



Biotech Daily

Wednesday April 19, 2017

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH EVEN: ACTINOGEN UP 8%, DIMERIX DOWN 12.5%
- * ROYAL SOCIETY BACKS MARCH FOR SCIENCE
- * RESEARCH AUSTRALIA: 'DOES SCRAPPING THE 457 VISA AFFECT YOU?'
- * TGA APPROVES CSL AFSTYLA FOR HAEMOPHILIA A
- * PATRYS SELECTS PAB-DX1 FOR CANCERS
- * USCOM POSTS MAIDEN CASH FLOW POSITIVE QUARTER
- * ITL SIGNS NZ BLOOD SERVICE FOR SAMPLOK SAMPLING KIT
- * TWO US PATENTS FOR REDHILL'S BEKINDA (RHB-102) FOR GASTRO
- * VICTORIA TO EXPORT 4-D SCANNERS
- * BIOXYNE TO RAISE \$3m FOR NZ ASIA SALES, NAM HOAT CHUA CEO
- * MD ANDERSON APPROVES ONCOSIL PANCREATIC CANCER TRIAL
- * PRIMA 3rd TACTIMEL MELANOMA TRIAL COHORT APPROVED
- * CYNATA READY FOR FDA PRE-IND MEETING FOR STEM CELL DEVELOPMENT
- * RESAPP EXTENDS SMARTCOUGH-C STUDY TO 1500 PATIENTS
- * ZELDA EXPANDS MEDICAL MARIJUANA TRIALS TO AUTISM
- * BENJAMIN KARASIK TAKES 10% OF ESENSE
- * NITZAN ORGAL TAKES 6% OF ESENSE
- * SIENNA PROMOTES COO MATTHEW HOSKIN TO CEO
- * BIO-MELBOURNE CONNECTING WOMEN LUNCH TICKETS SELLING FAST

MARKET REPORT

The Australian stock market fell 0.56 percent on Wednesday April 19, 2017 with the ASX200 down 32.7 points to 5,804.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, 12 traded unchanged and two were untraded. All three Big Caps fell.

Actinogen was the best, up 0.6 cents or eight percent to 8.1 cents with 1.1 million shares traded. Clinuvel, ITL, Mesoblast, Polynovo and Universal Biosensors were up more than four percent; Prima and Reva were up more than three percent; Neuren and Uscom rose more than two percent; with Admedus and Pharmaxis up more than one percent.

Dimerix led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 12.4 million shares traded. Orthocell lost 7.7 percent; IDT and Viralytics fell more than six percent; Compumedics, Impedimed, Medical Developments, Psivida and Sirtex shed more than two percent; Airxpanders, Avita, Nanosonics and Opthea were down one percent or more; with Cochlear, CSL and Resmed down by less than one percent.

MARCH FOR SCIENCE AUSTRALIA

The Royal Society of Victoria has backed the Melbourne March for Science saying its members are “alarmed” at attacks on science.

“Many of our members have indicated their alarm at the recent tenor of domestic and global political debate and rhetoric, particularly where this foments uncertainty around the validity and integrity of scientists and the scientific process, apparently to suit ideological or commercial agendas before the interests of sound objective reasoning and evidence-based decision making,” the Royal Society said in a media release.

The Royal Society said it supported the March for Science movement in Melbourne and joined organisers in calling for action on universal literacy, open communication, informed policy and stable investment.

The Royal Society said that a well-informed community was essential to a free, democratic and successful society.

“We support education to promote broad public knowledge and discussion of scientific work,” the Society said.

“Publicly-funded scientists have a responsibility to communicate their research [and] public outreach and accessibility of scientific knowledge should be encouraged,” the Society said. “Communication of scientific findings and their implications must not be suppressed.”

“Public policy should be guided by peer-reviewed evidence and scientific consensus,” the Society said. “Public policy must enable scientists to communicate their publicly-funded research results and must support literacy in science, technology, engineering and mathematics”.

“A long-term, strategic approach to investment in scientific research and development is essential for driving true innovation,” the Society said. “Government commitments to stable science funding policy will deliver solutions to our complex challenges, promoting prosperity for all.”

March for Science Australia said in a media release that 10 Australian cities would host official March for Science events on this Saturday April 22, 2017, “bringing science enthusiasts together to champion science and its potential to increase everyone’s standard of living”.

More than 500 March for Science events will take place around the world, the organization said.

March for Science said that the Melbourne rally would be addressed by former Federal Minister for Science Barry Jones, Nobel laureate Prof Peter Doherty and molecular biologist Upulie Divisekera.

March for Science organizer Kate Ferris said that the rally was not “just for scientists, it is for everyone who understands the importance of science in our daily lives”.

Ms Ferris said that March for Science was “a grassroots movement championing publicly communicated and adequately funded science as a pillar of human freedom and prosperity”.

“It began as a single event in Washington DC and has grown to become a global movement,” Ms Ferris said.

“To date, 53 countries will host marches to coincide with Earth Day,” Ms Ferris said.

“The March for Science is nonpartisan ... [and] calls for all political leaders and policymakers to adopt evidence-based policies in the public interest,” Ms Ferris said.

March for Science said that the rally had been endorsed by the Royal Society of Victoria, Friends of CSIRO, Friends of Science in Medicine and the Australian Nursing and Midwifery Federation.

For more information, go to: <https://marchforscienceaustralia.org/melbourne>.

RESEARCH AUSTRALIA

Research Australia says it wants to hear from companies and institutions that may be affected by the abolition of the 457 temporary skilled work visa.

Research Australia said that the new “temporary skill shortage visa” announced by Prime Minister Malcolm Turnbull yesterday included the abolition of six life science categories, effective from March 2018.

The industry organization said that the temporary skill shortage visa program would comprise a short-term stream of up to two years and a medium-term stream of up to four years and would support businesses “in addressing genuine skill shortages in their workforce and will contain a number of safeguards which prioritize Australian workers”. Research Australia said that there was “a steady exchange of researchers and related occupations between Australia and overseas countries”.

“While 457 visas are not the only visa class used to bring researchers to Australia, it has been an important part of the exchange of ideas, skills and knowledge,” Research Australia said.

Research Australia said that occupations removed from the 457 visa class included biochemists, biotechnologists, life scientist (general), life scientist (not elsewhere classified), nurse researcher and research and development manager.

The industry organization asked whether companies and institutes were affected in recruiting scientific workers from overseas and whether the changes would impact existing collaborations with overseas researchers?

“Alternatively, do you think this will encourage new on-shore opportunities for Australian early and mid-career scientists?” Research Australia asked/

Research Australia said it was “keen to hear” companies and institutes.

Research Australia said that respondents should contact its head of policy Greg Mullins at greg.mullins@researchaustralia.org or on +613 9662 9420 and more information was at: <http://www.border.gov.au/Trav/Work/457-abolition-replacement>.

CSL

CSL says the Australian Therapeutic Goods Administration has approved its recombinant single chain coagulation factor VIII Afstyla for haemophilia A.

Afstyla was approved by the US Food and Drug Administration in 2016 and in Europe in January (BD: May 26, 2016, Jan 22, 2017).

CSL said that Afstyla, lonoctocog alfa, was indicated in all patients with haemophilia A, or congenital factor VIII deficiency, for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, control and prevention of bleeding episodes, perioperative management, or surgical prophylaxis.

The company said that Afstyla was “the first and only single-chain recombinant factor VIII product to treat haemophilia A” and the single chain design provided sustained protection from bleeds with a strong binding affinity to Von Willebrand factor.

CSL said that in clinical trials, patients undergoing prophylaxis with Afstyla experienced a median annualized spontaneous bleeding rate of zero with two to three times weekly dosing and was demonstrated to be well tolerated with no patients discontinuing the study due to adverse events.

The company said that for an estimated 81 percent of severe haemophilia A patients who received prophylaxis every second day or three times a week, the switch to extended dosing intervals with Afstyla would reduce the number of injections required for prophylaxis therapy without compromising control of bleeding.

CSL fell \$1.07 or 0.8 percent to \$127.64 with 755,753 shares traded.

PATRYS

Patrys says it has selected PAB-DX1 to be the lead candidate in its Deoxymab 3E10 pre-clinical program for a range of cancers.

Patrys chief executive officer Dr James Campbell told Biotech Daily that the Deoxymab platform was acquired from Yale University and 3E10 was the most advanced variant, with PAB-DX1 selected for efficacy, manufacturability and novelty (BD: Mar 29, 301, 2016).

The company said PAB-DX1 was selected for its performance in a suite of in-vitro assays in collaboration with Deoxymab lead inventor, Yale's Dr James Hansen.

Patrys said that PAB-DX1 outperformed other variants in its ability to penetrate into cells' nuclei, and kill cancers cells and it outperformed native forms of the 3E10 antibody.

The company said it would produce the antibody to be used in a range of mouse models of cancers over the coming months, with the first data expected by October 2017.

Patrys said that Deoxymab 3E10 might have application for malignancies including glioblastoma, melanoma, prostate, breast, pancreatic and ovarian cancers.

"We are delighted that we have been able to create a novel and highly potent form of Deoxymab 3E10 to progress through development," Dr Campbell said.

"This is a significant milestone for the company, and is a key step as we progress an exciting early stage discovery into a compelling clinical asset," Dr Campbell said.

Patrys said that Deoxymab 3E10 was an auto-antibody originally identified in models of lupus and while most antibodies bound to markers on the surface of cells, Deoxymab 3E10 penetrated cell nuclei, binding directly to DNA and inhibiting DNA repair causing damage to accumulate.

The company said that normal cells repaired such DNA damage, but Deoxymab 3E10 killed cells that had mutations or deficiencies in DNA repair mechanisms found in various cancer cells, and as well as showing single agent therapeutic potential, Deoxymab 3E10 significantly enhanced the efficacy of both chemotherapy and radiotherapy.

Patrys was unchanged at 0.7 cents.

USCOM

Uscom says it has posted its first cash flow positive quarter.

Uscom executive chairman Prof Robert Phillips told Biotech Daily that for the three months to March 31, 2017 the company had receipts from customers of \$913,744, along with a Federal Government R&D Tax Incentive payment of \$496,634, totaling \$1,410,378 in revenue compared to \$701,291 for the three months to December 31, 2016 and \$638,059 for the three months to March 31, 2016, with cash at March 31, 2017 of \$2,133,303 compared to \$1,922,086 at December 31, 2016.

Uscom was up half a cent or 2.3 percent to 22 cents.

ITL HEALTH GROUP

ITL says the New Zealand Blood Service has signed a two year supply agreement, with renewals options, for its Samplok Sampling Kit.

ITL said that the contract, through its bio-medical division, to the New Zealand Blood Service was for its specialty ancillary products for the blood culture testing market, estimated to be worth \$US3.3 billion globally in 2016.

The company said that the NZ Blood Services provided the public with safe, appropriate and timely access to blood and tissue products and related services and its Samplok Sampling Kit was used to transfer platelet samples during bacterial detection testing.

ITL was up 2.5 cents or 4.85 percent to 54 cents.

REDHILL BIOPHARMA

The Israel-based Redhill says the US Patent and Trademark Office has allowed two patents relating to Bekinda, or RHB-102 for gastrointestinal indications.

Redhill said that the patent applications, entitled 'Antiemetic Extended Release Solid Dosage Forms' and 'Ondansetron Extended Release Solid Dosage Forms for Treating Either Nausea, Vomiting or Diarrhea Symptoms', covered claims directed to ondansetron extended-release tablets and methods of treating patients with ondansetron extended-release solid dosage forms and when granted, were expected to provide intellectual property protection until at least 2034.

The company said that in addition to the two US patent applications, the patent portfolio covering Bekinda included one US patent, two pending US patent applications, 17 non-US patents and more than 35 pending non-US patent applications.

Redhill intellectual property and research director Dr Danielle Abramson said the two additional US patents were "an important addition" to the company's portfolio.

"We are approaching significant milestones with Bekinda in the coming months" with top-line results from the phase III study for gastroenteritis and gastritis expected by July 2017 and top-line results from the phase II irritable bowel syndrome with diarrhoea trial expected by October, 2017, Dr Abramson said.

Redhill said that Bekinda was "a proprietary, bi-modal extended-release, once-daily oral pill formulation of ondansetron, targeting several gastrointestinal indications ... [and] intended to provide patients with relief from nausea and vomiting symptoms for a full 24-hour period with a single oral tablet".

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

Last night on the Nasdaq, Redhill fell three US cents or 0.3 percent to \$US9.85 (\$A13.10) with 23,288 shares traded.

VICTORIA GOVERNMENT

The Victoria Government says a four-dimensional scanner manufactured in Melbourne will be exported to the US to better diagnose and treat lung conditions.

A media release from the Victoria Minister for Industry and Employment Wade Noonan said that the "world-first scanner" would be delivered to medical research hospitals around the world, allowing clinicians to capture images giving a highly-detailed look at the motion and airflow within breathing lungs, at a lower cost and at lower radiation levels.

The Government said that the scanner would provide doctors with "a better picture of lung diseases, helping them to intervene earlier and make better decisions".

The Victoria Government said that its Sector Growth Program provided funding to a consortium made up of 4Dx, Hydrix and Monash University for the \$2.4 million pre-clinical scanner project.

The media release said that the first two scanners would be delivered to the US by the end of this year, with a further three units to be supplied by the end of 2018, generating at least \$6.7 million in export revenue over a two year period.

The Government said its Sector Growth Program provided grants of up to \$1 million to support industries.

For more information about the grants, go to: www.business.vic.gov.au/sectorgrowth.

BIOXYNE

Bioxyne says it hopes to raise \$3,064,350 to acquire a New Zealand business to sell products in Asia, with Nam Hoat Chua to be appointed chief executive officer.

Bioxyne said that the New Zealand group comprised Global Treasure New Zealand, New Zealand Nutritional Research and Pan Global Treasure Biotech Sdn Bhd, with products including the functional foods BK18 and Allura and the skincare product Bessence.

The company said that it would conduct a placement of 28,106,524 shares at 1.9 cents each to raise \$534,024 and non-renounceable rights issue to raise \$2,530,326, with two new directors to be appointed to Bioxyne's board.

Bioxyne said Mr Chua had more than 33 years' experience in sales and was the previous New Zealand New Image nutritional foods Asia-Pacific vice president, establishing sales offices in Malaysia, Indonesia, Vietnam, Thailand, Taiwan and the Philippines.

Bioxyne chairman Tony Ho said it was "an exciting business opportunity for Bioxyne to partner with an existing product development and sales company to augment our clinically-tested and patented probiotic PCC".

Bioxyne fell 0.1 cents or 4.35 percent to 2.2 cents.

ONCOSIL MEDICAL

Oncosil says the University of Texas MD Anderson Cancer Centre has approved its clinical study program of Brachysil radiotherapy for pancreatic cancer.

Oncosil said that the MD Anderson approval was the final step for US hospitals to agree to participate in the study, with the first patient recruitment expected in May 2017.

Last year, the company said the US Food and Drug Administration had approved its application for the pivotal 300-patient, , randomized, open-label 'Oncopac-1' safety and efficacy pancreatic cancer trial (BD: Aug 2, 2016).

Oncosil was unchanged at 12.5 cents with 1.4 million shares traded.

PRIMA BIOMED

Prima says approval has been granted for the third cohort of six patients its Australian phase I trial of IMP321 in combination with Keytruda (BD: Mar 15, 2017).

Prima said that third cohort in its two active immune-therapeutics for melanoma (Tactimel) trial would recruit patients with unresectable or metastatic melanoma.

The company said that interim data from the first cohort indicated IMP321 at the 1mg dose level was safe and well-tolerated (BD: Dec 22, 2016).

Prima said that safety was confirmed in the second cohort dosed with 6mg of IMP321 and the third cohort would be dosed at 30mg of IMP321.

Prima was up 0.1 cents or 3.2 percent to 3.2 cents with 3.4 million shares traded.

CYNATA THERAPEUTICS

Cynata says it will have a pre-investigational new drug application meeting with the US Food and Drug Administration in May 2017.

Cynata said that it would meet with the FDA's Office of Cell, Tissue and Gene Therapy products, to discuss the regulatory approval path for its Cymerus mesenchymal stem cell products and the process for seeking regenerative medicine advanced therapy (RMAT) designation for lead product CYP-001 for graft-versus-host disease.

The company said it expected FDA's written advice from the meeting by July 2017.

Cynata was up half a cent or 1.05 percent to 48 cents.

RESAPP HEALTH

Resapp says it will extend the Smartcough-C study to the end of May 2017 and increase maximum recruitment to 1,500 patients, aged 29 days to 12 years.

Resapp said that enrolment had progressed well across 11 recruitment locations maintained by the three participating hospitals, however the incidence of pneumonia and croup among study patients was unseasonably low (BD: Dec 9, 2016).

The company said that increasing recruitment would “ensure the study generates statistically strong results and maximize the range of diseases” included in its de novo submission to the US Food and Drug Administration.

Resapp said that the co-primary endpoints of the study were the diagnosis of pneumonia compared to clinical and radiologic diagnosis

Resapp fell 2.5 cents or 7.1 percent to 32.5 cents with 3.96 million shares traded.

ZELDA THERAPEUTICS

Zelda says it will partner with Chile’s Fundación Daya expanding its medical marijuana clinical trial program to include autism as well as insomnia and eczema.

Zelda said that the non-profit patient advocate group Fundación Daya had “solid anecdotal evidence of positive quality of life outcomes using cannabinoid-based therapy”.

The company said that, subject to regulatory approval, it expected the trial to begin by the end of 2017, with trial protocols being developed and the trial to be conducted over a period of three to six months.

Zelda was up half a cent or 4.2 percent to 12.5 cents with 6.1 million shares traded.

ESENSE-LAB

The Ra’anana, Israel-based Benjamin Karasik says he has become a substantial shareholder in Esense with 6,298,2263 shares or 10.18 percent.

Mr Karasik said that he acquired the shares at 0.3 Israeli agarot each (NIS0.003 or 0.11 Australian cents) on April 13, 2016.

Esense fell 3.5 cents or 10.45 percent to 30 cents.

ESENSE-LAB

The Hashmonaim, Occupied West Bank-based Nitzan Orgal says he has become a substantial shareholder in Esense with 3,622,515 shares or 5.86 percent.

Mr Orgal’s substantial shareholder notice said he acquired the shares at 0.3 Israeli agarot each (NIS0.003 or 0.11 Australian cents) on September 26, 2016.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed Matthew Hoskin as its chief executive officer.

Sienna said that Mr Hoskin had been its chief operating officer for the past three years and would lead the business through its next phase of growth.

Sienna chairman Dr Geoffrey Cumming said the board was “extremely pleased with progress the company has made in recent times and recognises that Matthew’s leadership has been instrumental in driving that progress”.

The company said that Mr Hoskin held a Bachelor of Applied Science from Melbourne’s Swinburne University.

Sienna is a public unlisted company.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says tickets are selling out for its ninth annual Connecting Women Lunch on Friday June 2, 2017.

The Network said that the lunch connected more than 400 women representing all facets of the biotechnology, medical technology and pharmaceutical sector.

Bio-Melbourne Network interim chief executive officer Lusia Guthrie said that the Network was “delighted” the Governor of Victoria Linda Dessau would attend the lunch to present the 2017 Women in Leadership Awards.

Ms Guthrie said “the 2017 awards have attracted a record number of nominations and they provide an excellent opportunity to recognise the women who have made outstanding contributions to innovation in the industry”.

The Network said that the awards were unique in that nominees could hold any role engaged with the sector including, but not limited to, company executives, research and development practitioners and senior representatives from supplier and service provision organisations.

The Network said that CSL continued as the premier sponsor of the Connecting Women Lunch and the Commonwealth Scientific and Industrial Research Organisation had joined as a signature sponsor for 2017, along with major sponsors Johnson & Johnson Innovation, KPMG and the State Government of Victoria.

The Bio-Melbourne Network said that there were still tickets available for the Lunch June 2, 2017, with registration from 11.45am and lunch from 12.30pm to 3pm at Mural Hall, Level 6, Myer Emporium, Bourke Street, Melbourne.

For more information go to: <https://tinyurl.com/2017CWL-2nd-June>.