Biotech Daily

Monday February 24, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYCLOPHARM UP 8%; RESONANCE DOWN 30%**

*** MESOBLAST: 66% GVHD PATIENTS RESPOND TO RYONCIL AT DAY-28**

*** PROBIOTEC H1 REVENUE UP 33.5% TO $44m, PROFIT UP 65% TO $1.8m**

*** ALCIDION H1 REVENUE UP 12.5% TO $8.2m, LOSS UP 213% TO $1.8m**

*** STARPHARMA H1 REVENUE UP TO $5.7m, LOSS DOWN 19% TO $5.9m**

*** RESONANCE H1 REVENUE UP 3% TO $1.9m, PROFIT TO $1m LOSS**

*** TELIX REVENUE $3.5m, LOSS UP 102% TO $28m**

*** USCOM: 'CRITICAL CARE GUIDELINES BACK USCOM 1A FOR SEPSIS'**

*** STRYKER LEIBINGER EVALUATES DORSAVI SENSORS**

*** CLINUVEL SINGAPORE LABORATORY EXPANSION**

*** OVENTUS APPOINTS AEROFLOW OVENTUS DISTRIBUTOR**

*** LITTLE GREEN PHARMA $10m MORE MARIJUANA IPO OPENS DOWN 7%**

*** SIMAVITA REQUESTS 'PLACEMENT' TRADING HALT**

*** AUSCANN: CLIFFORD HALLAM REPLACES API AS DISTRIBUTOR**

*** EXOPHARM CLARIFIES CEVARIS STATEMENT**

*** NEUROTECH MENTE DISCOUNT CODE REFERRAL PROGRAM**

*** REGAL FUNDS BELOW 5% IN ONCOSIL**

MARKET REPORT

The Australian stock market fell 2.25 percent on Monday February 24, with the ASX200 down 160.7 points to 6978.3 points. Six of the Biotech Daily Top 40 stocks were up, 30 fell, three traded unchanged and one was untraded. All three Big Caps fell.

Cyclopharm was the best of the few, up 8.5 cents or 7.98 percent to $1.15 with 5,335 shares traded, followed by Proteomics up 7.8 percent to 34.5 cents with 80,176 shares traded. Patrys climbed 6.25 percent; Osprey and Uscom were up more than five percent; with Genetic Signatures up three percent.

Resonance led the falls, down six cents or 30 percent to 14 cents with eight million shares traded. Oncosil lost 12.1 percent; Antisense and Medical Developments fell more than 10 percent; Amplia shed 7.8 percent; Immutep and Polynovo were down more than six percent; Alterity, Avita, Imugene, Mesoblast, Nanosonics, Neuren, Orthocell, Starpharma, Telix and Volpara fell more than five percent; Cynata, Ellex, Impedimed and Pro Medicus fell more than four percent; Actinogen, Clinuvel, Cochlear, Compumedics, CSL, Kazia, LBT, Opthea and Paradigm were down three percent or more; Prescient and Resmed shed more than one percent; with Next Science down 0.8 percent.

MESOBLAST

Mesoblast says that aggregated results from 309 children with graft versus host disease treated with Ryoncil shows 66.0 percent had an overall response at 28 days.

Mesoblast previously referred to Ryoncil as remestemcel-L, originally named Prochymal when Mesoblast acquired the stem cell assets of Osiris in 2013 (BD: Oct 11, 2013).

Today, the company said the data from three trials was aggregated and presented at the American Society for Transplantation Cellular Therapy and the Center for International Blood & Bone Marrow Transplant Research meeting in Orlando, Florida on February 22.

Mesoblast said the data showed Ryoncil treatment resulted in consistent treatment responses and survival outcomes in children with steroid-refractory acute graft versus host disease (GvHD).

The company said “consistent safety and efficacy were observed across the continuum from first-line treatment after steroid failure through the most challenging patients who received Ryoncil as salvage after exhausting all other options”.

Mesoblast said that results were consistent across all grades of disease, and in the most severe patients, who accounted for 252 patients, or 81.55 percent of all treated patients, day-28 overall response was 65.1 percent, or 164 patients.

The company said that overall response at day-28 was strongly predictive of survival at day-100 and day-180 and a Mesoblast executive told Biotech Daily that of the 204 patients responding at day-28, 171 patients (83.8%) survived to day-100.

The executive said the data for day-180 survival was from a much smaller trial showing that 39 patients of 47 day-28 responders (83.0%) survived to day-180.

Mesoblast said that day-28 responders were more than twice as likely to survive as non-responders, with 84 percent of day-28 responders surviving to day-100 compared to 39 percent of day-28 non-responders at day-100, and 83 percent of day-28 responders surviving to day-180 compared to 38 percent of day-28 non-responders.

The company said that Ryoncil was well tolerated with no infusion-related toxicity and no identified safety concerns.

Mesoblast chief medical officer Dr Fred Grossman said the data showed “consistent efficacy and safety” for Ryoncil in children with steroid refractory acute GvHD.

The company said it had filed a biologics licence application to the US Food and Drug Administration for Ryoncil for paediatric steroid-refractory acute graft versus host disease and had requested priority review under the existing fast track designation and if approved, Ryoncil would be launched in the US in 2020.

Mesoblast fell 16 cents or 5.8 percent to $2.59 with 3.9 million shares traded.

PROBIOTEC

Probiotec says revenue for the six months to December 31, 2019 was up 33.5 percent to $44,108,841 with net profit after tax up 64.6 percent to $1,805,313.

Probiotec said revenue came from its contract drug manufacturing services and product development, with further revenue from the acquisition of Australian Blister Sealing and Contract Pharmaceutical Services of Australia which provided pharmaceutical, cosmetic and food packaging services (BD: Jul 31; Dec 10, 2019).

The company said net tangible assets per share fell 64.0 percent to 21.0 cents, diluted earnings per share rose 64.8 percent to 2.72 cents, and it had cash and cash equivalents of $8,372,640 at December 31, 2019 compared to $19,807,297 at December 31, 2018.

Probiotec said that a fully franked interim dividend of 1.5 cents a share for shareholders on the record date of March 4 would be paid on March 19, 2020.

Probiotec fell 15 cents or 6.4 percent to $2.20.

ALCIDION GROUP

Alcidion says revenue for the six months to December 31, 2019 was up 12.5 percent to $8,164,953 with net loss after tax up 212.6 percent to $1,760,546.
Alcidion said revenue was from sales and contracts of its hospital and healthcare patient management, communication and decision support technologies and the net loss of $1.8 million was due to “investments made to accelerate operations”.
Alcidion said diluted loss per share was up 185.7 percent to 0.2 cents, net tangible asset backing per share was up from 0.12 cents to 2.08 cents and it had cash and equivalents of $10,162,524 at December 31, 2019 compared to $1,324,043 at December 31, 2018.
Alcidion said it expected its revenue for the year to June 30, 2020 to be $15.4 million, compared to $16.9 million in the previous corresponding period.
Alcidion fell 1.5 cents or 7.3 percent to 19 cents with 5.2 million shares traded.

STARPHARMA

Starpharma says revenue for the six months to December 31, 2019 was $5,671,000, with net loss after tax down 19.3 percent to $5,863,000.
Starpharma said that revenue included a $US3 million ($A4.48 million) Astrazeneca milestone payment and $1,228,000 from sales and royalties of its Vivagel BV for bacterial vaginosis and Vivagel condoms (BD: Feb 11, 2020).
The company said net tangible assets per share fell 23.1 percent to 10 cents, with diluted loss per share down 19.4 percent to 1.58 cents, and it had cash and cash equivalents of $35,876,000 at December 31, 2019 compared to $41,251,000 at December 31, 2018.
Starpharma fell seven cents or 5.7 percent to $1.15.

RESONANCE HEALTH

Resonance says revenue for the six months to December 31, 2019 was up 2.6 percent to $1,891,000 with the previous $935,000 profit turned to a loss of $1,122,000.
Resonance said revenue mostly came from sales of its Ferriscan and Ferrismart liver iron diagnostics, along with the Ferriscan voucher program, clinical trials and other studies.
The company said that the loss was mostly due to director options expense of $1,695,899.
Resonance said net tangible assets per share was up 40.6 percent to 0.90 cents, the previous 0.23 cents diluted earnings per share turned to a 0.26 cents loss per share and it had cash and equivalents of $3,387,235 at December 31, 2019 compared to $2,144,370 at December 31, 2018.
Resonance fell six cents or 30 percent to 14 cents with eight million shares traded.

TELIX PHARMACEUTICALS

Telix says revenue for the 12 months to December 31, 2019 was $3,485,000 with net loss after tax up 101.5 percent to $27,867,000.
Telix said revenue came from the first significant sales of its prostate and renal cancer imaging technologies, including the $5.7 million deal with Advocate Aurora Health, and it spent $21,162,000 on research and development (BD: Jul 9, 2019).
Telix said that diluted loss per share was up 74.6 percent to 11.94 cents, with net tangible assets per share up from 6.67 cents to 25.99 cents for the year to December 31, 2019.
Telix said it had cash and cash equivalents of $44,598,000 at December 31, 2019 compared to $25,771,000 at December 31, 2018.
Telix fell nine cents or 5.6 percent to $1.51.

USCOM

Uscom says its ultra-sonic cardiac output monitor 1A (Uscom 1A) has been included in the Society of Critical Care Medicine guidelines for treating severe sepsis in children.

Uscom said the Guidelines were a consensus review of literature over the last 20 years, and published by the Mount Prospect, Illinois-based Society of Critical Care Medicine, the Brussels-based European Society of Intensive Care Medicine and the Geneva-based World Federation of Pediatric Intensive and Critical Care Societies.

The company said sepsis was “a serious and often fatal complication of all infectious diseases, including the seasonal infections such as ’flu and coronavirus”.

The company said the guidelines follow the inclusion of the Uscom 1A in the Chinese Government coronavirus national guidelines and in the Wuhan and Hubei paediatric coronavirus guidelines over the last two weeks.

Uscom executive chairman Prof Rob Phillips said the SCCM guideline “recognizes the effectiveness of our Uscom 1A in the diagnosis and treatment of the life-threatening complications of serious infections at a time of increasing global risk”.

Uscom was up 1.5 cents or 5.6 percent to 28.5 cents with 1.9 million shares traded.

DORSAVI

Dorsavi says it has a six-month, second stage agreement with Stryker Leibinger GmbH to use and evaluate its wearable sensors, software and algorithms.

In 2018, Dorsavi said the Freiburg im Breisgau, Germany-based Stryker it would evaluate the company’s Vimove2 wearable sensors (BD: Jul 18, 2018).

Today, Dorsavi chief executive officer Dr Andrew Ronchi said the second stage of the project would allow Stryker to capture data from patients and “explore the relevance of this data in improving the management of patients with orthopaedic conditions”.

Dorsavi was untraded at 2.1 cents.

CLINUVEL

Clinuvel says its Singapore subsidiary Vallaurix Pte plans to expand the research and development capacity of its laboratory, by July 1, 2020.

Clinuvel said the Singapore Economic Development Board would give Vallaurix $S500,000 ($A547,000) over three years to support the expansion, under the Research Incentive Scheme for Companies program.

The company said the expansion would include a new biological and analytical laboratory, which would operate under good laboratory practice standards.

Clinuvel fell 92 cents or 3.7 percent to $24.14 with 214,228 shares traded.

OVENTUS MEDICAL

Oventus says the Asheville, North Carolina-based Aeroflow Healthcare has begun to sell its mouthguard-styled products for obstructive sleep apnoea in the US.

Oventus said Aeroflow would distribute the Oventus Sleep Treatment Platform, including the O2Vent Optima, through shops, electronic commerce and agreements with referring sleep clinics across the south-eastern US states”

The company said Aeroflow would offer Oventus products under subcontracts with regional sleep groups across the US.

Oventus fell 3.5 cents or 5.3 percent to 62 cents.

LITTLE GREEN PHARMA

Little Green Pharma says it raised $10 million at 45 cents a share to grow marijuana and sell medical marijuana products.

Last week, Little Green opened down 6.7 percent at 42 cents, falling to a low of 32 cents and closing down 10 cents or 22.2 percent at 35 cents with 2.2 million shares traded.

In its prospectus, the company said it would offer up to 22,222,222 shares taking the total number of shares on issue to 133,371,868 shares and valuing the company at $60 million.

Little Green said its product range comprised “the classic line of oil-based oral medicinal cannabis products, providing three oil formulations with different [tetrahydrocannabinol to cannabidiol] ratios”.

The company said it had sold more than 4,500 units to more than 1,400 patients.

Little Green said it was continuing its stability testing which was currently for 24 months in cold storage (2-8°C) and 12 months at ambient conditions (below 25°C).

The company said that along with oil-based products it was able to produce dry cannabis flower, with interest for dry cannabis flower expressed from European distributors.

The Perth-based Little Green said its growing facility was in Western Australia with capacity for up to 15,000 bottles of cannabis oil a year, which was being expanded to more than 110,000 bottled of oil a year.

The company said it was chaired by Michael Lynch-Bell, with managing-director Fleta Jennifer Solomon, directors Angus Caithness and Dr Neale Fong, chief financial officer Bhavesh Morar, company secretary Craig Basson and chief operating officer Paul Long.

Little Green said its unnamed manufacturer could produce oil, gel cap, suppository, emulsion and spray products, it expected to be able to manufacture dry cannabis flower in early 2020 and introduce new delivery systems “as the market develops”.

Little Green said it distributed its products in Australia through Oxford Compounding Pty Ltd for patients in Western Australia and Health House International elsewhere.

The company said it had its first commercial order of 2,400 units to be distributed in Germany by the Densborn-based CC Pharma.

The prospectus said Cannacord Genuity was the lead manager to the offer.

Little Green fell five cents or 10.9 percent to 41 cents with 1.2 million shares traded.

SIMAVITA

Simavita has requested a trading halt “pending an announcement regarding a proposed placement to sophisticated and professional investors”.

Trading will resume on February 26, 2020 or on an earlier announcement.

Simavita last traded at two cents.

AUSCANN

Auscann says Melbourne’s Clifford Hallam Healthcare will replace Australian Pharmaceutical Industries as its Australian distributor.

Auscann said that Clifford Hallam would store and distribute its cannabinoid-based pharmaceuticals in Australia for 12 months.

The company said the agreement replaced its 2018 deal with Australian Pharmaceutical Industries which was “discharged by mutual agreement” (BD: Jan 22, 2018).

Today, Auscann said the agreement with Clifford Hallam was cost effective, consolidated its warehousing and logistics operations and extended its Australian distribution network.

Auscann said it had the option to extend the agreement after the initial 12 months.

Auscann was unchanged at 28 cents with 1.1 million shares traded.

EXOPHARM

Exopharm has clarified statements made last week to say “it intends to seek scientific publication” of its Cevaris exosome product for bladder and erectile dysfunction data.
Last week, Exopharm said that Cevaris provided “statistically significant improvement in muscle contraction and release” in ex-vivo models of erectile dysfunction and had been shown to work in an ex-vivo model of bladder dysfunction (BD: Feb 19, Feb 20, 2020).
Today, the company said that the announcements included a statement saying that the “test results will be published in more detail at a later time”.
Exopharm said the announcement should have said that “Exopharm intends to seek scientific publication of this data which if published by a scientific journal would be published at a later date”.
The company confirmed that all material results for the announcements dated February 19 and 20, 2020 “have been disclosed to the market”.
Exopharm fell two cents or 6.45 percent to 29 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has a referral model to allow parents of children with autism to link patient data to their therapy clinic, which would receive payment for referrals.
Neurotech said the referral model would provide an individual code which would give the parent a discount to the therapy.
The company said the linked data would enable “clinics to provide ongoing oversight, treatment planning and assessments”.
Neurotech said Mente clinics would be able to earn commissions for units referred and the referral code had been adopted by the San Jose, California-based Norcal Brain Centre, the Groningen, Netherlands-based Neurobics and Sydney’s Australian Neurofeedback Institute.
Last month, Neurotech said the Australian Therapeutic Goods Administration has revoked approval of the Mente Autism device, prohibiting its sale as a medical device (BD: Jan 28, 2020).
Neurotech was up 0.2 cents or 28.6 percent to 0.9 cents with one million shares traded.

ONCOSIL MEDICAL

Regal Funds Management says it has ceased its substantial holding in Oncosil, selling 3,148,386 shares between February 17 and 19, 2020 for $534,932 or 17 cents a share.
Last week, the Sydney-based Regal Funds said it had reduced its substantial shareholding in Oncosil from 41,906,317 shares (6.64%) to 34,632,579 shares (5.49%) (BD: Feb 19, 2020).
Biotech Daily calculates that Regal Funds holds 4.99 percent of the company.
Oncosil fell two cents or 12.1 percent to 14.5 cents with 7.3 million shares traded.