

Biotech Daily

Wednesday October 30, 2019

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: LBT UP 9%; ONCOSIL DOWN 17%
- * AUSBIOTECH NATIONAL CONFERENCE OPENS
- * TELIX \$30m TO AUSHEALTH FOR APOMAB FOR OVARIAN, LUNG CANCER
- * BIOCURATE, TAKEDA ACCELERATE THERAPEUTICS, DRUGS DISCOVERY
- * CLINUVEL: TGA SCENESSE PRIORITY REGISTRATION
- * GENETIC TECHNOLOGIES RAISES \$4.5m, NASDAQ COMPLIANCE
- * SIENNA, MINOMIC WORK ON PANCREATIC CANCER BLOOD TEST
- * SUDA \$1.5m CANN PHARMA DEAL FOR MARIJUANA SPRAY
- * SOMNOMED, APP-NEA DEAL FOR DOCTOR SOFTWARE
- * MEDICAL DEVELOPMENTS 18% OPPOSE REMUNERATION REPORT
- * RESPIRI SPILL CALL, NICK SMEDLEY IN, ALASTAIR BEARD INTERIM CEO
- * MESOBLAST AGM FOR 2.4m OPTIONS
- * NEUROSCIENTIFIC 3m DIRECTOR OPTIONS AGM
- * ALTHEA AGM FOR 1.2m JOSHUA FEGAN RIGHTS
- * GI DYNAMICS: LESS THAN ONE QUARTER CASH, \$US10m NOTES
- * CREDIT SUISSE BELOW 5% IN OPTHEA
- * PARADICE INCREASES, DILUTED TO 7.8% OF PROBIOTEC
- * PROBIOTEC CHAIRMAN GEOFFREY PEARCE DILUTED BELOW 5%
- * MERCHANT TAKES 11% OF SIENNA
- * PENDAL GROUP TAKES 5% OF ALTHEA
- * CLARITY APPOINTS DR COLIN BIGGIN CEO
- * VIVAZOME APPOINTS DR DAVID HAYLOCK CEO
- * LBT 13-YEAR DIRECTOR STEPHEN MATHWIN RETIRES
- * USCOM: DR ANTONIO FERRARIO EURO SALES, MARKETING MANAGER

MARKET REPORT

The Australian stock market fell 0.83 percent on Wednesday October 30, 2019, with the ASX200 down 55.9 points to 6,689.5 points.

Ten of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and one was untraded.

LBT was the best for the second day in a row, up 1.5 cents or 8.6 percent to 19 cents with 7.5 million shares traded.

Patrys and Starpharma climbed five percent or more; Proteomics and Uscom were up more than four percent; Neuren and Orthocell improved more than three percent; Volpara rose 2.9 percent; Cochlear and Pro Medicus were up one percent or more; with Mesoblast and Resmed up by less than one percent.

Oncosil led the falls, down two cents or 16.7 percent to 10 cents, with 8.1 million shares traded.

Impedimed lost 14.7 percent; Actinogen fell 8.3 percent; Osprey shed 7.1 percent; Compumedics was down 5.4 percent; Dimerix, Imugene, Next Science, Polynovo and Resonance fell four percent or more; Opthea and Prescient were down more than three percent; Avita, Kazia, Pharmaxis and Universal Biosensors shed more than two percent; Genetic Signatures, Medical Developments, Nanosonics and Paradigm were down one percent or more; with Clinuvel, CSL, Ellex and Telix down by less than one percent.

<u>AUSBIOTECH</u>

By ALICE LYNCH

Ausbiotech chief executive officer Lorraine Chiroiu has launched the industry organization's annual conference in Melbourne.

Ms Chiroiu told the audience of investors and biotechnology executives that the conference was Australia's largest annual gathering of the biotechnology industry, this year bringing together up to 1,400 people from across Australia and 25 countries.

Ms Chiroiu also launched Australia's Lifesciences Sector Snapshot 2019 report which compared figures with a benchmark set in 2017 and showed a 12 percent overall increase in life sciences companies, including a 16 percent increase in biotechnology companies.

The report said that life sciences employees increased 4.82 percent from 232,213 people in 2017 to 243,407 people in 2019, of which 36 percent were women.

Ms Chiroiu said that the number of women in leadership was "still lagging".

Ms Chiroiu said Australia was "on track to becoming the first country to eradicate [the human papillomavirus] linked to cervical cancer".

Victoria's Department of Jobs, Innovation and Business Engagement deputy secretary David Latina said that pharmaceuticals were the state's largest source of export income and noted that half of all panellists and speakers at the conference were women.

In a keynote speech titled 'Gene Therapy, the great disruptor', science writer Dr Elizabeth Finkel said gene therapy enabled the use of the term "cure" instead of treatment.

Dr Finkel said that gene therapy used two methods: in-vivo, which injected genes directly into the patient's affected tissue, which could get through the blood-brain barrier; and exvivo which took gene cells from the patient, transformed the cells in the laboratory and injected the transformed healthy cells back into the patient.

Dr Finkel said the major hurdles for gene therapy were treating patients at the youngest possible age and avoiding exposure to antibodies used as vehicles for the gene cells.

A session titled 'Realising the potential of gene therapies: as the development of gene therapies looks more and more promising, the barriers loom large' heard contributions from Monash University's Prof Alan Trounson, the Peter MacCallum Cancer Centre's Dr Dawn Driscoll, Medicines Australia chief executive officer Elizabeth de Somer, GE Healthcare's Dr Janet Macpherson and Novartis Oncology medical director Othon Gervasio.

Ms de Somer said that gene therapies would allow sick people and their carers to re-enter the workforce, pay taxes, and contribute to society.

The panel agreed that the Victorian and Federal Governments needed to provide support to gene therapy marketing and subsidies for treatment, and that doing so would boost the economy and reduce government spending in the long term.

Ms Chiroiu chaired the 'Global update: key issues facing big pharma globally' which included contributions from Johnson & Johnson Innovation executive Kathy Connell, Merck Inc head of business development and licencing Dr Steven Bartz, Pfizer head of Asia discovery laboratories Dr Yuan-Hua Ding and CSL head of search and evaluation Dr Emma Ball.

Ms Connell said that Johnson & Johnson had created Jlab incubators, a not-for-profit "no strings attached" innovation scheme that provided funding and workspace to start-up companies with intellectual property ownership over their technologies with opportunities to develop products, network and find investors.

Dr Bartz said that 50 percent of Merck's revenue came from licencing or distribution deals, highlighting the importance of commercial deals in raising capital for innovation.

The conference continues tomorrow and Friday with the Prof Nancy Millis oration to be delivered by CSL chief scientific officer Prof Andrew Cuthbertson.

The Australia Biotech Invest and Partnering 2019 begins tomorrow with eight-minute presentation.

Throughout the conference one to one partnering meetings are available for booking.

TELIX PHARMACEUTICALS

Telix says it will pay up to \$30 million to Aushealth to develop its Apomab platform for molecularly targeted radiation for ovarian and lung cancer.

Telix said the Adelaide-based private research organization Aushealth, would lead the clinical activity at the Royal Adelaide Hospital, with a planned clinical trial to test the suitability of Apomab to deliver targeted radiation.

The company said the Apomab technology used antibodies to deliver radiation to the surface of certain types of cancer cells, and has the potential to be used for multiple types of cancers, with lung and ovarian cancers as the initial focus.

Telix said it and Aushealth would each invest \$300,000 to fund the clinical proof-of-concept and subject to successful clinical and commercial development of the technology, Telix would pay up to \$30 million in future milestone and royalty payments.

Telix chief executive officer Dr Christian Behrenbruch said that targeted radiation had "tremendous therapeutic efficacy in many different types of cancer".

"The Apomab approach may enable the use of this treatment modality in several new cancer indications that are not currently covered by Telix's pipeline," Dr Behrenbruch said. "We are co-investing with Aushealth to fast-track an initial clinical proof-of-concept to assess the clinical potential, as well as to understand how this technology may be used in conjunction with other radio chemistry technologies currently under development by Telix." Telix fell 1.5 cents or 0.9 percent to \$1.61 with 677,418 shares traded.

BIOCURATE

Biocurate says it will share commercial and scientific expertise with Takeda Pharmaceutical Company to accelerate the discovery of therapeutics and drugs. Biocurate said that the Tokyo-based Takeda would collaborate directly and through participation in Biocurate's Industry and Scientific Advisory Committee to assess new therapeutic candidates arising from Biocurate's academic partners, the University of Melbourne and Melbourne's Monash University.

The company said it was established "with a specific focus to fast-track research discoveries into early therapeutic development by addressing the barriers that limit the translation and commercialization of early-stage research".

Biocurate chief executive officer Dr Glenn Begley said Takeda had "a unique approach to collaboration that leverages diverse partnership models to unlock the best science no matter where it resides and to translate into life-changing medicines for patients".

"Each of its partnerships is created with aligned incentives, designed to leverage what each partner does best across academia and industry," Dr Begley.

The company said that Takeda had more than 200 active partnerships and through its Centre for External Innovation, had developed more than 25 companies and 45 venture financings since 2016.

CLINUVEL PHARMACEUTICALS

Clinuvel says that the Australian Therapeutic Goods Administration has granted priority registration for Scenesse for erythropoietic protoporphyria.

Clinuvel said that the process established "a target scientific evaluation timeframe" of 150 working days and it intended to submit the scientific evaluation to the TGA by April, 2020. Earlier this month, Clinuvel said that the US Food and Drug Administration approved Scenesse (BD: Oct 9, 2019).

Clinuvel fell 17 cents or 0.5 percent to \$31.19 with 330,217 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has raised \$4.5 million in a capital raising, and the company is now in a position to comply with Nasdaq listing requirements.

Earlier this month, Genetic Technologies said it raised \$4.5 million in an underwritten one-for-two rights offer at 0.4 cents a share (BD: Oct 27, 2019).

Today, the company said the funds would be used to commence sales of its breast cancer and colorectal cancer risk assessment tests in both the US and Australia.

In May, Genetic Technologies said the Nasdaq had informed it that it was below the minimum market capitalization of \$US2,500,000 (\$A3,643,281) at December 31, 2018. (BD: May 3, 2019)

Today, Genetic Technologies said that with the completed rights, it believes it has regained compliance with the Nasdaq's listing requirements.

Genetic Technologies fell 0.1 cents or 20 percent to 0.4 cents with 24.7 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has signed a research agreement with Sydney's Minomic to develop a blood test for the early detection of pancreatic cancer.

Sienna said that there was "independent evidence that the protein GPC-1 on exosomes [was] strongly elevated in the blood from pancreatic cancer patients" and it would use its Exonet exosome capture technology to isolate exosomes, with Minomic using its anti-GPC-1 antibody in a pilot study to test the feasibility of developing a pancreatic cancer assay.

The company said the collaborate would begin by determining the feasibility of producing a blood test for the screening, diagnosis and prognosis of pancreatic cancer.

Sienna said the study would be the first application of its Sienet and Exonet capture technology acquired with Sevident in April (BD: Apr 2, 2019).

Sienna said that its Exonet technology could "rapidly" capture exosomes from blood and other body fluids, and that Minomic's intellectual property could help determine if they contained the pancreatic cancer associated protein glypican-1 (GPC-1).

Sienna fell 0.4 cents or 9.1 percent to four cents.

SUDA PHARMACEUTICALS

Suda says it has a \$1.5 million deal to develop its Oromist oro-mucosal spray for marijuana derivatives with Canberra's Cann Pharmaceutical Australia.

Suda said the agreement was to develop "a novel oral spray of pharmaceutical-grade cannabinoid derivates for the treatment of drug resistant epilepsy, melanoma and motion sickness".

The company said it would arrange the manufacture and supply of the product with a 10 percent handling fee and would receive \$100,000 upfront, \$50,000 on completion of its feasibility study, \$50,000 on receipt of the feasibility study final report, \$650,000 on completion of development milestones, \$650,000 on completion of commercial milestones and 10 percent of net sales of the product.

Suda said further product development costs would be determined on completion of the feasibility study and would be funded by Cann Pharmaceutical.

Suda fell 0.1 cents or 33.3 percent to 0.2 cents with 9.9 million shares traded.

SOMNOMED

Somnomed says it has a partnership with New York's App-Nea LLC to deliver a software platform to enable dentists and physicians to collaborate on patient treatment.

Somnomed said App-Nea's internet-based information sharing platform allowed medical specialists to refer patients to sleep dentists and would enhance physician confidence to prescribe its Somnodent snoring devices to qualified sleep medicine dentists.

The company said the partnership, effective from October 1, 2019, would open a new revenue source in the sharing of one-off subscription fees by App-Nea. Somnomed was up 19 cents or 7.5 percent to \$2.71.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments has faced moderate opposition to its remuneration report with 8,661,807 votes (81.9%) in favor and 1,919,900 votes (18.1%) against.

The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.

The re-election of directors Max Johnston and Leon Hoare were passed by overwhelmingly.

Medical Developments most recent Appendix 3B new issue announcement said it had 65,607,269 shares on issue, meaning that the vote against the remuneration report amounted to 2.9 percent of shares on issue, not sufficient to requisition extraordinary general meetings.

Medical Developments fell nine cents or 1.5 percent to \$5.81 with 186,057 shares traded.

RESPIRI

Respiri says dissident shareholders have requested a meeting to appoint Nicholas Smedley as a director replacing Ross Blair-Holt and Mario Gattino.

In three separate announcements, Respiri said it received the meeting request, Mr Smedley had been appointed a director, company secretary Alastair Beard would replace former chief executive officer Mr Gattino as interim chief executive officer, with Mr Gattino continuing as a director (BD: Oct 9, 2019).

Last week, the company said Mr Blair-Holt and Prof Bruce Thompson urged the annual general meeting to vote against the re-election of Mr Gattino (BD: Oct 25, 2019).

Today, Respiri said it received a Section 249D notice under the Corporations Act 2001 to request a meeting to elect Mr Smedley and remove Mr Blair-Holt and Mr Gattino.

The company said the meeting requisition came from investors Carldem Pty, Benjamin and Victoria Richards, William and Mary Richards, Gary Heath, Raymond and Dorit Harvey, Peter Karl Braun and Rosamund Braun.

Respiri did not say when it received the request in relation to the appointment of Mr Smedley, and Biotech Daily had not received a response at the time of publication. The company said Mr Smedley was an "experienced investment banker" and had 14 years' experience at UBS and KPMG and previously worked on merger and acquisitions in the UK, Hong Kong, China and Australia.

The company said Mr Smedley held a Bachelor of Commerce from Monash University and was a "cornerstone investor in the company's last share placement in August 2019 and continues to be a key supporter of the company".

Respiri climbed 0.9 cents or 15 percent to 6.9 cents with 1.1 million shares traded.

MESOBLAST

Mesoblast will vote to grant chief executive Prof Silviu Itescu 1,885,334 options, with 500,000 options to three directors.

Mesoblast said it proposed to grant 300,000 options, exercisable at \$1.48 each, to chairman Joseph Swedish and 100,000 options each to directors Dr Eric Rose and William Burns, exercisable at \$1.83 each.

The company said it proposed to issue 538,667 short term incentive options and 1,346,667 long term incentive options to Prof Itescu, all exercisable at \$1.47 each. Mesoblast said investors would vote on the remuneration report, to elect directors Dr Rose and Mr Burns, approve the employee share option plan and ratify a previous share issue. The meeting will be held at Baker McKenzie, Level 19, 181 William Street, Melbourne, on November 27, 2019 at 9am (AEST).

Mesoblast was up one cent or 0.6 percent to \$1.785.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its annual general meeting will vote to issue 3,000,000 options to directors Brian Leedman, Matthew Liddelow, Dr Anton Uvarov and Stephen Quantrill. Neuroscientific said it would vote to issue Mr Leedman 1,200,000 options, Mr Liddelow 700,000 options, Mr Uvarov 700,000 options and Mr Quantrill 400,000 options. The company said the options were exercisable at 20 cents a share by March 7, 2021. The company said investors would vote on the remuneration report, to re-elect director Mr Quantrill, approve the 10 percent placement facility and adopt a new constitution. The meeting will be held at the NSB offices, Level 1, 45 Stirling Highway, Perth on November 29, 2019 at 10am (AWST).

Neuroscientific was unchanged at 24 cents.

ALTHEA GROUP

Althea's annual general meeting will vote to grant managing director Joshua Fegan up to 595,828 in performance rights and 595,828 retirement rights.

Althea said Mr Fegan's 595,828 retirement rights would vest in two equal tranches and not lapse on cessation of employment, while the 595,828 performance rights would have a term of 15 years, pending compound annual growth rate hurdles.

The company said shareholders would vote on the remuneration report, approval for the 10 percent placement capacity, to re-elect director Alan Boyd and approve the rights plan. The meeting will be held at DLA Piper Australia, Level 21, 140 William Street, Melbourne on November 27, 2019 at 2pm (AEDT).

Althea fell 1.5 cents or 3.8 percent to 38 cents with one million shares traded.

GI DYNAMICS

GI Dynamics says its net operating cash burn for the three months to September 30, 2019 was \$US3,012,000 (\$A4,390,126), with cash at the end of the quarter of \$US1,403,000 (\$A2,044,936).

GI Dynamics said it expected to spend \$US3,335,000 for the three months to December 31, 2019.

Earlier this month, the company said it had \$US10 million in convertible notes and warrants with Crystal Amber (BD: Oct 4, 2019).

GI Dynamics was untraded at 3.9 cents.

OPTHEA

Sydney's Credit Suisse Holdings says it has ceased its substantial holding in Opthea. Credit Suisse said that between October 22 and October 24, 2019, it bought, sold, borrowed and returned shares with a single largest sale 15,221 shares for \$53,737 or \$3.53 a share.

Opthea fell 12 cents or 3.5 percent to \$3.32 with 321,096 shares traded.

PROBIOTEC

Sydney's Paradice Investment Management says it has increased and been diluted in Probiotec from 5,270,000 shares (8.779%) to 5,796,747 shares (7.752%).

Paradice said that on October 1, 2019 it bought 526,747 shares for \$927,075 or \$1.76 each, the same price as the September placement which raised \$10.56 million. Probiotec fell four cents or 1.96 percent to \$2.00.

PROBIOTEC

Probiotec non-executive chairman Geoffrey Pearce says his shareholding has fallen below the five percent substantial mark.

Last year, Mr Pearce said that he held 3,063,628 shares or 5.04 percent of the company (BD: Mar 5, 2019).

Yesterday, Mr Pearce said that he bought shares between March 6 and April 27, 2018. In September, Probiotec raised \$10.56 million in a placement of 6,000,000 shares at \$1.76 per share, and later issued 8,750,000 shares through the executive option plan.

SIENNA CANCER DIAGNOSTICS

Perth's Merchant Funds Management says it has increased its holding in Sienna Cancer Diagnostics from 24,566,667 shares (9.19%) to 29,764,649 shares (10.99%).

Merchant said that between September 14, 2018 and October 28, 2019 it bought and sold shares, with the single largest purchase 5,066,667 shares for \$323,221 or 6.37 cents a share.

Yesterday, Merchant managing-director Andrew Chapman told Biotech Daily that the change related to the realignment and amalgamation of two funds.

ALTHEA GROUP HOLDINGS

Pendal Group says it has become a substantial shareholder in Althea with 12,000,000 shares or 5.14 percent of the company.

The Sydney-based Pendal said that between August 8 and October 25, 2019 it bought 9,183,232 shares, with a single largest purchase on October 25 of 6,000,000 shares for \$2,400,000 or 40 cents a share.

CLARITY PHARMACEUTICALS

Clarity says it has appointed acting chief executive officer Dr Collin Biggin as chief executive officer and managing director of the company.

Clarity said Dr Biggin had more than 15 years' experience, including eight years at the Oslo, Norway-based Algeta ASA.

The company said Dr Biggin had development and commercialization experience and held a Bachelor of Science and Doctor of Philosophy from the University of Glasgow. In April, Clarity appointed chief operating officer Dr Collin Biggin as acting chief executive officer, replacing Dr Matt Harris. (BD: Apr 3, 2019) Clarity is a public unlisted company.

VIVAZOME THERAPEUTICS

Vivazome says it has appointed Dr David Haylock as chief executive officer effective from November 1, 2019.

Vivazome said Dr Haylock joined the company in 2019 as chief scientific officer and had previously held leadership and management roles at CSIRO, the Australian Stem Cell Centre, the Peter MacCallum Cancer Centre and the Institute for Medical and Veterinary Sciences.

The company said in his role as chief executive officer, Dr Haylock would continue his chief scientific officer responsibilities.

Vivazome is a private company.

LBT INNOVATIONS

LBT says that non-executive director Stephen Mathwin will retire as a director, effective from today.

LBT said that Mr Mathwin was a member of the company's board since November 2006, and "provided leadership by supporting both the strategy and development of the company".

LBT chairman Kate Costello said that Mr Mathwin had been "an important and valued member of the board over the last 13 years and ... I would like to thank him for his input, diligence and assistance over this time".

LBT was up 1.5 cents or 8.6 percent to 19 cents with 7.5 million shares traded.

USCOM

Uscom says it has appointed Dr Antonio Ferrario as European sales and marketing manager to help coordinate its sales and marketing site in Budapest, Hungary. Uscom said Dr Ferrario had more than 30 years' experience in sales and marketing of medical devices, including five years at Uscom.

The company said Dr Ferrario held a Doctor of Philosophy.

Uscom was up half a cent or 4.35 percent to 12 cents.