Biotech Daily

Tuesday May 29, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: FACTOR UP 12%; ELLEX DOWN 10%**

*** VOLPARA REVENUE UP 53% to $2.6m, $8m LOSS; $5m PLAN**

*** VIRALYTICS 99% BACK MERCK TAKEOVER, '5.5-BAGGER' IN 5 YEARS**

*** MESOBLAST, CARTHERICS UNITE FOR OVARIAN, GASTRIC CANCER**

*** COMPUMEDICS REQUESTS 'CHINA CONTRACT' TRADING HALT**

*** IDT RECEIVES FDA WARNING**

*** OVENTUS COMBINATION IMPROVES SLEEP APNOEA**

*** MEDICAL DEVELOPMENTS IN IRAN; 4 COUNTRIES APPROVE PENTHROX**

*** MEDIGARD, BIO-LINK NEW PRODUCTS AGREEMENT**

MARKET REPORT

The Australian stock market was up 0.16 percent on Tuesday May 29, 2018 with the ASX200 up 9.6 points to 6,013.6 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and three were untraded. All three Big Caps were up.

Factor Therapeutics was the best, up half a cent or 11.6 percent to 4.8 cents with 1.8 million shares traded.

Airxpanders climbed 9.2 percent; ITL was up eight percent; Volpara improved 6.3 percent; Impedimed was up 5.1 percent; Cyclopharm and Prescient were up more than four percent; Telix was up 3.2 percent; Bionomics, Dimerix and Mesoblast rose more than two percent; Avita, Clinuvel, CSL and Neuren were up more than one percent; with Cochlear, Resmed, Sirtex and Viralytics up by less than one percent.

Ellex led the falls, down six cents or 9.7 percent to 56 cents with 282,530 shares traded.

Optiscan lost 6.25 percent; Benitec fell 5.9 percent; Oncosil was down 3.1 percent; Actinogen and Medical Developments shed more than two percent; Pharmaxis and Starpharma were down more than one percent; with Nanosonics and Pro Medicus down by less than one percent.

VOLPARA HEALTH TECHNOLOGIES

Volpara says revenue for the 12 months to March 31, 2018 was up 52.9 percent to $NZ2,812,000 ($A2,586,880) with net loss after tax down 7.9 percent to $NZ8,818,00 ($A8,112,070).

Volpara said that loss per share fell 14.3 percent from seven NZ cents to six NZ cents, net tangible assets per share fell 66.6 percent from nine NZ cents to three NZ cents with cash and cash equivalents at March 31, 2018 of $NZ4,842,000, compared to $NZ12,876,000 at March 31, 2017.

Earlier this month, the company said it raised $A15 million in an over-subscribed placement to institutions at 60 cents a share (BD: May 7, 2018).

Today Volpara said that it had subscriptions for $A12.5 million in shares for the planned $A3 million share plan, which would be capped at $A5 million.

The company said that annual recurring revenue, the contracted revenue expected to be booked over the next 12 months from current contracts, was up 223.5 percent to $NZ3,571,000 compared to the previous year.

Volpara chief executive officer Dr Ralph Highnam said that the transition from a capital revenue to software as a service method was proceeding well.

Dr Highnam said the first two quarters of the financial year were generally the company's weakest but the current first quarter had "started strongly".

Dr Highnam said that the company was about to begin the second stage of its Procas II project with the UK National Health Service.

In February, Volpara said its breast cancer density risk and risk-based screening software would be trialled on 8,000 women in the UK NHS 'Predicting Risk of Cancer at Screening' (Procas) study, which aimed to enhance the NHS Breast Screening Programme by including breast cancer risk prediction for women when they attended routine breast screening (BD: Feb 19, 2018).

Volpara was up five cents or 6.3 percent to 84 cents.

VIRALYTICS

Viralytics shareholders have voted overwhelmingly in favour of the $502 million Merck acquisition, with 98.86 percent of shareholders in favor.

Viralytics said that 1,276 individual holders voted for the acquisition at $1.75 a share, while 73 individual shareholders with a total of 2,063,520 shares (1.14%) opposed the transaction.

In February, Viralytics said the US-based Merck Inc (Merck Sharp and Dohme) offer was a 160 percent premium to the one-month volume-weighted average price and a 184.5 percent premium to the previous night's 61.5 cents close (BD: Feb 22, 2018).

The $1.75 offer is a 455.6 percent premium to the 31.5 cents share price when Dr Malcolm McColl was appointed chief executive officer in 2013 (BD: Jan 21, 2013).

The Merck offer is a 302.5 percent premium to the post-consolidation 56 cents share price in 2008 when Paul Hopper was appointed a director and 775 percent above the 10-year low of 20 cents (BD: Sep 4, 2008).

Today, Viralytics said that the scheme required Federal Court of Australia approval and a hearing had been set for June 4, with the scheme of arrangement expected to be effective the following day, with the company delisting from the ASX on June 5 and formal implementation on June 20, 2018.

Viralytics was up half a cent or 0.3 percent to $1.74.

MESOBLAST, CARTHERICS PTY LTD

Mesoblast says it has a partnership with Cartherics Pty Ltd to develop allogeneic off-the-shelf CAR-T cells with multiple targeting receptors for use in solid cancers.
Mesoblast said that off the shelf chimeric antigen receptor enhanced killer T (CAR-T) cell therapies had "the potential to reduce costs dramatically and open up this very effective treatment to millions of cancer patients across the world".
The company said that the initial targets of the collaboration were relapsed ovarian and gastric cancers and the two companies would jointly own the intellectual property produced using their combined technologies.
Cartherics chief scientific officer Prof Richard Boyd told Biotech Daily that the company was a private start-up housed at the Hudson Institute within the Monash Health Translation Precinct at the Monash Medical Centre in Melbourne's Clayton.
Cartherics said that cell-based immuno-oncology treatments, such as CAR-T, sought "to harness the power of the body's immune system to target and kill cancer, re-arming T-cells with seek-and-destroy capacity".
Cartherics chief executive officer Prof Alan Trounson said that his company was "excited to now be in a position to produce unique, timely and cost-effective off-the-shelf therapies that may remove many barriers to treatment for cancer".
Mesoblast said that the program would be funded by $12.6 million in direct and in-kind contributions from collaborators in the Federal Government Cooperative Research Centres Program, including Cartherics, Monash University, Hudson Institute of Medical Research and Cell Therapies Pty Ltd, with Mesoblast making "an in-kind contribution of its allogeneic cell platform technology as well as providing scientific expertise".
The company said that clinical results using CAR-T cells had yielded "unprecedented complete clearance response rates in certain blood cancer patients [but] the process poses daunting challenges".
Mesoblast said that CAR-T cells were derived from individual patient's T-cells, a complex, time-consuming and patient-specific process with a manufacturing could of more than $US400,000 and a multi-dose CAR-T therapy costing up to $US1.5 million per patient.
The company said that combining the companies' technology platforms aimed to facilitate large scale production of allogeneic CAR-T cells from induced pluripotent stem cells.
Mesoblast said that clinical-grade manufacturing and banking methods would be used to convert gene-edited induced pluripotent stem cells to "potentially limitless numbers of killer T-cells, eliminating costly resources required to produce autologous [or patient's own] CAR-T cells [which] could provide large numbers of cancer patients with access to cost-effective off-the-shelf CAR-T therapies".
Mesoblast chief executive Prof Silviu Itescu said that "with our combined technology platforms and expertize, we are ideally placed to greatly increase accessibility to this very promising new field of cancer therapeutics through the development of highly-scalable, allogeneic cellular immunotherapies".
Mesoblast was up four cents or 2.7 percent to $1.505, with 856,412 shares traded.

COMPUMEDICS

Compumedics has requested a trading halt "pending a material contract with a third party in China, in relation to its Somfit consumer sleep technology".
Compumedics said the contract would "potentially and substantially alter the outlook for Compumedics".
Trading will resume on May 31, 2018 or on an earlier announcement.
Compumedics last traded at 41 cents.

IDT AUSTRALIA

IDT says it has received a warning letter from the US Food and Drug Administration following a scheduled audit of its facilities in December 2017.

IDT said that the warning letter had concerns regarding investigations of out-of-specification results and deviations and the timely implementation of appropriate corrective actions, as well as the ability of IDT's quality system to ensure integrity of data to support manufacture of its products.

The company said that its new management team was "taking this warning letter very seriously".

"Changes have already been made which include the recruitment of quality and operational personnel and remediation activities currently underway are directed at fully addressing the concerns expressed by the FDA," IDT said.

"IDT is acting on this letter with the utmost priority, whilst fulfilling our current and future obligations to our customers," the company said.

IDT fell half a cent or six percent to 7.8 cents.

OVENTUS MEDICAL

Oventus says a seven of 13 obstructive sleep apnoea patients using a combination of its mouthguard-based systems showed improvement.

Oventus said that the "hard to treat obstructive sleep apnoea patients … who were studied in a sub-group as part of the ongoing Neura Sydney study".

The company said that the 13 patients had failed previous treatment with oral appliances and continuous positive airways pressure (CPAP).

Oventus said that using its O2Vent with its Exvent oral expiratory positive airways pressure (EPAP) valve with or without the addition of a nasal EPAP valve resulted in a statistically and clinically significant improvement in the number of obstructive sleep events from baseline of 49 ($p < 0.01$).

The company said that seven of 13 patients that had failed previous treatment with oral appliances and/or CPAP were treated successfully with a 50 percent reduction in the number of obstructive events, moving their apnoea-hypopnea index score to below 10 obstructive events an hour, without the need for CPAP intervention.

Oventus said that previous studies showed that the O2Vent devices alone could "successfully treat at least 53 percent of patients".

The company said that adding its Exvent peak end expiratory pressure (PEEP) valve technology treatment success increased significantly, estimated to be more than 75 percent.

Oventus clinical director Dr Chris Hart said that previous results showed that the O2Vent treated at least 53 percent of patients and combining trial results, "we can see that across our whole Oventus sleep treatment platform of O2Vent devices and add-on accessories, 78 percent of patients across the full spectrum from mild to severe [obstructive sleep apnoea], may able to be treated using our devices without the need for CPAP".

Oventus said that the Neura study was being conducted as part of a $2.95 million Ausindustry-funded Cooperative Research Centres Programme project, titled 'Targeted therapy for sleep apnoea: A novel personalised approach' which aimed to improve the efficacy, compliance and monitoring of sleep apnoea therapy using a tailored suite of treatments to suit the needs of the individual patient.

Oventus was up one cent or three percent to 34 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has appointed the Darman Ara group's Nikkan Pharma to distribute its Penthrox inhaled methoxyflurane analgesic in Iran.
Medical Developments said Penthrox had been approved for sale in Romania, Bulgaria, Slovenia and Cyprus and it had received its first orders for Sweden, Norway, Austria, Denmark, Finland, Slovakia and Poland as well as second orders for Austria and Slovakia.
Medical Developments chief executive officer John Sharman said that Darman Ara was working with the company to have Penthrox approved for sale by the Iran Ministry of Health, expected by July 2019.
"We have already conducted a clinical trial in Iran and Penthrox is successfully through the first stage of the regulatory approval," Mr Sharman said.
"Iran is a wealthy, highly-regulated and controlled healthcare market," Mr Sharman said.
"Penthrox is a fast-acting non-opioid, non-addictive yet powerful analgesic so the opportunity for Penthrox in treating trauma and surgical pain in Iran is significant," he said.
Medical Developments fell 13 cents or 2.2 percent to $5.85.

MEDIGARD

Medigard says it has an agreement with Bio-Link Australia Pty Ltd to assist with a new technology management and commercialization program.
Medigard said the program would "identify, manage and commercialize new products to augment our existing syringe technology partnered with Sol-Millennium".
In 2014, the company said it had a $300,000 convertible note with partner the China-based Shanghai Sol-Millennium Medical Products Co to be used for working capital, patent costs and further product development (BD: Feb 2, 2011).
The company said has made very few announcements to the ASX but last year said it had appointed Noxopharm director and Cynata founder Dr Ian Dixon as an executive director starting on $240,000 a year, following a review of business and technology opportunities by Dr Dixon's Altnia Group (BD: No 22, 2017).
In December, the company said it hoped to raise up to $640,000 in a share plan at two cents, a discount of 33.3 percent to its price at the announcement (BD: Dec 7, 2017).
On January 2, 2018 filed an Appendix 3B new issue announcement saying it would issue 18,150,000 shares at two cents a share, valued at $363,000.
Today, Medigard said the Bio-Link deal aimed "to extend [its] capabilities into selected medical-related research, intellectual property development and commercialization".
Dr Dixon said "we will progress selected [research and development] projects to the point of proof-of-concept relatively quickly and without spending large amounts of money".
Medigard said it would pay Bio-Link consulting fees and all new intellectual property arising from the program would be owned by Medigard.
The company said it had about 118 million shares on issue and cash of about $400,000.
Medigard said its executives participated in a placement last year and the funds remained in the company as a loan until shareholder approval was obtained, which would result in the issue of a further 10 million shares.
Medigard was untraded at 1.8 cents.