Biotech Daily

Thursday February 11, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 5%; ACTINOGEN DOWN 8%**

*** MESOBLAST BACK PAIN TRIAL 'NOT STATISTICALLY SIGNIFICANT'**

*** BARD1 CLAIMS OVARIAN CANCER TEST '100% SPECIFICITY, SENSITIVITY'**

*** CLINUVEL: ISRAEL APPROVES SCENESSE FOR EPP**

*** PHARMAXIS H1 REVENUE UP 240% TO $14m, LOSS TO $46k PROFIT**

*** ECOFIBRE H1 REVENUE DOWN 49.5% TO $14.7m, PROFIT TO $5.5m LOSS**

*** ACTINOGEN SHORTFALL RAISES $3.55m; TOTAL $10.9m**

*** MEDLAB: 'NRGBIOTIC SIGNIFICANTLY REDUCES DEPRESSION'**

*** ZELIRA JOINS US NATIONAL CANNABIS ROUNDTABLE**

*** INCANNEX APPOINTS NEW YORK'S EAS FOR US DUAL-LISTING**

*** STARFISH, MICHAEL PANACCIO INCREASE, DILUTED TO 29% IN DORSAVI**

*** DORSAVI CEO DR ANDREW RONCHI, AR BSM BELOW 5%**

*** PARADIGM APPOINTS HELEN FISHER DIRECTOR**

*** ONCOSIL: DR RALPH PETERS CMO, DAVID TURNER MEDICAL AFFAIRS**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Thursday February 11, 2021, with the ASX200 down 6.8 points to 6,850.1 points. Nine of the Biotech Daily Top 40 stocks were up, 24 fell and seven traded unchanged.

Antisense was the best, up one cent or five percent to 21 cents, with 3.2 million shares traded. Optiscan was up 4.2 percent; Cyclopharm and Cynata rose more than two percent; Amplia, Mesoblast, Nova Eye and Orthocell were up more than one percent; with CSL and Opthea up by less than one percent.

Actinogen led the falls, down 0.2 cents or 8.3 percent to 2.2 cents, with 75.5 million shares traded. Nanosonics lost 6.6 percent; Compumedics, Kazia and Neuren were down more than five percent; Telix and Volpara fell more than four percent; Dimerix, Immutep, Patrys, Polynovo and Universal Biosensors lost more than three percent; Alterity, Pharmaxis, Proteomics and Starpharma shed more than two percent; Avita, Clinuvel, Genetic Signatures, Paradigm and Resonance were down one percent or more; with Cochlear, Medical Developments, Next Science, Pro Medicus and Resmed down by less than one percent.

MESOBLAST

Mesoblast says rexlemestrocel-L provides pain relief and opioid reduction for lower back pain, but “did not reach statistical significance across the entire study”.

Mesoblast said that the 404-patient, phase III, randomized, controlled trial of rexlemestrocel-L (formerly MPC-06-ID) with and without hyaluronic acid compared to placebo “did not reach statistical significance across the entire study” but published data showing the mesenchymal precursor cells were “safe, durable, and effective opioid-sparing therapy for patients with chronic inflammatory back pain due to degenerative disc disease, and that greatest benefits are seen when administered earlier in the disease process before irreversible fibrosis of the intervertebral disc has occurred”.

In 2015, Mesoblast said it had begun a phase III trial of MPC-06-ID for chronic low back pain, expecting top-line data in mid-2017 (BD: Jan 18, 2015).

The company said at that time that it had presented 24-month results from the phase II chronic low back pain trial, showing that in the randomized, placebo-controlled trial of 100 patients with chronic low back pain due to degenerative disc disease, a single injection of MPC-06-ID was well tolerated and resulted in substantial improvement in pain and function for at least 24 months.

According to its listing at www.clinicaltrials.gov the trial’s primary outcome was “treatment success (composite responder analysis of low back pain visual analogue scale (VAS) score, Oswestry disability index (ODI) score and no post-treatment interventions) … and to determine overall treatment success of rexlemestrocel-L alone or rexlemestrocel-L [with hyaluronic acid] through 24 months based on a composite responder analysis”.

Today, Mesoblast said that patients received a single intra-discal injection of either rexlemestrocel-L using a unit dose of six million allogeneic mesenchymal precursor cells (MPCs), with or without hyaluronic acid carrier, or saline control.

The company said that the arm receiving MPCs and hyaluronic acid had “significant and durable reductions” in pain through 24 months compared with saline and the greatest pain reduction was “in the pre-specified population with [pain] of shorter duration than the study median of 68 months” compared with saline controls, along with “significantly greater pain reduction in the pre-specified patient subset of opioid users (n = 168) at all time-points compared with saline controls”.

Mesoblast said that while “the composite outcomes of pain and function did not reach statistical significance across the entire study [there were] no safety concerns over the 24-month period of follow-up in the entire study population”.

The company said that treatment with MPCs and hyaluronic acid (HA) had “nearly four times more opioid users achieving 50 percent reduction in pain as well as reduction in opioid use by 24 months than those treated with saline”.

Mesoblast said that “patients who received MPCs alone had mean VAS reductions intermediate between saline and MPC plus HA, indicating an additive role for HA carrier, likely by increasing targeting of mesenchymal stromal cells to inflammatory sites”.

Mesoblast chief executive Prof Silviu Itescu said that “durable pain reduction for at least two years from a single administration indicates that rexlemestrocel-L has the potential to change the treatment paradigm for chronic low back pain due to inflammatory disc disease, a condition that affects as many as seven million patients across the United States and Europe, and to prevent or reduce opioid use and dependence”.

The company said that the US Food and Drug Administration had “prioritized a focus on new therapeutics that target both pain reduction and opioid avoidance” and it intended to meet the FDA to “discuss potential pathways towards approval for rexlemestrocel-L, including as an opioid sparing treatment in patients with [degenerative disc disease]”.

Mesoblast was up four cents or 1.6 percent to $2.60 with 15.6 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says data from 69 samples show that its SubB2M protein technology can detect “all stages of ovarian cancer with 100 percent specificity and 100 percent sensitivity”.
Bard1 said it held the exclusive rights to the mutation of the B subunit of the subtilase cytotoxin (SubB2M) protein technology, which was developed by researchers at the University of Adelaide and the Gold Coast, Queensland-based Griffith University.
Last year, the company said it would work with Griffith University to develop its ovarian, breast and lung cancer diagnostic technology (BD: Apr 2, 2020).
Today, Bard1 said SubB2M could bind specifically to the Neu5Gc sugar molecule, a potential multi-cancer biomarker found on a range of human tumor cells and tumor-associated molecules.
The company said data from Griffith University’s Institute for Glycomics showed that “serum from 47 patients with all stages of ovarian cancer had significantly elevated mean levels of Neu5Gc glycans compared to 22 cancer-free control individuals”.
Bard1 said the data concluded that detection of Neu5Gc-glycans using SubB2M had potential as a diagnostic marker for early-stage ovarian cancer, as well as a tool for monitoring disease progression in late-stage cancer.
The company said that ovarian cancer was often diagnosed at a late stage, resulting in a poor prognosis with an overall 5-year survival rate of 46 percent.
Bard1 chief executive officer Dr Leearne Hinch said the company was “focused on early detection of cancer and our SubB2M technology provides the potential for developing tests for monitoring and detection of multiple cancers”.
Dr Hinch said the company would collaborate with Griffith University “to develop and validate commercial assays for monitoring treatment response and recurrence in ovarian cancer patients to improve health outcomes for this critical unmet medical need”.
Bard1 chief scientific officer Dr Peter French said that “whilst this data is preliminary, the outstanding results indicate the high specificity and sensitivity of SubB2M for ovarian cancer monitoring and detection”.
Bard1 was up 85 cents or 114.1 percent to $1.595 with 20.9 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says its Scenesse, or afamelanotide 16mg, for the prevention of phototoxicity in adults with erythropoietic protoporphyria (EPP) has been approved in Israel.
Clinuvel said Scenesse was approved by Israel’s Public National Advisory Committee and added to the National Health Basket of services and products reimbursable in Israel.
Clinuvel fell 29 cents or 1.3 percent to $21.50.

PHARMAXIS

Pharmaxis says that revenue for the six months to December 31, 2020 was up 240.4 percent to $13,687,000, with net loss after tax turned to net profit of $46,000.
Pharmaxis said revenue was primarily milestone payments of $10.1 million for approval of Bronchitol for cystic fibrosis in the US and Brazil (BD: Nov 2, 2020, Jan 17, 2021).
The company said Bronchitol sales were up 1.3 percent to $2,196,000 with sales of its Aridol asthma diagnostic down 18.4 percent to $890,000.
Pharmaxis said diluted loss per share was nil compared to 0.03 cents the previous year, net tangible assets per share fell 81.8 percent to 0.2 cents, and cash and equivalents of $18,249,000 at December 31, 2020 compared to $25,864,000 at December 31, 2019.
Pharmaxis fell 0.2 cents or 2.2 percent to 8.8 cents with 1.5 million shares traded.

ECOFIBRE

Ecofibre says revenue for the six months to December 31, 2019 fell 49.45 percent to $14,673,000, with last year's net profit turned to a net loss of $5,546,000.
Ecofibre said revenue from sales of its marijuana and hemp-based food additives and textiles was impacted by Covid-19, particularly in the US.
The company said diluted loss per share was 1.73 cents a share, down from a profit of 2.36 cents a share in the six months to December 31, 2019, net tangible assets per share was up 7.8 percent to 17.19 cents, with cash and equivalents of $13,495,000 at December 31, 2020 compared to $23,184,000 at December 31, 2019.
Ecofibre fell 17.5 cents or 9.7 percent to $1.625.

ACTINOGEN MEDICAL

Actinogen says it has raised about $3.55 million in a shortfall placement taking the total raised to $10.91 million.
Last year, Actinogen said it had raised $6 million in an "over-subscribed" placement at 2.2 cents a share and raised $1.36 million of a hoped-for $4.9 million in an entitlement offer (BD: Oct 15, Nov 13, 2020).
Today, the company said the funds would be used for clinical trials of Xanamem for mild cognitive impairment due to Alzheimer's disease and Fragile X syndrome.
Actinogen fell 0.2 cents or 8.3 percent to 2.2 cents with 75.5 million shares traded.

MEDLAB CLINICAL

Medlab says its bacteria-based NRGBiotic probiotic can "significantly" reduce depression scores when used as an adjunct to anti-depressants ($p < 0.001$).
Last year, Medlab said it had completed its 150-patient, double-blind, placebo-controlled, phase IIa trial of its NRGBiotic in patients with major depression and had closed the trial early with 120 patients rather than the full 150 patients, after it found "a distinct trend line in the blinded trial data" (BD: Apr 1, 2020).
Today, the company said trial investigated the use of NRGBiotic versus a placebo as an adjunct to the commonly prescribed anti-depressant medications of selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI).
Medlab medical research director Prof Luis Vitetta said the preliminary analysis of patients who were administered NRGBiotic in combination with the patient's prescribed anti-depressant medication "showed a significant reduction in depression scores from baseline to eight weeks, a statistically significant, preliminary result" ($p < 0.001$).
Prof Vitetta said the trial confirmed safety and tolerability for the NRGBiotic administered cohort with no adverse effects from the probiotic formulation.
Medlab said the results showed a statistically significant improvement in quality of life from baseline at eight weeks post-treatment ($p = 0.006$) and a statistically significant improvement in psychosocial functioning baseline a week-eight ($p < 0.001$).
The company said that NRGBiotic, contained Lactobacillus acidophilus, Bifidobacterium bifidum and Streptococcus thermophilus with orotic acid showed a significant faecal abundance increase in the concentration of Bifidobacterium bifidum from baseline.
Medlab said the NRGBiotic treated group showed a significant increase in the immune bacterial genus Bifidobacteria, which was associated with the inflammatory regulating properties in the intestines.
The company said the results had been delayed due to Covid-19.
Medlab was up five cents or 16.7 percent to 35 cents with 1.5 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has been appointed as a director of the US National Cannabis Roundtable in Washington DC, represented by US chief executive officer Dr Oludare Odumosu.
Zelira said the Roundtable was a non-partisan advocacy group for Federal marijuana reform in the US with the aim to remove Federal restrictions that prohibit research into medical marijuana medical and allow marijuana companies to operate legally.
Zelira fell 0.4 cents or 4.7 percent to 8.1 cents with 7.4 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has appointed New York's EAS Advisors to assist with a potential listing on the New York Stock Exchange or the Nasdaq.
Incannex said EAS would "facilitate introductions to US banks and institutions" and generate company awareness with investors in the US, Europe, Asia, and Australia.
Incannex was up 2.5 cents or 12.8 percent to 22 cents with 25.2 million shares traded.

DORSAVI

Starfish, Michael Panaccio, John Dyson and Trujon say they have increased but been diluted in Dorsavi from 101,819,921 shares (35.20%) to 102,875,786 shares (29.41%).
Melbourne's Starfish Ventures, Dorsavi director Mr Panaccio, Mr Dyson and Trujon said that on November 20, 2020 they bought 1,055,865 shares in Dorsavi's rights offer at 3.2 cents and were diluted following the issue of shares in the company's capital raising.
Last year, Dorsavi said it has raised $1.85 million in a placement and $300,000 of a hoped-for $1.85 million through a one-for-four rights offer at 3.2 cents a share, and earlier this month, Dorsavi said it had placed $1.55 million in its rights offer shortfall taking the total raised to $3.7 million (BD: Oct 22, Nov 18, 2020, Feb 2, 2021).
Dorsavi was unchanged at 3.3 cents with 3.5 million shares traded.

DORSAVI

Dorsavi chief executive officer Dr Andrew Ronchi says that with AR BSM Pty Ltd, he has ceased his substantial shareholding in the company.
Dr Ronchi said that on February 9, 2021 his 17,103,889 shares were diluted from 5.96 percent to below five percent, following Dorsavi's capital raising (see above).
According to Dorsavi's most recent Appendix 2A new shares notice the company had 349,848,572, and Biotech Daily calculated that Dr Ronchi retained 4.89 percent of

PARADIGM BIOPHARMACEUTICALS

Paradign says it has appointed Helen Fisher as a non-executive director, effective from February 23, 2021.
Paradigm says Ms Fisher was currently the chief executive officer of Bio Capital Impact Fund, chair of the Victoria branch of Ausbiotech and a director of Calix, and was previously a director of Sienna Cancer Diagnostics.
The company said Ms Fisher held a Bachelor of Laws, a Bachelor of Science and a Master of Law from the University of Melbourne, and a Master of Commerce from Sydney's University of New South Wales.
Paradigm fell five cents or 1.8 percent to $2.70 with 422,329 shares traded.

ONCOSIL MEDICAL

Oncosil says it has appointed Dr Ralph Peters as chief medical officer and David Turner as head of medical affairs.

Oncosil said Dr Peters had more than 30 years' experience in interventional radiology and had been an executive at Sirtex Medical for 15 years.

The company said Mr Turn had more than 40 years' experience in the pharmaceutical, medical device, and health technology industries and was previously head of marketing at Sirtex.

Oncosil was unchanged at 11.5 cents with 4.1 million shares traded.