Biotech Daily

Tuesday August 11, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: RESONANCE UP 11%; MESOBLAST DOWN 31%**

*** MESOBLAST FALLS ON FDA REMESTEMCEL-L FOR GVHD QUESTIONS**

*** REGENEUS: KYOCERA $26m PROGENZA KNEE OSTEOARTHRITIS DEAL**

*** PAINCHEK RAISES $10m**

*** ADALTA PLACEMENT RAISES $4m, RIGHTS OFFER FOR $4.1m MORE**

*** SUDA PLACES $533k; TOTAL $3.56m**

*** ACRUX: HARRIS FOR US GENERIC EMLA ANAESTHETIC CREAM SALES**

*** TELIX SUBMITS TLX101 GLIOBLASTOMA DRUG MASTER FILE TO FDA**

*** NUHEARA WINS ISO 9001:2015 CERTIFICATION**

*** PARADIGM PPS ORPHAN APPROVALS, REGULATORY FEEDBACK**

*** PERENNIAL TAKES 5.5% OF 4D MEDICAL**

*** REGAL FUNDS REDUCES, DILUTED TO 8.9% OF VISIONEERING**

*** IMPEDIMED PROMOTES TIMOTHY CRUICKSHANK TO CFO**

MARKET REPORT

The Australian stock market was up 0.47 percent on Tuesday August 11, 2020, with the ASX200 up 28.5 points to 6,138.7 points. Nine of the Biotech Daily Top 40 stocks were up, 25 fell and six traded unchanged.

Resonance was the best, up 1.5 cents or 10.7 percent to 15.5 cents, with 1.25 million shares traded. Actinogen and Amplia climbed eight percent or more; Kazia was up four percent; Proteomics improved 3.1 percent; Impedimed and Paradigm rose more than two percent; Cochlear was up 1.4 percent; with Avita, CSL and Next Science up by less than one percent.

Mesoblast led the falls, down $1.51 or 31.0 percent at $3.36, with 57.8 million shares traded. Alterity lost 9.2 percent; Oncosil fell 8.7 percent; Cynata shed 6.7 percent; Osprey was down 5.1 percent; Optiscan fell four percent; Imugene, LBT, Medical Developments, Nova Eye, Polynovo and Prescient lost three percent or more; Dimerix, Nanosonics, Neuren and Pro Medicus shed two percent or more; Antisense, Compumedics, Cyclopharm and Genetic Signatures fell more than one percent; with Clinuvel, Opthea, Resmed, Starpharma, Telix and Volpara down by less than one percent.

MESOBLAST

Mesoblast fell as much as 32.85 percent to $3.27 following the publication of two US Food and Drug administration documents for a planned August 13 regulatory meeting.

The two FDA Briefing Documents for the Oncologic Drugs Advisory Committee meeting on August 13, 2020 were titled 'Session on Product Characterization' and 'Session on Clinical Evidence' relating to the biologics licence application for Mesoblast's Remestemcel-L mesenchymal stem cell product for graft-versus-host disease.

The Clinical Evidence document questioned the trial designs cited in the application and the second document discussed the product characterization.

The FDA Clinical Evidence document said that MSB-GVHD001 met its primary objective and the primary endpoint results "were statistically significant, the measured response was durable (median 54 days), and the results were consistent across sub-populations and secondary efficacy endpoints".

The document discussed the "limitations of single-arm study design" including the subjectivity of acute graft-versus-host disease grading (aGvHD); inability to ascertain the similarities in prognostic factors between the MSB-GVHD001 study and historical control data; the influence of confounding factors; the adequacy of the historical data to support a null hypothesis; the clinical development program with two randomized studies with negative results; and the differences in outcomes in different studies, prior to Mesoblast acquiring the products from Osiris in 2013 (BD: Oct 11, 2013).

The FDA said the Mesoblast and Osiris trials had "substantial differences in the patient populations, trial design, study conduct, and primary endpoint evaluations".

"Due to these design differences, it is unclear that these study results are relevant to the proposed indication for use of remestemcel-L as a single-agent treatment of [steroid-refractory] aGvHD in paediatric patients, but it raises the uncertainties associated with interpreting the observed efficacy outcomes between studies," the document said.

"In fact, a treatment effect has not been identified in any of the previous clinical trials conducted in immune modulated diseases such as type 1 diabetes mellitus and Crohn's Disease," the FDA Clinical Evidence document said.

"Therefore, it is unclear how to interpret the results of one statistically-positive single-arm trial in a landscape of multiple negative clinical trials," the document said.

Under 'Adverse Events of Special Interest' the document said: "In general, no safety signal of concern was identified in the studies of remestemcel-L", but asked whether an additional clinical trial should be required and what design would be required?

The Product Characterization document raised questions about the uniform production of stem cells, the product attributes of remestemcel-L and their relation to product quality and effectiveness.

"The product attributes the applicant has identified as related to potency and activity, however, do not have a demonstrated relationship to the clinical performance of specific [drug product] lots, and that the product's proposed immune-modulatory mechanism of action has not been demonstrated in-vivo in study subjects receiving remestemcel-L," the Product Characterization document said. "Additionally, given the limitations of the current [critical quality attributes], we ask that the committee discuss other product characteristics not previously identified as [critical quality attributes] for remestemcel-L that might provide more meaningful measures of product quality and potency and therefore provide better assurance of product quality from lot-to-lot."

In a release to the ASX, Mesoblast said it had "extensively prepared" for the meeting with 127-page briefing book available at: https://www.fda.gov/media/140996/download and other briefing materials available on the FDA website.

Mesoblast closed down $1.51 or 31.0 percent at $3.36 with 57.8 million shares traded.

REGENEUS

Regeneus says it has a $26.4 million licence and collaboration agreement with Tokyo's Kyocera Corp for its stem cell platform Progenza OA for knee osteoarthritis.
In March, Regeneus said Kyocera would pay $1.4 million for exclusive negotiation rights of Progenza for knee osteoarthritis (BD: Mar 2, 2020).
In May, the company said Kyocera had completed due diligence on Progenza OA for knee osteoarthritis and had until the end of July 2020 to negotiate a commercial licence for Progenza in Japan (BD: May 18, 2020).
Today, Regeneus said it would receive $US19 million ($A26.4 million) in upfront, development and regulatory milestones payments, including $US9 million upfront and $US10 million in regulatory and development milestones.
The company said it would also receive additional single to high double-digit royalties on product sales in Japan and Kyocera would fund manufacturing, development and commercialization costs and would have the right of first refusal for other indications, including outside of Japan.
Regeneus said the agreement included technology transfer and joint research on Progenza in Japan and the company would retain rights to negotiate licences with other parties for other indications inside and outside of Japan.
Regeneus chief executive officer Leo Lee said the Kyocera agreement was "an exciting development for Regeneus and is an endorsement of our Progenza platform technology".
"It provides a clear commercialization pathway for Progenza and is a significant market given osteoarthritis potentially affects more than 25.6 million people in Japan alone," Mr Lee said.
Regeneus was up four cents or 36.4 percent to 15 cents with 14.5 million shares traded.

PAINCHEK

Painchek says it has commitments to raise $10 million through a placement at 11 cents a share, a 14.1 percent discount to the 15-day volume weighted average price.
Painchek said the funds would be used to target international expansion of its adult dementia application, launch its home care dementia application in Australia in 2020 and other markets in 2021, and target regulatory clearance for its children's application in Australia and Europe in 2021.
Painchek said Bell Potter Securities and Canaccord Genuity were the joint lead managers to the placement.
Painchek fell half a cent or 3.85 percent to 12.5 cents with 13.0 million shares traded.

ADALTA

Adalta says it has commitments to raise $4 million in a placement and hopes to raise a further $4.1 million in a non-renounceable one-for-four rights offer at 10 cents a share.
Adalta said the placement was oversubscribed and was at a 14.1 percent discount to the 15-day volume weighted average price and a 4.8 percent discount to the last closing price.
The company said the record date for the rights offer would be August 14, it would open on August 19 and close on September 2, 2020.
Adalta said the funds would be used to further develop AD-214, improve its platform, initiate discovery projects to add new pipeline assets and for working capital.
Adalta said that WG Partners would receive six percent of the funds as the lead manager and bookrunner to the placement.
Adalta was up half a cent or 4.8 percent to 11 cents.

SUDA PHARMACEUTICALS

Suda says it has completed its placement to raise $533,453 at 2.5 cents a share.
Last week, Suda said it had raised $3.56 million through a “heavily oversubscribed” one-for-one non-renounceable pro rata entitlement offer, scaled back from applications for $5.2 million, and would place a further 21,338,159 shares at 2.5 cents a share to raise $533,453 (BD: Aug 3, 2020).
Suda fell 0.1 cents or 2.4 percent to 4.1 cents with 1.45 million shares traded.

ACRUX

Acrux says it has a five-year US sales, marketing and distribution agreement with Harris Pharmaceuticals for its generic Emla anaesthetic cream.
Acrux said its subsidiary Acrux DDS would share profits from sales of the eutectic mixture of local anaesthetics (Emla) cream with Harris, who would be responsible for commercialization.
According to the Emla Australia website, the combination lidocaine and prilocaine cream was a topical numbing anaesthetic for the skin.
Acrux chief executive officer Michael Kotsanis said the agreement with Harris “aligns their dermatological experience with the product we have developed”.
“This is the third licencing agreement that we have entered into this year and it too represents another significant step in implementing Acrux’s generics strategy,” Mr Kotsanis said.
Acrux was up one cent or 6.25 percent to 17 cents with 3.2 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has submitted a drug master file to the US Food and Drug Administration for TLX101 for glioblastoma multiforme.
Telix said its large neutral amino acid transporter (LAT-1) targeting candidate TLX101 was currently in phase I/II development in a combination trial with external beam radiation therapy, and was recruiting at five European and Australian sites, with preliminary data expected by December 31, 2020.
Telix chief executive officer Dr Christian Behrenbruch said, “the filing of a drug master file with the FDA for our [glioblastoma multiforme] therapy product is an important step towards enabling luminary academic and pharma collaborators to initiate investigator-led studies with this product in the US, as well as potentially expanded access use in the longer term, subject to the requisite FDA approvals”.
“The filing of a [drug master file] for this product will potentially accelerate the generation of further clinical data in both glioblastoma and other LAT-1 expressing malignancies,” Dr Behrenbruch said.
Telix fell half a cent or 0.4 percent to $1.36.

NUHEARA

Nuheara says it has ISO 9001:2015 certification for its quality management system for research and development, product design, engineering, support, sales and marketing.
Nuheara said the certification and audits were conducted by Chicago’s SAI Global.
Nuheara chief executive officer Justin Miller said the certification “reflects our company’s commitment to quality, continuous improvement, and our customer focus”.
Nuheara was up 0.1 cents or 1.85 percent to 5.5 cents with 9.7 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has orphan drug designation approval and feedback from regulatory agencies for its pentosan polysulphate sodium for muco-poly-saccharidosis.
Paradigm said the European Medicines Agency had approved orphan status for muco-poly-saccharidosis type-VI (MPS-VI) and it would receive benefits, including qualified clinical testing, a waiver of new drug application and biological license application user fees, and it would also be eligible for seven-year marketing exclusivity on approval.
The company said it had positive feedback from a parallel scientific advice meeting with both the European Medicines Agency and the US Food and Drug Administration for a phase II/III trial for MPS-VI.
Paradigm said that the meeting clarified the design of the clinical program and the company received feedback on the regulatory pathway.
The company said it also had ethics committee approval for an open-label, single-centre, pilot phase II trial for MPS type-1 (MPS-1) at Adelaide's Women's and Children's Hospital, evaluating safety and tolerability.
Paradigm was up seven cents or 2.4 percent to $2.95 with 2.2 million shares traded.

4D MEDICAL

Perennial Value Management says it has become a substantial shareholder in 4D Medical with 14,526,356 shares or 5.49 percent.
The Sydney-based Perennial said that between July 27 and August 10, 2020 it acquired 15,249,986 shares for $11,145,837 or 73.1 cents a share.
4D Medical fell six cents or 3.5 percent to $1.64 with 5.3 million shares traded.

VISIONEERING TECHNOLOGIES

Regal Funds says it has reduced and been diluted in Visioneering from 83,960,912 shares (10.11%) to 83,018,688 shares (8.87%).
The Sydney-based Regal Funds said that between June 30 and July 8, 2020 it sold 942,224 shares for between 1.3 and 2.2 cents a share.
Regal Funds said that it was diluted on August 3, 2020 due to the release of 62,366,750 restricted shares in lieu of remuneration.
Visioneering fell 0.1 cents or 5.9 percent to 1.6 cents with 1.9 million shares traded.

IMPEDIMED

Impedimed says it has promoted interim chief financial officer and head of finance Timothy Cruickshank to its chief financial officer.
In March, Impedimed said chief financial officer Morten Vigeland had resigned and Mr Cruickshank had been appointed in the interim (BD: Mar 20, 2020).
Today, the company said Mr Cruickshank had been with the company since 2008 and held a Bachelor of Science and Accounting from Syracuse University and a Master of Financial and Accounting Management from the Queens, New York-based Keller Graduate School of Management.
Impedimed was up 0.2 cents or 2.5 percent to 8.1 cents with 2.6 million shares traded.