Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CLINUVEL UP 11%, BIOTRON DOWN 5%**

*** ONEVENTURES $20m FOR CLINICAL GENOMICS TEST, DR PAUL KELLY**

*** TBG: 2 TESTS ON THE MARKET, 20 MORE IN 2 YEARS**

*** MRCF $4m FOR CSIRO PARTNER MECRX**

*** 3D PARTNER 333D TO RAISE UP TO $5m FOR OZ BREWING BACKDOOR**

*** PHARMAXIS, SYNAIRGEN: 'IN-VITRO LOXL2 SUCCESS FOR IPF'**

*** PROTEOMICS TO SCREEN VENOMS FOR ANALGESICS, ANTIBIOTICS**

*** PROTEOMICS RELEASES 829k ESCROW SHARES**

*** GI DYNAMICS APPOINTS SCOTT SCHORER CEO, STARTING ON $524k**

*** USCOM APPOINTS EX-J&J CHAO XIAN DAVID HE DIRECTOR**

*** ADHERIUM: OPENS US OFFICE APPOINTS JAMES HATTERSLEY**

*** RESAPP LOSES DIRECTOR ADAM SIERAKOWSKI**

*** MEDADVISOR APPOINTS NICK ENGLAND ADVISOR**

MARKET REPORT

The Australian stock market fell 0.47 percent on Wednesday March 23, 2016 with the ASX200 down 24.3 points to 5,142.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and six were untraded.

Clinuvel was the best, up 41 cents or 10.9 percent to $4.16 with 38,226 shares traded. Cellmid was up 5.6 percent; Anteo, Benitec and Pharmaxis climbed more than four percent; Impedimed and Polynovo were up more than three percent; Atcor and Prima rose more than two percent; Orthocell was up 1.3 percent; with Cochlear and Pro Medicus up by less than one percent.

Biotron led the falls for the second day in a row, down 0.4 cents or 5.3 percent to 7.1 cents with 489,000 shares traded. Admedus and Mesoblast lost more than three percent; Acrux, Actinogen, Nanosonics, Opthea and Sirtex shed more than two percent; with CSL, Ellex, Medical Developments, Reva and Viralytics down one percent or more.

ONEVENTURES, CLINICAL GENOMICS

Oneventures says partner Dr Paul Kelly will join the Clinical Genomics board having raised $US15 million ($A19.7 million) to launch its colorectal cancer diagnostic.

The Sydney-based Oneventures venture capital firm said that the Clinical Genomics blood-based test was “2.5 times more accuracy than the current blood monitoring method and an opportunity to explore a blood-based DNA screening test for [colorectal cancer]”.

Oneventures said that the funds would advance commercialization of the two-gene blood test for post-surgical monitoring of colorectal cancer recurrence, developed in conjunction with the Commonwealth Scientific and Industrial Research Organisation.

The company said that Clinical Genomics would launch the test in collaboration with partner and shareholder, the New York-based Quest Diagnostics.

Oneventures said that the test would be marketed initially as a laboratory developed test, an in-vitro diagnostic designed, manufactured and used within a single laboratory, following testing at Clinical Genomics’ Edison, New Jersey facility with US marketing planned for “later this year”.

Oneventures said that partner and managing-director Dr Paul Kelly was the co-founder and former chief executive officer of Gemini Genomics and would be appointed a director of Clinical Genomics.

“Clinical Genomics has been a leader in the field of colorectal cancer diagnostics for some years now,” Dr Kelly said.

“Having introduced the first faecal immunochemistry test, marketed as Insure FIT … the company is already a leader in the [colorectal cancer] screening market with over three million tests sold last year, and has recently gained regulatory approval from the Chinese [Food and Drug Administration],” Dr Kelly said.

“While addressing a significant immediate opportunity in [colorectal cancer] monitoring with its highly sensitive and specific blood-based two-gene test, Clinical Genomics is also uniquely positioned to transform colorectal cancer screening in the general population,” Dr Kelly said.

“The investment opportunity fits well within the Oneventures Innovation Fund II mandate of financing later stage companies which require $5 million to $15 million to launch new products and fuel growth in international markets,” Dr Kelly said.

“This focus addresses the second valley-of-death, a term used to describe the lack of later stage venture or other funding available in Australia,” Dr Kelly said.

Clinical Genomics chief executive officer Dr Lawrence LaPointe said that part of the standard of care for post-surgical monitoring for colorectal cancer recurrence, three-monthly or six-monthly blood-based testing to measure carcino-embryonic antigen levels had poor sensitivity and specificity.

“Clinical Genomics has developed a new blood test to detect tumor-specific methylated DNA biomarkers that leak from active lesions into the circulatory system,” Dr LaPointe said. “Current data suggest that a genomic test specific for these biomarkers is more sensitive than [carcino-embryonic antigen] testing and highly specific.”

Oneventures said that colorectal cancer was a leading cause of cancer-related deaths, accounting for more than 600,000 deaths each year, but diagnosed before the cancer spread, the relative five-year survival rate was 90 percent, with about four out of 10 cases detected early.

The company said that of patients undergoing surgical treatment, 30 percent to 40 percent recurred, the majority of which presented in the first two to three years following initial diagnosis and treatment, but the early and concentrated pattern was “relatively unusual among cancers” offering the opportunity to detect signs of recurrence.

Clinical Genomics is a private company.

TBG DIAGNOSTICS (FORMERLY PROGEN PHARAMCEUTICALS)

TBG says it has two revenue earning transplant molecular diagnostics on the market with as many as 20 more in development in the coming two years.

Former Progen executive chairman and now TBG chairman Jitto Arulampalam oversaw the transformation of the company, which halted a phase III trial of PI-88 for liver cancer in 2008, triggering a demand from major investors for a return of funds raised for the trial along with a series of board spills, attempted mergers, hostile mergers and failed mergers (BD: Jul 23, Dec 1, 2008; Mar 9, 27, 2009).

Progen was 19.7 percent owned by Taiwan's Medigen, which acquired PI-88 and sold its wholly-owned subsidiary TBG Diagnostics to Progen in a back-door listing, with Medigen currently holding 51.76 percent of the company and director Edward Chang's Eternal Materials Co holding a further 18.48 percent (BD: May 1, 2015; Feb 4, 2016).

Today, Mr Arulampalam, TBG chief executive officer Eugene Cheng and director Emily Lee were in Melbourne to brief investors and the media on the new company.

The Taiwan-based Mr Cheng said that TBG had two human leukocyte antigen (HLA) diagnostics designed to match the gene on the surface of white blood cells for transplantations.

Mr Cheng said that there were more than 12,000 different human leukocyte antigens and TBG could test for the overwhelming majority.

He said that the company's US Food and Drug Administration-approved sequence specific primer diagnostic grouped the HLAs into sub-groups which was sufficient for organ transplants, but for bone marrow transplants the whole HLA gene needed to be sequenced, which theoretically included the discover of new genes.

Mr Cheng said that TBG currently had sales of about $2 million a year, of which 60 percent came from Asia and the remainder from Italy, Portugal and Germany.

Mr Cheng said that the company's diagnostic pipeline of 20 tests "will cover the full spectrum including oncology, infectious diseases, genetic diseases and blood screening".

He said the company previously had a blood screening test which was developed on 2007 and sold to the Waltham, Massachusetts-based Perkin Elmer in 2012.

Mr Cheng said that a blood screening product to detect hepatits C, hepatits B and HIV in "a few hours" was being developed at the Shanghai-based Haoyuan company and was expected to enter a Taiwan-based clinical trial in early 2017 for launch by the end of 2018.

Mr Cheng said that an oncology diagnostic product, detecting the three biomarkers EGFR, B-Raf and K-ras, would be in clinical trials this year and was being developed at the company's manufacturing plant in Xiamen, China.

He said that the test could "tell whether the drug would work and identifies mutations" and hoped to have the diagnostic on the market in 2018.

Mr Cheng said that apart from these reagents the company was also developing its own real-time, polymerase chain reaction (PCR) machine to create and next generation fully integrated machine.

Mr Arulampalam said that with $16.5 million in the bank and a total projected spend of about $12 million a year, as well as $2 million in revenue, the company had funds for about one a half years.

"We have revenue, potential acquisitions and other growth options and would like to expand the Australian shareholder base," Mr Arulampalam said.

Mr Arulampalam said that part of the company's strategy was market-based leveraging its connections in China and selling or licencing products directly to hospitals and laboratories.

He said that the fast-growing molecular diagnostics market was worth about $US6 billion.

TBG was untraded at 22 cents.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION,

The CSIRO says the Melbourne-based Mecrx has secured $4 million from the Medical Research Commercialisation Fund for its accelerating drug discovery technology.

The Commonwealth Scientific and Industrial Research Organisation said that it was collaborating with the Melbourne-based Mecrx to validate its technology platform to develop starting points for new anti-cancer drugs.

CSIRO said that it would share the research and development costs in return for milestone payments and shares in Mecrx, based on their success.

The Organisation said it had a 14.6 percent equity stake in the company and its “risk-sharing agreement” with a Victoria Government Innovation Voucher, enabled Mecrx to secure the MRCF investment.

CSIRO said that Brandon Capital managed the Medical Research Commercialisation Fund and investment manager Dr Chris Smith was also a director of Mecrx.

“Mecrx is a shining example of how the research and commercial sector can work together to accelerate Australian innovation and make a significant commercial impact,” Dr Smith said.

"CSIRO and the Victorian government were crucial in getting our technology off the ground,” Dr Smith said. “Without their funding support and expertise the idea would never have been tested and the huge potential our platform offers for new drug discovery would have gone unrealised.”

The CSIRO said that it and Mecrx were working with the Peter MacCallum Cancer Centre to develop and test a drug lead for inhibiting the biological target cMyc, a driver of destructive cell mutation in many cancers.

CSIRO chemistry group leader Dr Jack Ryan said that an effective way to successfully inhibit cMyc had eluded scientists for the past 30 years.

"We're delighted to see this work translated to drug development, which we hope will ultimately lead to clinical trials through our partners at Peter Mac and commercialization of the world's first cMyc drug," Dr Ryan said.

Peter MacCallum Cancer Centre laboratory research associate director Prof Ricky Johnstone said that the drug lead “directly targets cMyc a protein which causes cancerous cells from a wide range of organs and tissues to divide uncontrollably [and] if successful, the resulting medicine would have broad application in a large number of cancers”.

Mecrx is a private company.

3D MEDICAL

3D Medical says that partner 333D Pty Ltd is raising capital to list on the ASX through Oz Brewing and 3D investors have a priority allocation in the placement.

The prospectus said the companies hoped to raise up to $5,000,000 at two cents a share.

3D said it had a service level agreement with 333D to provide three-dimensional printing needs for the medical and healthcare sector.

Last year, 3D Medical executive chairman Dr Nigel Finch told Biotech Daily that Frank Pertile was a director of both 3D and 333D, with the latter having a sub-lease agreement to share a proportion of the office and commercial space at 3D Medical’s Port Melbourne facility (BD: Sep 7, 2015).

Today, the company said that the agreement between 3D and 333D included the priority allocation for 3D shareholders.

3D said that more information on the offer was available in the prospectus which was available at: www.ozbrewing.com.au.

3D Medical fell 0.1 cents or 1.7 percent to 5.9 cents.

PHARMAXIS

Pharmaxis says in-vitro data from collaborator Synairgen Plc supports its selective inhibitor to the lysyl oxidase type 2 enzyme for idiopathic pulmonary fibrosis.

Last year, Pharmaxis said that the Southampton, England-based Synairgen would fund further activity of the lysyl oxidase type 2 (LOXL2) enzyme inhibitor program at Pharmaxis, use its bio-bank and in-vitro lung model platform and collaborate with the idiopathic pulmonary fibrosis research team at the University of Southampton to complete pre-clinical and early clinical development (BD: Aug 5, 2015).

The company said that the idiopathic pulmonary fibrosis program would be managed by a joint steering committee through to the end of phase I or phase IIa clinical trials, at which time the collaboration would seek a licence partner.

Pharmaxis said that idiopathic pulmonary fibrosis was a potentially fatal disease that affected about 100,000 people in the US and LOXL2 enzyme was targeted because it was known to promote scar tissue which hardened and irreparably damaged the lungs of idiopathic pulmonary fibrosis patients.

Pharmaxis said it was hoped that the inhibition of LOXL2 would slow the build-up of scar tissue and improve survival rates that were worse than for many cancers.

Today, Pharmaxis said that Synairgen had announced data generated in an in-vitro model of idiopathic pulmonary fibrosis showing that the Pharmaxis enzyme inhibitors, by inhibiting LOXL2, were “able to reduce cross-linking of collagen fibres essential for the stabilization of fibrotic tissue”.

“The results of the experiments … show that the Pharmaxis enzyme inhibitors, by inhibiting LOXL2, are able to reduce cross-linking of collagen fibres in a dose dependent manner,” an attached media release from Synairgen said.

“Additionally it has also been found that collagen fibres were less organised in the presence of the inhibitors [and] it is hypothesized that this will result in less stiff lung tissue and that this may beneficially alter the course of this devastating disease,” Synairgen said.

Synairgen said it would focus on the pharmacology of the inhibitors and expected to progress one of the inhibitors into phase I clinical trials during 2017.

Pharmaxis was up one cent or 4.35 percent to 24 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has begun a therapeutic drug discovery program targeting the discovery of new analgesic, or painkilling, and antibiotics compounds.

Proteomics said it would test 50 to 100 venoms in the program, with no additional costs apart from sourcing venom samples and it had the potential to deliver significant returns.

Proteomics said it would assess potential new drug compounds from animal venom with analytical work including mass spectrometry proteome mapping to catalogue the peptides from venom by July 2016 and use its software algorithm to predict the function and activities of the peptides by October 2016, with potential lead compound testing to validate the predicated function and activities by the end of 2016.

Proteomics said the best molecules would enter pre-clinical development and begin the path towards clinical testing and potentially commercialization, and once lead compounds had been identified the company would seek to engage with pharmaceutical companies to out-licence the drug candidate or candidates.

The company said that previously it had conducted an 18-month pilot study, pre-screening 10 venoms and 2,000 compounds, with 12 molecules selectively tested and five lead compounds discovered with the potential to become mainstream drugs.

Proteomics was up two cents or 8.3 percent to 26 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that 828,952 shares will be released from escrow on April 8, 2015.
Proteomics company secretary Karen Logan told Biotech Daily that following the release of the shares, the Proteomics would have 21,352,390 shares available for trading, with a further 29,251,563 shares held in ASX escrow, for a total of 50,603,953 shares on issue.

USCOM

Uscom says it has appointed Chao Xian David He as a director.
Uscom said that Mr He was born in Shanghai, educated in Sydney and for the last nine years was based in Shanghai and Singapore as Johnson & Johnson's head of Asia Pacific business development.
The company said that Mr He previously was an associate at McKinsey & Co in Shanghai, where he was involved in mergers and acquisitions and strategy projects.
Uscom said that Mr He's appointment was "strategically conceived to strengthen the connections between Uscom and the Chinese medical market".
Uscom was untraded at 19 cents.

GI DYNAMICS

GI Dynamics says Scott Schorer has been appointed chief executive officer, effective immediately and starting on $US400,000 ($A524,401) a year.
GI Dynamics said that Mr Schorer had nearly 20 years of executive experience in the medical device industry, having founded and/or led numerous companies in the healthcare space.
The company said that following a military career as an infantry officer in the 82nd Airborne Division, Mr Schorer was a sales representative for a surgical distributor and later co-founded and was chief executive officer of Centrimed.
GI Dynamics said that following Centrimed's acquisition by Global Healthcare Exchange, Mr Schorer founded and led Innovative Spinal Technologies and was its chief executive officer for nine years achieving Conformité Européenne (CE) mark and US Food and Drug Administration approvals for five products before the company was sold to Integra Spine.
The company said that Mr Schorer led the turnaround at Systagenix Wound Management, the former Advanced Wound Care division of Johnson & Johnson and more recently was a consultant to numerous companies in the medical device, biologics and related markets.
GI Dynamics said that Mr Schorer was a co-inventor of six patents.
"I know that the company has experienced issues recently, and I intend to develop a path forward that will help Endobarrier achieve its full potential as a potentially life-changing solution for patients with type 2 diabetes," Mr Schorer said.
"I have been impressed by the positive data generated through GI Dynamics' multiple clinical studies and thousands of patients receiving Endobarrier therapy, as well as the vocal advocacy of the clinicians who have implanted Endobarrier," Mr Schorer said.
GI Dynamics said that Mr Schorer held Bachelor of Arts and Bachelor of Engineering degrees from the Hanover, New Hampshire-based Dartmouth College.
GI Dynamics fell 0.1 cents or 4.55 percent to 2.1 cents.

ADHERIUM

Adherium says it has opened an office in San Francisco, California and appointed James Hattersley as head of North America business development.
Adherium said that Mr Hattersley would lead Adherium North America's partnering and market expansion.
Adherium chief executive officer Garth Sutherland said that establishing operations in North America was "a key milestone".
"James brings a proven track record of identifying and executing commercial partnerships," Mr Sutherland said.
Adherium said that Mr Hattersley was previously Nektar Therapeutics head of business development and before that was Sun Pharmaceutical Industries head of business development.
Adherium was unchanged at 47 cents.

RESAPP HEALTH

Resapp says that Adam Sierakowski has resigned as a non-executive director.
Mr Sierakowski is a director of the Perth, Western Australia-based Trident Capital and was involved in the transition from Narhex Life Sciences to Resapp which included a capital raise of $4 million (BD: Jul 3, 2015).
Resapp fell one cent or 3.7 percent to 26 cents with nine million shares traded.

MEDADVISOR

Medadvisor says it appointed pharmacy consultancy IQ Consulting principal Nick England to its advisory board.
Medadvisor said that Mr England's "extensive international network and experience will help Medadvisor identify and prioritize global opportunities".
The company said that Mr England was formerly Alliance Boots group director head of retail at Alliance Unichem, now Walgreens Boots Alliance, in London.
Medadvisor said that Mr England was a pharmacist.
Medadvisor fell 0.1 cents or 2.9 percent to 3.3 cents.