

Biotech Daily

Monday December 19, 2016

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: BENITEC UP 9%, IDT DOWN 8%
- * UNIVERSAL BIO BUYS CANADA LAB FOR XPRECIA TEST STRIPS
- * GENENTECH \$2.75m FOR PHYLOGICA LICENCE FOR ANTIBIOTICS
- * GLOBAL KINETICS, UMOTIF PARTNER FOR PARKINSON'S TRIALS
- * IMUGENE FILES 4 IMMUNO-ONCOLOGY PATENT APPLICATIONS
- * RUSSIA GRANTS PROTEOMICS PROMERKERD DIABETES TEST PATENT
- * DORSAVI SIGNS \$100k+ BAGGAGE HANDLING HEATHROW CONTRACT
- * SIMAVITA RECEIVES \$1.7m FEDERAL R&D TAX INCENTIVE
- * SIRTEX CEO GILMAN WONG STEPS ASIDE FOR SHARE DEAL INQUIRY
- * OPTISCAN REQUESTS FUNDRAISING TRADING HALT
- * UP TO 37% OF PSIVIDA OPPOSE PAY, DIRECTORS
- * PRIMA CHANGES ADR RATIO TO MEET NASDAQ \$US1 BID RULE
- * GAVIN SMITH REPLACES POLYNOVO CFO ANDREA GOLDIE FOR LEAVE

MARKET REPORT

The Australian stock market climbed 0.53 percent on Monday December 19, 2016 with the ASX200 up 29.2 points to 5,562.1 points. Nine of the Biotech Daily Top 40 stocks were up, 15 fell, 13 traded unchanged and three were untraded.

Benitec was the best, up 0.8 cents or 8.7 percent to 10 cents with 59,122 shares traded. Bionomics and Orthocell climbed more than three percent; Ellex, Mesoblast, Opthea, Orthocell and Resmed rose more than one percent; with Airxpanders, Compumedics and CSL up by less than one percent.

Friday's best, IDT, led the falls, down 1.5 cents or 8.1 percent to 17 cents with 161,338 shares traded. Genetic Signatures lost 6.7 percent; Anteo, Factor Therapeutics and Sirtex fell more than four percent; both Neuren and Oncosil were down 3.3 percent; Acrux, Cyclopharm, Impedimed, Medical Developments and Nanosonics shed more than one percent; with Cochlear, Pro Medicus, Starpharma and Viralytics down by less than one percent.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has acquired Lifelabs' haemostasis reference laboratory to meet increased production demands of Siemen's Xprecia Stride test strips Universal Biosensors said that a wholly-owned Canadian operating subsidiary would acquire the Hamilton, Ontario-based Lifelabs LP haemostasis reference laboratory business which provided "high-quality coagulation testing and calibration services to international customers for more than 20 years" including five years for Universal Biosensors and had "one of the most diverse offerings of specialized coagulation services in the world".

The company said that acquisition terms were confidential.

In October, the US Food and Drug Administration cleared the Xprecia Stride coagulation analyzer, a handheld device which delivered prothrombin time international normalized ratio (PT/INR) testing for point-of-care monitoring and assessment of patients taking oral anticoagulation therapy warfarin and used test strips produced at the company's Rowville, Victoria facility (BD: Oct 5, 2016).

The analyzer was launched in Europe in May 2015 (BD: Dec 9, 2014; May 14, 2015). Today, Universal Biosensors said the Lifelabs laboratory had 16 different coagulation analyzers available, representing every major manufacturer for a very diverse list of testing options, and the 14 employees would transfer to Universal Biosensors' whollyowned Canadian subsidiary.

The company said that its test strips were required to be calibrated so that all PT/INR products agreed with an international standard and the acquisition gave it "more control, certainty and reduces risks in meeting expanded production demand".

Universal Biosensors said that the acquisition was funded with existing cash reserves and was not expected to have a material impact on consolidated results.

Universal Biosensors executive chairman Andy Denver said that the production demand for Siemen's Xprecia StrideM test strips had "increased significantly".

"The acquisition of [Lifelabs' haemostasis reference laboratory's] assets is a strategic move to ensure that we have better control of our entire manufacturing process and to streamline [our] production of test strips with more certainty to continue to meet stringent international standards," Mr Denver said.

Universal Biosensors was untraded at 29 cents.

PHYLOGICA

Phylogica says that Genentech will pay \$US2 million (\$A2.75 million) to extend its exclusive licence agreement to use its Phylomer drug discovery platform for antibiotics. Phylogica said that the Roche-owned Genentech research collaboration included its cell penetrating peptide discovery technology.

The company said that under the original December 2014 agreement, Phylogica was eligible to receive research, development, and commercialization milestone payments totalling up to \$US142 million (BD: Aug 18, 2014; Jan 18, 2015).

Phylogica founder and chief scientific advisor Prof Paul Watt said that the company was "delighted with the progress of our collaboration with Genentech over the last year".

"This alliance has the potential to address a critical unmet need to develop novel antibiotics to treat bacterial infections including antimicrobial-resistant infections," Prof Watt said.

"The World Health Organisation has identified antimicrobial resistance as one of the three most important problems for human health," Prof Watt said.

Phylogica was up 0.2 cents or 12.5 percent to 1.8 cents with 4.0 million shares traded.

GLOBAL KINETICS CORP

Global Kinetics says it will partner with Umotif for a validated, simple-to-use data capture platform for the treatment and understanding of Parkinson's disease.

Global Kinetics said that the combined platform using the London UK-based Umotif's technology could measure and demonstrate the value of medications, devices and services in Parkinson's disease, from clinical through to commercial phases of development.

The company said that the platform used its Parkinson's Kinetigraph, which incorporated a wrist device and internet "cloud" based algorithms to record movement symptoms including bradykinesia, dyskinesia, tremor and the relationships of these to medication timing, sleep and exercise as well as Umotif's mobile telephone and internet platform for trial data capture allowing the electronic capture of patient reported data including patient reported outcomes and clinical assessments, diaries and symptom tracking.

Global Kinetics said that its Parkinson's Kinetigraph, or PKG, system was in use in 200 clinics in 17 countries and more than 13,000 reports had been delivered to date.

The company said that its second generation Kinetigraph was designed to allow continuous use and had US Food and Drug Administration clearance, with Conformité Européenne (CE) mark expected shortly (BD: Sep 23, 2016).

Global Kinetics said that the Umotif platform had been "at the forefront of patient-centred data capture in Parkinson's disease and 15 other clinical conditions" since 2012 and was "the only platform to be proven through a large-scale randomised controlled trial" in the British National Health Service and its '100 for Parkinson's' observational study was the world's largest bring-your-own-device study, with more than 4,200 participants in the UK and US capturing millions of research data points, and validating the platform in a multi-national study.

Global Kinetics chief executive officer Timothy Still said the partnership with Umotif was "a significant strategic move for our company alongside our fast growing clinical product for routine management of Parkinson's disease".

Global Kinetics is a private company.

IMUGENE

Imugene says it has filed four new immuno-oncology patent applications with IP (intellectual property) Australia that if granted, will provide cover until 2037. Imugene said that three patents were filed under its name and were all entitled 'A vaccine composition and uses thereof' with the fourth patent filed in the name of Medizinische Universität Wien, or the Medical University of Vienna, entitled 'A method of producing a vaccine composition and uses thereof'.

The company said that three patents filed under its name protected new mimotope B-cell vaccine compositions directed to commercially validated immuno-oncology targets. Imugene said that each target already has a monoclonal antibody synthetic drug on the market and generating sales worth hundreds of millions of dollars treating cancers including melanoma, non-small-cell lung cancer, multiple myeloma and bladder cancer. The company said that the patent filed under the name of the Medical University of Vienna protected "a broad technology platform related to identifying mimotopes from available monoclonal antibodies".

Imugene chief executive officer Leslie Chong said that "maintaining and strengthening our already strong international intellectual property position is a key area of focus in maintaining the competitive advantage of our B-cell mimotope peptide vaccine portfolio". Imugene was unchanged at 1.5 cents with 10.7 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has been granted a patent in the Russian Federation protecting its Promarkerd diagnostic and prognostic test for diabetic kidney disease.

Proteomics said that the patent, entitled 'Biomarkers Associated with Pre-Diabetes, Diabetes and Diabetes Related Conditions' became effective on August 10, 2016 and would extend until September 20, 2031.

Proteomics chief executive officer Dr Richard Lipscombe told Biotech Daily that the formal documentation was received last week.

The company said that patent protection for the Promarkerd test had been granted in the US, Australia, Singapore and China, with patents pending in other jurisdictions.

Proteomics said that Russia had 16.6 million adults with diabetes, the fifth largest country after China, India, the US and Brazil, resulting in an estimated \$US14 billion in diabetes-related health expenditure.

Proteomics fell one cent or four percent to 24 cents.

<u>DORSAVI</u>

Dorsavi says it has signed a more than \$100,000, 12-month contract with Heathrow Airport to deliver Visafe wearable sensor monitoring health and safety services. Dorsavi said that the three phase program followed a 2015 Heathrow Visafe comparison assessment on the musculo-skeletal impact of using manual handling aids for the transfer of airport baggage compared to transferring baggage without the use of aids and would also return revenue through the use of the Myvisafe program.

The company said that study led to a significant increase, from 20 percent use to 80 percent use, in compliance with manual handling aids among baggage handlers. Dorsavi said Heathrow planned to make a large terminal-wide investment in new manual handling aids and had shortlisted two products.

The company said that Heathrow would using Visafe assessments to provide the evidence and data on which it would base its decision.

Dorsavi said that in January 2017 it would deliver Visafe comparison assessments to compare the safety profile of the two alternative manual handling aids to assist baggage handlers and assess the two products with respect to musculoskeletal risk, productivity and ease of use.

The company said that the second phase would use the data to help optimize manual handling practices and would use the data in an interactive training application and an internal communications campaign to effect behavior change.

Dorsavi said that third phase would see the Myvisafe program used through the baggage handling area to monitor and promote safe practice.

Dorsavi Europe head of sales and operations Zoe Whyatt said Heathrow had shown vision and would take health and safety "within the baggage handling community to a new level by using Visafe in an integrated way over the coming 12 months".

Dorsavi was up three cents or 6.25 percent to 51 cents.

<u>SIMAVITA</u>

Simavita says it has received \$1,659,600 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Simavita said the rebate related to research and development expenditure for the year to June 30, 2016

Simavita was untraded at 8.3 cents.

SIRTEX MEDICAL

After the market closed on Friday, Sirtex said that chief executive officer Gilman Wong had stepped aside while his share trading was investigated

In an announcement at 6.09pm on Friday evening, Sirtex said Mr Wong had "volunteered to take temporary leave across the New Year period" and the investigation was a result of shareholder and other enquiries and media reports, and it had engaged legal advisers Watson Mangioni to coordinate the investigation into the trading of shares in Sirtex in October 2016 by Mr Wong.

The company said that the results of that investigation were expected to be available in January 2017.

Sirtex said that Mr Wong denied any wrong-doing and the company said that its decision was made "solely for the purpose of ensuring that the concerns raised with the company are appropriately investigated, and in no way implies any wrongdoing on the part of Mr Wong".

In November, Mr Wong said he sold 74,968 shares of his 274,968 shares "to cover the tax incurred in relation to the recently vested tranche of rights" (BD: Nov 7, 2016).

Earlier this month, Sirtex downgraded its SIR-Spheres growth estimates leading to a significant fall in the share price (BD: Dec 9, 2016).

Last week, Sirtex answered an ASX query regarding the timing of the sales growth figure revision (BD: Dec15, 2016).

Sirtex fell 63 cents or 4.05 percent to \$14.94 with 1.55 million shares traded.

OPTISCAN

Optiscan has requested a trading halt "pending the release of an announcement to the market in relation to a capital raising".

Trading will resume on December 21, 2016 or on an earlier announcement. Optiscan last traded at 5.1 cents.

PSIVIDA

Up to 37.2 percent of Psivida's annual general meeting voted against most of the 15 proposed resolutions.

The strongest opposition was against the advisory resolution on executive compensation with 6,015,860 votes (37.2%) against and 10,136,615 votes (62.8%) in favor.

Psivida's notice of results said that the approval of the 2016 incentive plan and the issue of stock options to chairman Dr David Mazzo and directors Michael Rogers, Douglass Godshall, Dr James Barry and Dr Jay Ducker, were opposed by a similar number of votes. The election of those directors saw similar levels of "withheld" votes, with the exception of newly appointed chief executive officer Nancy Lurker who faced 3,343,463 withheld votes, but 13,249,154 votes in favor.

Psivida said that Ms Lurker received similar support for the approval of stock options and the grant of restricted stock units.

The ratification of the appointment of auditors Deloitte & Touche LLP was carried with more than 21 million votes in favor and 3.2 million against and on all resolutions other than the auditor appointment there were 7,829,221 broker non-votes.

The company's most recent Appendix 3B new issue announcement said that Psivida had 34,176,999 shares on issue, meaning that the largest opposition vote amounted to 17.7 percent of the company, sufficient to requisition extraordinary general meetings. Psivida was untraded at \$2.14.

PRIMA BIOMED

Prima says it will change its ratio of Australian shares to American depositary receipts (ADRs) from 30-to-one to 100-to-one to comply with Nasdaq listing rules.

Prima said the change would take effect on December 28, 2016 and followed the August 10, 2016 Nasdaq notification that it was non-compliant with the minimum bid price of \$US1.00 a share rule.

The company said that ADR holders on the record at the close on December 27, 2016 would receive one new ADR for every 3.33 old ADRs held.

Prima said that it expected the price of the ADRs would increase proportionally and meet the Nasdaq minimum bid price requirement.

On the Nasdaq on Friday, Prima was up 1.5 US cents or 2.1 percent to 73 US cents with 66,931 shares traded.

Today on the ASX, Prima was unchanged at 3.4 cents.

POLYNOVO

Polynovo says that Gavin Smith will replace chief financial officer and company secretary Andrea Goldie when she takes maternity leave from February 6, 2017.

Polynovo said that Mr Smith had experience as a chief financial officer and company secretary across several industry sectors including industrial, agribusiness, mining and financial services and his global commercial experience would be valuable as the company realizes sales in multiple markets.

Polynovo was unchanged at 28 cents with 1.4 million shares traded.