



Biotech Daily

Thursday October 6, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: MESOBLAST UP 12%; CELLMID, DIMERIX DOWN 8%**
- * **VICTORIA SECURES 5 US COMPANIES FOR CLINICAL TRIALS**
- * **REDHILL READY FOR PHASE II YELIVA FOR LIVER CANCER STUDY**
- * **SIENNA US, UK DISTRIBUTORS, EXPECTS REVENUE INCREASE**
- * **MESOBLAST MPC KIDNEY FAILURE EFFICACY, SAFETY PUBLISHED**
- * **REPRODUCTIVE HEALTH RIGHTS ISSUE RAISES \$488k, \$502k TO GO**
- * **ANATARA TO RELEASE 12.7m ESCROW SHARES**
- * **NANOSONICS 56k RIGHTS, 279k OPTIONS; DOUBLE NED PAY AGM**

MARKET REPORT

The Australian stock market climbed 0.55 percent on Thursday October 6, 2016 with the ASX200 up 30.1 points to 5,483.0 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and three were untraded.

Mesoblast was the best, up 13.5 cents or 12.1 percent to \$1.25 with 1.96 million shares traded, followed by Avita up 10 percent to 11 cents with 766,697 shares traded.

Polynovo and Prima climbed more than five percent; Anteo, Bionomics, IDT and Neuren were up four percent or more; Ellex was up 3.3 percent; Living Cell, Orthocell and Universal Biosensors rose more than two percent; Admedus, Clinuvel and Impedimed were up more than one percent; with CSL, Nanosonics, Opthea, Resmed and Starpharma up by less than one percent.

Cellmid and Dimerix led the falls, both down 8.3 cents to 3.3 cents and 1.1 cents, respectively, with six million and 3.3 million shares traded, respectively.

Actinogen lost six percent; Compumedics and Oncosil fell more than four percent; Psivida was down 3.8 percent; Airxpanders and Prana shed more than two percent; Acrux, Medical Developments, Pharmaxis and Pro Medicus were down more than one percent; with Cochlear, Reva, Sirtex and Viralytics down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says that five US companies will conduct clinical trials in the State on malaria, arthritis, asthma, neuro-degenerative disorders and heart conditions. A media release from Victoria's Minister for Small Business, Innovation and Trade Philip Dalidakis said that Victoria Government representatives in the US "played a key role in securing the trials for Victoria, successfully using our reputation as a global leader in biotechnology, medical and pharmaceutical research and development".

The media release said that the San Francisco firm Kezar Life Sciences would conduct "world-first clinical trials in Melbourne for a drug that could help treat autoimmune and inflammatory disorders such as rheumatoid arthritis and lupus" and fellow San Francisco firm Annexon Bioscience had established an Australian subsidiary in Melbourne to further its work in neuro-degenerative research.

The Victoria Government said that the Massachusetts-based Merrimack Pharmaceuticals was conducting multiple clinical studies in lung and pancreatic cancer with two of its late-stage therapeutics and the Maryland-based Synermore Biologics was conducting a first-in-human trial on a drug for asthma and allergic rhinitis, with additional clinical trials for other biological products in planning.

The media release said the San Francisco-based Incarda Therapeutics had established a Melbourne subsidiary for work on an inhaled therapy for cardiovascular diseases.

Mr Dalidakis said that Victoria was "leading the country in clinical trials and with our reputation as a global leader in medical technology and research".

SIENNA CANCER DIAGNOSTICS

Sienna says Statlab and Histocyte will distribute its telomerase-based adjunct diagnostic for bladder cancer in the US and UK, respectively, leading to increased revenue.

Sienna chief operating officer Matthew Hoskin said that "ninety percent of cancers up-regulate telomerase and the detection of telomerase in cytology samples will be an important adjunct test for the diagnosis of cancer".

"The product will initially address an unmet need in bladder cancer diagnosis by improving the sensitivity of current urine-based diagnostic methods," Mr Hoskin said.

The company said that the McKinney, Texas-based Statlab Medical Products would distribute the in-vitro diagnostic throughout the US, while the Newcastle University, England-based Histocyte Laboratories would distribute the product in the UK, with registration expected by the end of 2016.

Sienna said that both distributors had extensive networks within the pathology market in their respective regions.

Sienna chief financial officer Tony Di Pietro said that the company had a significant increase in product revenues for the 12 months to 30 June 2016 to \$640,000, the company's first full year of product income from the Uniondale, New York-based uropathology service provider Bostwick Laboratories for its anti-hTERT antibody.

Last year, Sienna said that the first clinical application of its telomerase test technology, the anti-hTERT SCD-A7 antibody-based adjunct diagnostic could enable more accurate results with fewer indeterminate results than the existing cytology tests for bladder cancer (BD: Jan 18, 2015).

Today the company said that using its first generation product for initial, targeted market entry, Bostwick launched its own immuno-stain to detect telomerase in cells shed in urine samples as an aid to bladder cancer diagnosis.

Mr Di Pietro said he expected revenues to increase in the coming financial years.

Sienna is a public unlisted company.

REDHILL BIOPHARMA

Redhill says it expects to begin enrolment “shortly” in a phase II safety and efficacy study of Yeliva (ABC294640) for advanced hepatocellular carcinoma.

In September, Redhill said it had begun a phase Ib/II study of Yeliva for refractory or relapsed multiple myeloma and had a collaboration with Stanford University to evaluate Yeliva for prevention of mucositis in head and neck cancer patients (BD: Sep 9, 13, 2016).

Redhill said ABC294640 was licenced from the Hummelstown, Pennsylvania-based Apogee Biotechnology in 2015, and in 2010 it bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney’s Giaconda (BD: Aug 17, 2010).

Today, Redhill said Yeliva was an oral, sphingosine kinase-2 (SK2) selective inhibitor with anti-cancer and anti-inflammatory activities, and by inhibiting the SK2 enzyme Yeliva blocked the synthesis of sphingosine 1-phosphate (S1P), a lipid signaling molecule that promoted cancer growth and pathological inflammation.

The company said the study at the Medical University of South Carolina Hollings Cancer Center would evaluate Yeliva as a second-line monotherapy in up to 39 patients with liver cancer who had tumor progression following treatment with sorafenib.

Last night on the Nasdaq, Redhill fell 67 US cents or 4.79 percent to \$US13.31 (\$A17.52) with 60,364 shares traded.

MESOBLAST

Mesoblast says that data from its 30-patient phase II trial of mesenchymal precursor stem cells for diabetic nephropathy has been published in a peer-reviewed journal.

Last year, Mesoblast first published the results that concluded that “no treatment-related safety issues were identified during the 12 week study period following a single [mesenchymal precursor cell] infusion ... [and] benefit was similar with both ... doses” and concluded that “efficacy testing showed preservation or improvement in [the kidney disease measure, glomerular filtration rate] at 12 weeks, persisting for at least 24 weeks, in [mesenchymal precursor cell] treated subjects relative to placebo” (BD: Jun 9, 2015).

Today, Mesoblast said the data was published in the journal Ebiomedicine in an article entitled ‘Allogeneic Mesenchymal Precursor Cells (MPC) in Diabetic Nephropathy: A Randomized, Placebo-controlled, Dose Escalation Study’ which was available at:

[http://www.ebiomedicine.com/article/S2352-3964\(16\)30418-2/abstract?cc=y](http://www.ebiomedicine.com/article/S2352-3964(16)30418-2/abstract?cc=y).

Mesoblast climbed 13.5 cents or 12.1 percent to \$1.25 with 1.96 million shares traded.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says its one-for-five, fully underwritten rights issue has raised \$487,928 through acceptances for 6,505,700 shares at 7.5 cents a share.

Reproductive Health said that the shortfall of 6,695,333 shares worth \$502,150 would be allocated to Taylor Collison in accordance with the underwriting agreement.

Reproductive Health was up one cent or 13.3 percent to 8.5 cents.

ANATARA LIFESCIENCES

Anatara says that 12,746,095 shares will be released from voluntary escrow on October 16, 2016.

Anatara said that following the release of the shares from escrow there would be a total of 49,413,236 shares available for trading on the ASX with no further shares held in escrow.

Anatara fell four cents or 3.3 percent to \$1.16.

NANOSONICS

Nanosonics will vote to chief executive officer Michael Kavanagh and Dr Ron Weinberger performance rights and options and double directors' remuneration to \$1,000,000.

Nanosonics said that it proposed to issue Mr Kavanagh 42,138 'performance' shares and 211,306 options and issue technology development and commercialization head Dr Weinberger 13,445 performance rights and 67,419 options.

The company said that the options were exercisable at \$2.85 each and all performance rights and options would vest in three tranches on August 31, 2019 with the options exercisable within three years of vesting.

Nanosonics said that the vesting of the free performance rights was subject to total shareholder return performance conditions measured against the long-term incentive scheme comparator groups 1 and 2, with the first comparator group including no or low revenue companies as well as companies currently in suspension.

The second comparator group included companies in the S&P ASX Small Ordinaries.

Nanosonics said that shareholders would vote to increase the total non-executive directors remuneration from \$500,000 to \$1,000,000.

The company's notice of meeting said shareholders would vote on the remuneration report, the omnibus equity plan, and the re-election of chairman Maurice Stang and directors Steven Sargent and Marie McDonald.

The meeting will be held in the Brisbane Room, Sofitel Wentworth Hotel, 61-101 Phillip Street, Sydney on November 4, 2016 at 11am (AEDT).

Nanosonics was up two cents or 0.6 percent to \$3.40 with 442,181 shares traded.