Biotech Daily

Tuesday February 19, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: CYCLOPHARM UP 5%; PROTEOMICS DOWN 9%**

*** COCHLEAR H1 REVENUE UP 11% TO $712m, PROFIT UP 16% TO $129m**

*** VISIONEERING REVENUE UP 214% TO $4.6m, LOSS DOWN 1.5% TO $23.5m**

*** HEMIDEINA RAISES $1m FOR HERA WIRELESS HEARING AID IMPLANT**

*** TAKEOVERS PANEL DISMISSES PURA VIDA FACTOR COMPLAINT**

*** VICTORIA $1.5m FOR 'TELETRIALS' PROGRAM**

*** ALCIDION LAUNCHES MIYA PRECISION AT NZ MID-CENTRAL HEALTH**

*** LAST PATIENT DOSED IN PHASE III MESOBLAST HEART TRIAL**

*** TGA OKAYS MAYNE KAPANOL (MORPHINE) FOR BREATHLESSNESS**

*** ADMEDUS: 'TAVR SAFE, POTENTIAL BENEFITS, IN SHEEP'**

MARKET REPORT

The Australian stock market was up 0.28 percent on Tuesday February 19, 2019, with the ASX200 up 17.1 points to 6,106.9 points.

Eleven of the Biotech Daily Top 40 stocks were up, 11 fell, 16 traded unchanged and two were untraded.

Cyclopharm was the best, up five cents or 4.8 percent to $1.10 with 7,000 shares traded.

Avita, Clinuvel and Opthea improved more than three percent; Prana rose 2.5 percent; Medical Developments, Optiscan, Polynovo and Resmed were up one percent or more; with Mesoblast, Nanosonics and Paradigm up by less than one percent.

Proteomics led the falls, down 3.5 cents or 9.3 percent to 34 cents, with 221,035 shares traded.

Cochlear lost 8.1 percent; Orthocell shed 7.1 percent; Patrys fell 4.35 percent; Immutep, Kazia and Pro Medicus were down more than three percent; Neuren, Oncosil and Volpara shed more than two percent; CSL and Ellex were down more than one percent; with Cynata down 0.6 percent.

COCHLEAR

Cochlear says that revenue for the six months to December 31, 2018 was up 11.3 percent to $711,900,000 with net profit after tax up 16.1 percent to $128,600,000.
Cochlear said diluted earnings per share was up 15.8 percent to $2.230 with net tangible assets per share up 23.0 percent to $4.933 compared to December 31, 2017.
The company said that a fully franked interim dividend of $1.55 a share for shareholders on the record date of March 26 would be paid on April 16, 2019.
Cochlear said research and development expenditure was up 9.4 percent to $88,200,000 compared to the previous period or 12.4 percent of total revenue.
The company said revenue was led by cochlear implants, up 5.2 percent to $413.9 million, the services sector was up 28.2 percent to $207.2 million and the acoustics division including bone conduction and acoustic implants was up 7.2 percent to $90.8 million.
Cochlear said that Americas sales revenue was up 10.5 percent to $350.5 million, Europe, Middle East and Africa was up 12.0 percent to $248.4 million, with the Asia Pacific up 12.2 percent to $113.0 million.
Cochlear chief executive officer Dig Howitt said the services business was increasing in importance as the recipient base grew and was “almost 30 percent of our sales revenue”.
“Cochlear's recipients have enthusiastically embraced the Nucleus 7 sound processor, the world’s first made-for-Iphone cochlear implant sound processor, launched in October 2017, with the addition of the Nucleus smart [application] for android, released in June 2018,” Mr Howitt said.
Mr Howitt said the company continued to invest in long-term product innovation and had announced a totally implantable cochlear implant, with a feasibility study underway.
“Over the past 18 months we have seen the expansion of clinical indications and/or reimbursement for cochlear implants in Japan and Taiwan, Greater China,” Mr Howitt said. “Health authorities in the UK … are currently reviewing cochlear implantation criteria and are expected to expand clinical indications and funding in the next few months”.
Cochlear said it expected to deliver a net profit of $265 million to $275 million, an eight to 12 percent increase in 2018-’19 compared to 2017-’18.
The company said it had “a number of large long-term investment projects including the development of the China manufacturing facility” with the construction phase expected to be completed by July 2020, and expected to increase capital expenditure levels to $80 million to $100 million a year over the next few years.
Cochlear said it expected “a lower rate of cochlear implant growth” across the developed markets for 2018-’19, but emerging market growth rates over time continued to be strong.
Cochlear fell $15.83 or 8.1 percent to $178.58 with 411,872 shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says that revenue for the 12 months to December 31, 2018, was up 214.1 percent to $US3,294,353 ($A4,627,182), with net loss after tax down 1.5 percent to $US16,735,070 ($A23,500,222).
Visioneering said its revenue came from sales of its multi-focal contact lenses and its increased revenue was “a result of the continued expansion in the United States and commercial launch in Australia, New Zealand, Norway, Sweden and Denmark”.
The company said that diluted loss per share had decreased 2.7 percent to 0.08 US cents for the 12 months to December 31, 2018, with net tangible assets per share down 60 percent to 0.04 US cents and cash and cash equivalents of $US7,275,000 at December 31, 2018, compared to $US16,584,000 at December 31, 2017.
Visioneering fell three cents or 22.2 percent to 10.5 cents.

HEMIDEINA

Hemideina says it has raised $1 million in a series A investment first round of equity financing to develop and commercialize its Hera wireless implant hearing aid.
Hemideina said the funds would support research and development of the Hera wireless implant in preparation for clinical testing, market development activities and the broadening of the company's intellectual property.
Hemideina co-founder and chief executive officer Dr Elizabeth Williams said the Hera implant would "significantly disrupt the global hearing implant market by removing current technical barriers to miniaturization, battery life and sound quality".
"We're excited to have investment partners on board that bring global experience in medical devices, strategy and commercialization to help us achieve our mission," Dr Williams said.
The company said that co-founder and chief technology officer Dr Kate Lomas invented the Hemideina technology "having taken inspiration from insect hearing".
Hemideina said that at New Zealand's Auckland University Dr Lomas investigated insect hearing systems, leading to the development of new acoustic technology that would "transform hearing implants and the quality of life for the profoundly deaf".
Dr Williams told Biotech Daily that the hearing technology was developed by Dr Lomas from research on the New Zealand tree weta, or Hemideina, an insect related to crickets, which had ears on their front legs.
Dr Williams said the Hera processing technology included a cochlear implant and a 10mm ear canal bud signal processor which was the controller for the system.
Dr Williams said the system was expected to be cheaper than existing cochlear ear implant systems and the company said it would "disrupt the hearing implant market worth $1.8 billion".
The company said that Chatsworth Associates managing-director Andrew Maxwell had been appointed the company's chairman with former Ausbiotech chief executive officer Dr Anna Lavelle appointed a non-executive director.
Hemideina is a private company.

FACTOR THERAPEUTICS

The Takeovers Panel says it will not conduct proceedings against Factor Therapeutics on an application from Pura Vida Energy NL, a party to a board spill application
In a media release, the Panel said the application concerned a placement made by Factor shortly after the applicant and another shareholder gave a Corporations Act 2001 Section 249D board spill notice to the company (BD: Feb 5, 7, 2019).
"The Panel concluded there was no reasonable prospect that it would make a declaration of unacceptable circumstances and the applicant had not provided a sufficient body of material to justify the Panel making further enquiries as to the placement," the Panel said.
"Accordingly, the Panel declined to conduct proceedings" and said it would publish reasons for the decision in due course on its website www.takeovers.gov.au.
Factor did not comment on the announcement.
Earlier this month, the dissident investors called for a spill to replace chair Dr Cherrell Hirst and directors Tim Hughes and John Michailidis, with Bruce Lane and David Sanders
A substantial shareholder notice signed by David Sanders said the co-investors held 155,078,397 shares (14.87%) and included the Abu Dhabi-based Steven Scott Day and the Perth, Western Australia based Pura Vida, Freshero, Canadian Nickel Corp, Alitime Nominees Pty Ltd for the Honeyham Family, David Neesham and Pamela Neesham.
Factor Therapeutics was up 0.05 cents or 16.7 percent to 0.35 cents.

VICTORIA GOVERNMENT

The Victoria Government says it is providing $1.5 million to the Victorian Comprehensive Cancer Centre's Teletrials program.
A media release from the Victoria Minister of Health Jenny Mikakos said the Teletrial program was part of a $20 million funding to increase clinical cancer trials and would help people access trials run by cancer hospitals such as the Peter MacCallum Cancer Centre, through partnerships between regional and metropolitan centres, and the program would be extended from Bendigo and Albury Wodonga to other parts of regional Victoria.
The Government said that fewer than five percent of Victorians outside Melbourne participated in clinical trials due to travel and time away from home.
The Victoria Government said $3.7 million was granted to four new projects to help more than 6,000 patients access trials through the Victorian Comprehensive Cancer Centre Investigator-Initiated Trial Capacity Building Program and would focus on radiotherapy before surgery, pain management, combining treatments to enhance success of blood stem cell transplantation and better anaesthetics during surgery.
The Government said that in 2017, a total of 34,557 Victorians were diagnosed with cancer, there were 95 new diagnoses each day and 10,955 deaths.
The media release said that Victoria had "some of the best cancer survival rates in the world" and the five-year survival rate for Victorians diagnosed with cancer had increased from 46 percent in 1982 to 68 percent in 2016.

ALCIDION GROUP

Alcidion says its Miya Precision software system has been launched at a New Zealand Mid-Central District Health Board hospital and health centre.
Alcidion said the first installation of the Miya hospital management software system at Palmerston North Hospital and Horowhenua Health Centre, north of Wellington, had "already seen noticeable improvements to bed allocation, smoother patient flow, and a more efficient allocation of hospital resources".
Alcidion managing-director Kate Quirke said the installation was "a really important project for Alcidion, with Mid-Central DHB being the first roll-out of the … platform".
The company said that Miya Precision was being used in 17 wards and the emergency department at Palmerston North Hospital, and two wards at Horowhenua Health Centre.
Alcidion said the system delivered patient flow information and bed management updates to staff and could be accessed by clinicians using a laptop or tablet at the bedside, workstation, and patient flow boards in each ward.
The company said that the software had been integrated with five clinical information systems at Mid-Central District Health Board, including Webpas, Carestream Radiology, Clinical portal and Pathology to provide clinical staff with detailed patient information displayed on the ward's patient flow board.
Alcidion said that clinicians at the bedside could use Miya Precision to view the patient's admission history, demographics and test results, "making it simple and fast for them to make the right care decisions based on real-time information" and the platform provided Mid-Central with an inter-operability platform to which they could add patient safety algorithms and apply artificial intelligence to improve outcomes.
Alcidion said the Miya Precision Hospital Operations Centre gave managing nurses "a high-level overview of hospital bed occupancy … with the ability to drill down into individual departments and wards for more detailed insight" allowing staff to quickly allocate the best beds for each individual patient and minimizing wait times.
Alcidion was unchanged at four cents.

MESOBLAST

Mesoblast says the last of 566 patients has been dosed in its phase III trial of its mesenchymal precursor cell product candidate Revascor for congestive heart failure.
Mesoblast said that the trial of the Revascor allogeneic stem cell product, formerly known as MPC-150-IM, would be completed when sufficient primary endpoint events had accrued, which was likely to be within 12 months.
In 2016, the company said that Israel's Teva handed back the cardiac program, Mesoblast had arranged a facility to fund it, with results expected in 18 months (BD: Jun 14, 2016).
In 2017, Mesoblast said the data monitoring committee approved continuing the trial following an analysis of the efficacy endpoint for the first 270 patients (BD: Apr 10, 2017).
The company said at that time that the committee had "no safety concerns" relating to MPC150-IM and recommended the trial continue as planned.
The company said the primary efficacy endpoint was a comparison of recurrent non-fatal, heart failure-related major adverse cardiac events in moderate to advanced heart failure patients receiving either MPC-150-IM by injection into the damaged heart muscle or sham.
Today, Mesoblast said that results from a prior phase II trial identified the patients most likely to benefit from Revascor were those at high risk of recurrent hospitalization and death, and that data guided the trial design and selection criteria for the phase III trial, to maximize the probability that the phase III results would confirm the phase II results.
The company said it was "confident that the total number of randomized patients enrolled in the phase III trial is sufficient to show whether Revascor is superior to placebo in the trial's primary endpoint of reduction in heart failure-related hospital admissions and in the key secondary endpoint of reduction in cardiac deaths".
Mesoblast said that its cardiovascular partner in China, Tasly Pharmaceutical Group, was planning to meet with China's National Medical Products Administration, formerly known as the China Food and Drug Administration, by April 2019 to discuss the regulatory approval pathway for Revascor in China.
The company said the objective was to begin a phase III trial of Revascor in China using similar clinical endpoints and targeting a similar patient population and the two companies would leverage each other's trial results in China, the US and other territories to support their respective regulatory submissions.
Mesoblast was up one cent or 0.9 percent to $1.175.

MAYNE PHARMA GROUP

Mayne says the Australian Therapeutic Goods Administration has approved Kapanol sustained-release 10mg and 20mg morphine capsules for chronic breathlessness.
Mayne chief executive officer Scott Richards said "the repurposing of low dose morphine for chronic breathlessness is a world first registration for this indication".
"More than 70,000 Australians suffer from chronic breathlessness and will now have access to Kapanol to manage their breathlessness symptoms," he said.
Mr Richards said many chronic breathlessness patients were "housebound and limited in their day-to-day activities".
"The clinical studies undertaken by Palliative Care Clinical Studies Collaborative under Prof David Currow have shown the use of Kapanol in severe breathlessness can reduce their debilitating breathlessness symptoms," Mr Richards said.
Mayne said it had made an application to the Pharmaceutical Benefits Advisory Committee to expand the Pharmaceutical Benefits Scheme reimbursement of Kapanol to include the treatment of chronic breathlessness.
Mayne fell half a cent or 0.6 percent to 82 cents with 5.3 million shares traded.

ADMEDUS

Admedus says a sheep study of its single-piece, three-dimensional, transcatheter aortic valve replacement suggests it can be implanted safely and has potential benefits.

Admedus said five sheep had been implanted to date at Belgium's Katholieke Universiteit Leuven and would be monitored for five months.

The company said at four weeks, four sheep showed effective orifice areas (EOA) of 2.0cm2 to 2.5cm2, above those in the market, of 1.6cm2 to 2.0cm2.

Admedus said the valves were functional after 400 million cycles, equivalent to 10 years of human use, there was a low-pressure gradient across the valves of 4mmHg to 6mmHg and no regurgitation was observed.

Katholieke Universiteit Leuven cardiac surgeon Prof Bart Meuris said the study "demonstrated that these stentless valves can be implanted with reasonable ease, without any major adverse event".

"The echocardiograms revealed superior functional valves with optimal haemodynamic profiles," Prof Meuris said.

"We support the progression to a first-in-human clinical trial and believe clinical implantation of this device is certainly possible in the short-term and can be beneficial to many patients," Prof Meuris said.

Admedus chief executive officer Wayne Paterson said "calcification is a major issue for surgeons and patients today when treating valvular disease".

"Our Adapt tissue is the only product of its kind that has data demonstrating 10 years without calcification or degradation," Mr Paterson said.

"Combining this unique benefit with the first and only single piece 3D valve could be a major disruption in the treatment strategies for patients in the future," Mr Paterson said.

Mr Paterson said its Adapt transcatheter aortic valve replacement (TAVR) "would be a breakthrough for patients needing valve replacement".

He said that the TAVR market was expected to be $US12 billion ($A16.85 billion) by 2025 and "if the earlier results translate to true clinical superiority, Adapt TAVR could be well placed to be the market leader".

Admedus was up 0.3 cents or 8.8 percent to 3.7 cents with 1.4 million shares traded.