expected approvals next year, with trials able to begin by July 2017.
Zelda said it would leverage “the significant amount of anecdotal evidence and data for the compounds’ effectiveness in treating sleep disorders accessed through its exclusive agreement with [California’s] Aunt Zelda’s”.
The company said that insomnia was estimated to affect about 35 percent of the world’s population and was considered to be a prime factor for chronic disability in the workforce.
Zelda said that the global sleep aids market was valued at $US58.1 billion in 2014 and was expected to expand to reach $US80.8 billion by 2020.
The company said that due to the safety data already in place for medicinal cannabis extracts, it was able to progress directly to human clinical trials, rapidly accelerating the time to commercialisation.
Zelda said that with positive trial results it would pursue approvals to register the product and make it available for sale as a sleep aid.
Zelda executive chairman Harry Karelis said the sleep disorder market was “a significant opportunity for medical cannabis treatments … [with] consumers looking for safe, effective, affordable alternatives to current prescription medication”.
“Our exclusive access to Aunt Zelda’s patient data has provided us with the ability to trial a formula that already has existing evidence and data to demonstrate its efficacy in this particular disorder,” Mr Karelis said.
“The purpose of these trials is to establish robust, clinical evidence and to create a comprehensive data pack that can be used to progress later stage trials and/or seek product registrations … and generate product sales in the medium term,” Mr Karelis said.
Zelda was up 0.1 cents or 2.6 percent to 3.9 cents with 6.1 million shares traded.

PHOSPHAGENICS

Phosphagenics says that Germany's Tesa Labtec GmbH has reformulated its transdermal tocopheryl phosphate mixture-oxymorphone patch.

Phosphagenics said it previously developed prototype tocopheryl phosphate mixture (TPM) oxymorphone patches delivering therapeutic amounts of oxymorphone over three days in clinical phase I trials, with Tesa Labtec tasked with finalizing the patch to a commercial product with enhanced physical aspects while maintaining or surpassing the delivery profile (BD: Sep 19, 2013; Jul 28, Aug 11, 2014; May 14, Oct 22, 2015).

The company said that the reformulation work also took into account its growing relationship with Japan's Terumo Corp, which was investigating the potential use of the TPM-oxymorphone patch.

Phosphagenics said that "key technical differences were identified in the requirements for the Japanese market compared to those required for North America" and Tesa Labtec was tasked with developing a reformulated patch taking account of the separate technical and commercial requirements of both markets.

Phosphagenics said that Tesa Labtec produced more than 200 different variants of the TPM-oxymorphone patch to ensure they had identified the optimal composition and the most promising patches increased transdermal flux in-vitro compared to the previous clinical patch, as well as enhanced physical and chemical stability across a range of standard stress tests.

The company said that the performance of the patch in these assessments met or exceeded its expectations for a commercial product and the reformulation program produced TPM-oxymorphone patches appropriate for commercialization in either Japan or US and the patches had been submitted for final stability assessments.

Phosphagenics chief executive officer Dr Ross Murdoch said that the program provided "an enhanced TPM-oxymorphone patch … [and] multiple patch candidates that appear to have all the attributes needed for commercialization in either Japan or the USA".

"We look forward to continuing the development of the product and progressing negotiations with Terumo in respect of an exclusive license for Phosphagenics' TPM-oxymorphone patch in Japan," Dr Murdoch said.

Phosphagenics said that at the conclusion of the final stability study it would resume development of the TPM-oxymorphone patch, with "the exact course … [to] be determined once the outcome of the negotiations with Terumo are finalized".

Phosphagenics was unchanged at 2.9 cents with 4.2 million shares traded.

MEMPHASYS (FORMERLY NUSEP)

Memphasys says it hopes to raise up to $1 million through the issue of convertible notes secured against it Federal R&D Tax Incentive for the year to June 30, 2017.

Memphasys said that the minimum raising would be $800,000 and would be led by chairman Alison Coutts and directors Andrew Goodall contributing $300,000 and $500,000 respectively.

The company said the one-year notes carried a 10 percent per year interest, payable at the end of period, converting at 0.6 cents a share and subject to shareholder approval.

Memphasys said the funds would be used for working capital, primarily for the next generation Spermsep device and to fund litigation against Prime and Manukan in Singapore (BD: Sep 12, Nov 11, 2016).

Memphasys said it was continuing with its negotiations to settle the dispute with Prime and Manukan and was "hopeful that a satisfactory resolution will be achieved shortly".

Memphasys was untraded at 0.6 cents.

CELLMID

Cellmid says it expects to receive increasing royalties from midkine diagnostic licencee Pacific Edge Biotechnology.

Cellmid said that in 2010, the Dunedin, New Zealand-based Pacific Edge, licenced midkine for use in its tests for the diagnosis, prognosis and disease management of bladder cancer (BD: May 19, 2010).

The company said it had derived total revenue of $1,221,048 to date from the Pacific Edge licence, including a $92,000 royalty due to be received for the six months to September 30, 2016.

Cellmid said that Pacific Edge had announced the achievement of a number of material milestones in recent months, which were expected to positively influence future royalty payments.

The company said that Pacific Edge had signed a US Federal supply schedule in February 2016 providing access to the Cxbladder test for 10.2 million veterans enrolled in the Veteran's Administration as well as for military personnel at 150 US Department of Defence facilities and in October it became an approved provider to Tricare Health Plan Networks in the US, which provided health care to 9.4 million beneficiaries of the US Military health system.

Cellmid said that in October 2016 Cxbladder Monitor was adopted as a replacement for cystoscopy for low-risk patients monitored for recurrence of bladder cancer by the Waitemata District Health Board.

The company said that this month study results of the CxBladder Monitor were accepted for publication in the American Journal of Urology.

Cellmid said that the study confirmed strong performance of 93 percent sensitivity and 97 percent negative predictive value of the test and the potential of it to replace cystoscopy in low risk patients.

The company said that monitoring patients with bladder cancer was one of the most significant market opportunities for Pacific Edge as its non-invasive Cxbladder was "a clear improvement in patient care".

Cellmid said that many patients had up to 24 visits to their urologist over a five year period and might have lifelong monitoring for recurrence.

The company said that adoption by urologists would continue to depend on delivery of performance data.

Cellmid said that in November Pacific Edge announced interim results for the six months ending September 30, 2016 including a 67 percent increase in operating revenue compared with the same period in 2015.

Cellmid chief executive officer Maria Halasz congratulated Pacific Edge.

"As more data is expected to emerge from clinical collaborations on performance, we expect a broadening use of the Cxbladder tests," Ms Halasz said

Cellmid was up 0.2 cents or 7.7 percent to 2.8 cents with 3.0 million shares traded.

GI DYNAMICS

GI Dynamics has requested a trading halt "to allow it sufficient time in which to complete [a] capital raising".

Trading will resume on December 14, 2016 or on an earlier announcement.

GI Dynamics last traded at 2.5 cents.

BIONOMICS

Bionomics says issuing warrants over 16,082,988 shares to the US investors who participated in the December 2015 capital raising, is “less dilutive” than repaying cash.
Bionomics said the December 2015 $US12 million placement was to fund the phase II trial of BNC210 for post-traumatic stress disorder (BD: Jun 30, 2016).
Last year, Bionomics raised $16,404,649 at 40.8 cents a share for the post-traumatic stress disorder trial, when it had been trading around 48 cents, which led to complaints from investors about the 15 percent discount (BD: Dec 8, 2015).
In March, the Sydney-based CVC called for the removal of Bionomics chairman Graeme Kaufman and director Trevor Tappenden (BD: Mar 16, 2016).
In August, Alan Fisher replaced director Trevor Tappenden, following the departure of chairman Graeme Kaufman and CVC withdrew its notice of intention to call a general meeting (BD: Aug 15, 31, 2016).
Today, Bionomics said that the US investors were due to receive the warrants by December 15, 2016 or it would have to make a cash payment based on the value of the warrants on December 16, 2016.
Bionomics said that the warrants would be less dilutive to shareholder value per share than the cash alternative of about $4.3 million.
The company said that the retained cash would be used to expand the post-traumatic stress disorder trial,
Bionomics said that the warrants would be issued under its refreshed placement capacity and would be exercisable at 59.38 cents by December 12, 2021.
The company said that if exercised, it would receive about $9.6 million in cash and the new shares would account for about 3.1 percent of the total issued shares plus existing options and warrants outstanding.
Bionomics fell half a cent or 1.4 percent to 34.5 cents.

RACE ONCOLOGY

Race says it has appointed oncologist and acute myeloid leukaemia (AML) specialist Prof Martin Tallman to its scientific advisory board.
Race said that Dr Tallman was the New York-based Sloan Kettering Cancer Center’s leukaemia chief “and a world-recognized expert in AML”.
The company said that Dr Tallman was also a Weill Cornell Medical College professor of medicine and had been chair of the Eastern Cooperative Oncology Group Leukemia committee for 16 years, one of three oncology groups in the US responsible for coordinating large clinical trials of new therapies for acute and chronic leukaemias.
Race said that previously, Prof Tallman was at the Chicago, Illinois-based Northwestern University Feinberg School of Medicine and the Robert H Lurie Comprehensive Cancer Center for more than 20 years, where he directed the leukaemia program and was co-director of the haematologic malignancy program and associate chief of haematology oncology.
The company said that Prof Tallman joined Dr Douglas Smith and Dr Roland Walter in providing guidance for its clinical development of Bisantrene for relapsed and refractory acute myeloid leukaemia.
Race was unchanged at 21 cents.