Biotech Daily

Thursday February 22, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: VIRALYTICS UP 170%; ITL DOWN 17%**

*** MERCK $502m FOR VIRALYTICS' CAVATAK CANCER IMMUNOTHERAPY**

*** MESOBLAST: US PHASE III GVHD TRIAL 'MET PRIMARY ENDPOINT'**

*** STARPHARMA RECEIVES $3.7m FEDERAL R&D TAX INCENTIVE**

*** ITL H1 REVENUE DOWN 25% TO $13m, PROFIT UP 313% TO $8.7m**

*** IMPEDIMED REVENUE DOWN 34% TO $2.3m, LOSS UP 4% TO $14.4m**

*** CELLMID H1 REVENUE UP 47% TO $3.2m, LOSS DOWN 28% TO $1.1m**

*** ALLEGRA H1 REVENUE DOWN 11% TO $2.4m, PROFIT to $198k LOSS**

*** NAL VALIDATES NUHEARA EAR ID**

*** STRYKER ADOPTS DORSAVI VISAFE**

*** US PATENT FOR ORTHOCELL 'CELL FACTORY'**

*** IMAGION APPOINTS DR FARIDEH BISCHOFF FOR CLINICAL RESEARCH**

MARKET REPORT

The Australian stock market was up 0.12 percent on Thursday February 22, 2018 with the ASX200 up 7.2 points to 5,950.9 points. Twenty of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and three were untraded. All three Big Caps rose.

Unsurprisingly, Viralytics was the best (see below) up $1.065 or 170.4 percent to $1.69 with 7.45 million shares traded. Mesoblast and Oncosil climbed more than 11 percent; Psivida and Telix were up more than eight percent; Starpharma was up 7.8 percent; Neuren and Opthea improved more than five percent; Cyclopharm and Orthocell were up more than four percent; Acrux, Clinuvel, Dimerix, Nanosonics and Pro Medicus were up more than three percent; Optiscan and Volpara rose more than two percent; Bionomics, Cochlear and Pharmaxis were up more than one percent; with CSL, Ellex and Resmed up by less than one percent.

ITL led the falls, down 6.5 cents or 17.1 percent to 31.5 cents with 245,394 shares traded. Benitec lost 6.8 percent; Avita fell 3.2 percent; Admedus and Airxpanders shed two percent or more; Compumedics, Reva, Universal Biosensors and Uscom were down more than one percent; with Sirtex down 0.3 percent.

VIRALYTICS

Viralytics says that Merck Inc will acquire the company for its Cavatak oncolytic immunotherapy for $502 million, with the deal expected to close on June 20, 2018.

Viralytics said that the US-based Merck Inc (Merck Sharp and Dohme) would offer shareholders $1.75 a share through a scheme of arrangement.

The company said the offer was a 160 percent premium to the one-month volume weighted average price and a 184.5 percent premium to last night's close of 61.5 cents.

Viralytics chairman Paul Hopper said in an email last night that it was "truly a monumental day, not just for Viralytics shareholders, but also the Australian biotech industry where home-grown Australian technology developed by our scientific founder, Prof Darren Shafren at Newcastle University, receives both international scientific accolades, and also financial recognition in one of the biggest Australian biotech deals ever".

"It has been a long journey from the near bankrupt status of the company when I became chairman, to today's news," Mr Hopper said. "I well remember the days when our market cap was $5 million and raising funds was well nigh impossible."

"I want to record my thanks to Viralytic's leadership team and our staff for the way they have built momentum in the company which has led to one of the most prestigious pharmaceutical companies globally, to see the merit and promise in our Cavatak technology," Mr Hopper said.

"I want to pay tribute to Darren Shafren for his unswerving belief in his technology - in the early days treating cancer with a virus was seen as on the fringe - he never gave up," Mr Hopper said.

"[Dr] Malcolm McColl, our chief executive officer, has done an outstanding job in his stewardship of the company and built an impressive team around him," Mr Hopper said.

"He is highly regarded by international life science funds as evidenced by the blue-chip share register he has built over the past years," Mr Hopper said.

"We would not be where we are today without both of them," Mr Hopper said.

"Cavatak is in safe hands with Merck and we will follow its development with great interest for the incredible promise it holds for cancer patients," Mr Hopper said.

"It is one of the highlights of my business career to have chaired Viralytics," Mr Hopper said.

In a media release to the ASX, Viralytics said that Cavatak was based on its formulation of the oncolytic virus Coxsackievirus type A21 that had been shown to preferentially infect and kill cancer cells (BD: Feb 10, 2017).

The company said Cavatak was being evaluated in multiple phase I and phase II trials, both as an intra-tumoral and intravenous agent, including in combination with Merck's Keytruda, or pembrolizumab, an anti-programmed cell death protein 1 (PD-1) therapy.

Viralytics said the November 2015 agreement with a Merck Sharp and Dohme subsidiary was investigating the use of the Cavatak and Keytruda combination in melanoma, prostate, lung and bladder cancers.

Merck Research Laboratories chief medical officer Dr Roy Baynes said that "Viralytics' approach of engaging the innate immune system to target and kill cancer cells complements our immuno-oncology strategy, which is focused on the rapid advancement of innovative monotherapy approaches and synergistic combinations to help the broadest range of cancer patients".

"This proposed acquisition culminates years of dedicated work by the Viralytics team and represents an opportunity for significant value creation for our shareholders," Dr McColl said.

Viralytics said the deal was subject to shareholder and regulatory approvals.

Viralytics closed up $1.065 or 170.4 percent to $1.69 with 7.45 million shares traded.

MESOBLAST

Mesoblast says its phase III paediatric trial of MSC-100-IV for steroid refractory acute graft versus host disease met the primary endpoint of day-28 overall response.

Mesoblast said that 55 children were enrolled in the open-label study at 32 US sites, with an overall response rate at day-28 of 69 percent, a statistically significant increase compared to the protocol-defined historical control rate of 45 percent ($p = 0.0003$).

The company said that among the 50 patients who received at least one treatment infusion and were followed up for 100 days, the mortality rate was 22 percent, compared to day-100 mortality rates as high as 70 percent in patients who fail to respond to initial steroid therapy.

Mesoblast acquired its mesenchymal stem cells assets from Osiris in 2013 for up to $105.7 million in cash and scrip, including Prochymal which was available at that time under an extended access program for graft versus host disease (BD: Oct 11, 2013).

Today the company said that MSC-100-IV, which it named "remestemcel-L" was well tolerated and the incidence of adverse events was "consistent with that expected from the underlying disease state and in line with previous remestemcel-L use".

In 2016, Mesoblast said that the 60-patient trial had passed a "futility test" consistent with the 241-patient expanded access program (BD: Feb 22, Nov 14, 2016).

Today, Mesoblast said the 55-patient safety and efficacy results were consistent with the 241-patient data.

The company said that the phase III results were presented at the tandem meetings of the Centre for International Blood and Marrow Transplant Research and the American Society of Blood and Marrow Transplantation in Salt Lake City from February 21 to 25, 2018.

Mesoblast said that full results from the ongoing trial would be provided by July 2018.

The company's senior investigator Dr Joanne Kurtzberg said the children were "a very challenging patient population as they suffer from a particularly aggressive and life-threatening disease for which there are currently no available treatments".

"We are now seeing that children who receive remestemcel-L can have significant overall response rates and reduced early mortality," Dr Kurtzberg said.

Mesoblast said that, based on interactions with the US Food and Drug Administration, it believed that successful results from the trial, together with day-180 safety and quality of life parameters, might provide sufficient clinical evidence for filing for accelerated approval of remestemcel-L in the US.

Mesoblast chief executive Dr Silviu Itescu said the results were "tremendous … [and] show the potential of our cell therapies to make a substantial difference in the treatment of patients with serious and life-threatening diseases".

Mesoblast was up 16.5 cents or 11.7 percent to $1.575 with 4.4 million shares traded.

STARPHARMA

Starpharma says it has received $3,746,905 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Starpharma said the rebate related to Australian research and development expenditure for the year to June 30, 2017, for work on its Vivagel and dendrimer drug delivery programs.

Starpharma chief executive officer Dr Jackie Fairley said the Federal Government Tax Incentive program was "a significant driver of innovation in Australia and has assisted Starpharma to advance its dendrimer technology into late-stage and commercial products".

Starpharma was up 10.5 cents or 7.8 percent to $1.445.

ITL

ITL says revenue for the six months to December 31, 2017, was down 25.0 percent to $13,098,000 with the net profit after tax up 313.1 percent to $8,745,000.
ITL said its Australia healthcare division profit was up 313.1 percent primarily due to the sale of its supplies packing business to the Salt Lake City, Utah-based Merit Medical Systems for $14.4 million in October last year (BD: Oct 3, 2017).
The company said that, excluding the sale of its supplies packing business, it had recorded a loss of $207,000 for the six months to December 31, 2017, compared to the $2,117,000 net profit after tax for the six months to December 31, 2016.
The company said that net tangible asset backing per share was up 63.5 percent to 17.0 cents at December 31, 2017, while diluted earnings per share was up 300.0 percent from 2.2 cents to 8.8 cents, with cash and cash equivalents of $4,722,000 at December 31, 2017 compared to $1,371,000 at December 31, 2016.
ITL fell 6.5 cents or 17.1 percent to 31.5 cents.

IMPEDIMED

Impedimed says that revenue for the six months to December 31, 2016 was down 25.1 percent to $2,287,000 with net loss after tax up 4.5 percent to $14,417,000.
Impedimed said the revenue was primarily from sales of its L-Dex U400 lymphoedema test, as well as its body composition diagnostic technology and the increase in net loss after tax was primarily attributed to a decrease in gross profit as it began to “transition existing customers … to Sozo”.
The company said that diluted loss per share was constant at 4.0 cents for the six months to December 31, 2017, while net tangible assets per share fell 42.1 percent to 11.0 cents, compared to 19.0 cents at December 31, 2016, with cash and cash equivalents of $42,406,000 at December 31, 2017, compared to $73,236,000 at December 31, 2016.
Impedimed was unchanged at 72 cents.

CELLMID

Cellmid says its revenue for the six months to December 31, 2017 was up 47.1 percent to $3,205,540 with net loss after tax down 27.8 percent to $1,091,134.
Cellmid said most of its revenue was from sales of its Évolis hair loss treatment.
Cellmid said that net tangible assets per share was down 51.1 percent to 5.0 cents at December 31, 2017, with diluted loss per share down 36.9 percent to 2.12 cents and it had cash and cash equivalents of $3,509,134 at December 31, 2017 compared to $5,345,308 at December 31, 2016.
Cellmid was up 1.5 cents or three percent to 52 cents.

ALLEGRA ORTHOPAEDICS

Allegra says that revenue for the six months to December 31, 2017 fell 11.1 percent to $2,357,418 with last year’s $179,277 net profit after tax turned to a loss of $198,057.
The company said that last year’s diluted earnings per share of 0.28 cents turned to a diluted loss per share of 0.22 cents for the six months to December 31, 2017, while net tangible assets per share climbed 27.2 percent from 5.33 cents at December 31, 2016 to 6.78 cents at December 31, 2017 and it had cash and cash equivalents of $2,251,183 at December 31, 2016, compared to $1,075,133 at December 31, 2016.
Allegra was unchanged at 16 cents.

NUHEARA

Nuheara says the Sydney-based National Acoustic Laboratories has clinically validated its Ear ID hearing assessment procedure.
Nuheara said the Ear ID technology created “a unique personal hearing profile by evaluating … [individual] hearing capabilities”.
The company said the assessment procedure had shown Ear ID to be as reliable as conventional clinical hearing tests when conducted in a quiet environment.
Nuheara said that 97.5 percent of hearing thresholds derived by the Ear ID system were within five decibels (5dB) of those measured on subsequent retests and that the results indicated a “high level of repeatability of threshold determination using the technology”.
National Acoustic Laboratories researcher Dr Elizabeth Beach said that “while the tests were done in a quiet controlled environment, these results are quite impressive”.
“Although Ear ID is not a substitute for having a hearing health professional test the health of one’s hearing, the results demonstrate that Ear ID is a valid means of personalising Nuheara’s Iqbuds Boost devices to a person’s unique hearing ability,” Dr Beach said.
Nuheara was up 0.2 cents or 3.3 percent to 6.2 cents.

DORSAVI

Dorsavi says it has signed an agreement with the Kalamazoo, Michigan-based Stryker Corp to use its Visafe wearable sensor workplace assessment product.
Dorsavi said that Stryker manufactured products and services for the orthopaedics, medical and surgical, and neurotechnology and spine fields.
The company said that Visafe had been adopted by companies in the healthcare, aged care, transport, and utilities industry, reflecting its “broad applicability, open market opportunity and growing demand for data-driven [products]”.
Dorsavi chief executive officer Dr Andrew Ronchi said that “work-related musculoskeletal pain is a well-reported occupational health issue among a broad range of workers with physically demanding roles”.
The company provided no further details of the agreement.
Dorsavi was up half a cent or 2.3 percent to 22.5 cents.

ORTHOCELL

Orthocell says it has been granted a US divisional patent for to its “cell factory derived bioactive molecules” to generate tissue-specific growth factors for regeneration.
Orthocell said that the patent, entitled ‘Method of producing native components, such as growth factors or extracellular matrix proteins, through cell culturing of tissue samples for tissue repair’ would provide intellectual property protection until 2027.
Orthocell managing-director Paul Anderson said the patent added value to the company’s regenerative medicine product portfolio.
“As the population ages and musculoskeletal conditions become more prevalent, doctors and patients are seeking innovative and cost-effective treatments that alleviate symptoms and return patients to activities of daily living,” Mr Anderson said.
“Implantation of cultivated cell-derived proteins have the potential to be a clinically effective procedure for regeneration of bone, cartilage and other soft tissue injuries either on their own or combination with Orthocell’s Celgro collagen scaffold,” Mr Anderson said.
Orthocell said that the intellectual property was based on research by its director Prof Lars Lidgren at Sweden’s Lund University.
Orthocell was up 1.5 cents or 4.8 percent to 32.5 cents.

IMAGION BIOSYSTEMS

Imagion says it has appointed Dr Farideh Bischoff as head of clinical research.

Imagion said that Dr Bischoff would lead the company's Magsense cancer detection technology clinical program "working to achieve regulatory approval as a diagnostic device for the early detection of malignant tumor cells".

The company said that Dr Bischoff previously worked for the San Diego, California-based Biocept and led the US National Institute of Health's non-invasive foetal trisomy test, or prenatal down syndrome test.

Imagion said that Dr Bischoff held a Doctorate of Philosophy from the University of Texas, Houston and that her doctoral thesis had "led to the discovery of the p53 tumor suppressor gene".

Imagion fell 0.3 cents or 4.6 percent to 6.2 cents.