Biotech Daily

Tuesday July 31, 2018

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: BENITEC UP 8%; ADMEDUS DOWN 30%**

*** CELLMID RAISES $9m, SHARE PLAN FOR $1m MORE**

*** BIOCURATE INITIAL $1.5m FOR 6 BIOMEDICAL RESEARCH PROJECTS**

*** REDHILL RHB-104 (MYOCONDA) EFFECTIVE FOR CROHN'S DISEASE**

*** CYNATA: CYMERUS IMPROVES CARDIAC RECOVERY IN RATS**

*** IMMUTEP IMP321 CANCER TRIAL FDA IND APPROVED**

*** AUSTRALIAN PATENT FOR RECCE ANTIBIOTICS**

*** BIOTECH DAILY APPENDIX 4C QUARTERLY REPORTS POLICY**

*** ADMEDUS Q4 RECEIPTS UP 68% TO $7.6m; H1 $14m**

*** AVITA RECEIPTS FROM CUSTOMERS UP 22% TO $9.6m**

*** MACH7 RECEIPTS UP 14% TO $9.5m**

*** MESOBLAST RECEIPTS UP 207% TO $7.6m**

*** CELLMID REVENUE UP 21% TO $6.7m**

*** ADHERIUM RECEIPTS UP 127% TO $5.4m**

*** IQ3 RECEIPTS UP 36% TO $4.9m**

*** MEDLAB RECEIPTS UP 48% TO $4.7m**

*** NUHEARA RECEIPTS UP 114% TO $4.1m**

*** IMMUTEP RECEIPTS UP 313% TO $3.5m**

*** RHINOMED REVENUE UP 24% TO $2m**

*** USCOM RECEIPTS DOWN 26% TO $2.1m**

*** HYDROPONICS RECEIPTS UP 316% TO $1.4m**

*** MICRO-X RECEIPTS UP 114% TO $1.3m; ONE QUARTER CASH**

*** OBJ RECEIPTS UP 339% TO $1.2m**

*** G MEDICAL HAS LESS THAN TWO QUARTERS CASH**

*** HYDROPONICS: 'ENDOCA MEDICAL MARIJUANA IN AUSTRALIA'**

*** MGC APPOINTS PROF WENDYL D'SOUZA MEDICAL MARIJUANA ADVISER**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Tuesday July 31, 2018 with the ASX200 up 1.8 points to 6,280.2 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and two were untraded. All three Big Caps fell.

Benitec was the best, up 1.5 cents or 7.7 percent to 21 cents with 542,813 shares traded. Dimerix and Osprey climbed more than five percent; Clinuvel improved 4.5 percent; Opthea was up 3.6 percent; Mesoblast and Polynovo rose two percent or more; Airxpanders was up one percent; with Cynata up 0.4 percent.

Admedus led the falls, down seven cents or 29.8 percent to 16.5 cents with 11.3 million shares traded. Uscom lost 8.1 percent; Ellex fell 5.7 percent; Cyclopharm, Imugene, Oncosil, Orthocell and Prescient retreated more than four percent; Actinogen, Bionomics and Compumedics were down more than three percent; Genetic Signatures, Impedimed, Medical Developments, Nanosonics, Telix and Volpara shed two percent or more; Cochlear, Pro Medicus and Resmed were down more than one percent; with CSL and Sirtex down by less than one percent.

CELLMID

Cellmid says it has raised $9.0 million in a two-tranche share placement at 38 cents share and will offer a share purchase plan to raise a further $1 million

Cellmid said the placement and plan price of 38 cents was a 17.8 percent discount to the 30-day volume-weighted average price to the last day of trading on July 26, 2018.

The company said that 12.5 percent of the placement would be issued to directors; with 11.1 percent to the Dennis Eck family, 0.3 percent to Dr Martin Cross and 1.1 percent to chief executive officer Maria Halasz.

Cellmid said the placement's second tranche and the issue to directors would be subject to shareholders' approval at the next general meeting expected about September 7, 2018.

The company said that the proceeds raised would be used to drive growth in the consumer health business, specifically the flagship Évolis hair growth product range and the exclusive distribution agreement with Fillerina in Australia and New Zealand.

Cellmid said that "a significant portion of the capital raised will be used to increase inventory and boost the company's sales and marketing capabilities".

Cellmid chairman Dr David King said the company was "delighted to secure funding for the expansion of our consumer health business at this critical stage, when distribution channels are set up in major global markets such as China and the US".

"The funding will allow us to turbo charge our growth plans and take the company closer to profitability," Dr King said.

Cellmid said that under the share plan each eligible shareholder would be able to apply for up to $15,000 of Cellmid shares.

The company said the share plan record date was July 30, the plan would open on August 6 and close on August 30, 2018.

Cellmid said that Blue Ocean Equities Pty Ltd acted as the sole lead manager to the placement.

Cellmid fell 5.5 cents or 12.0 percent to 40.5 cents.

BIOCURATE PTY LTD

Biocurate says it has provided an initial $1.5 million for six early-stage drug discovery projects from research groups at the University of Melbourne and Monash University.

Last year, Biocurate said it was a venture launched in 2016 by Monash University and the University of Melbourne and supported by the Victorian Government, with former Victoria Treasurer and Premier John Brumby as its chair (BD: May 2, 2017).

Mr Brumby said at that time that Biocurate's ambition was "to unlock the exceptional research capabilities of the University of Melbourne and Monash University and their partners in hospitals, medical institutes and industry, enabling significant new discoveries to be translated more rapidly into new medicines".

Today, the company said the first tranche of investments for the six projects would be supplemented by more funds as they reached development milestones.

Biocurate said the recipients were Dr Glen Carter and Prof Jonathan Baell for a new class of antibiotics; Dr Natalie Borg and Prof David Jans for a new target for both viral infection and cancer; Prof Charles Mackay, Dr Remy Roberts and Prof Mark Sleeman for a new cancer therapeutic; Prof Rob Widdop, Prof Mibel Aguilar and Dr Mark Del Borgo for an anti-fibrotic therapy; Prof Ray Norton for a new treatment for autoimmune diseases; and Dr Sheena McGowan and Prof Peter Scammells for infection and cancer therapeutics.

In a media release, Biocurate chief executive officer Prof Glenn Begley said his company was "building on the combined research strength of these two outstanding Australian universities, accelerating and strategically guiding these high value projects to give them the best possible chance of commercial and clinical success".

Biocurate said that all of the projects had "compelling clinical and commercial reasons to support their early investment and development … [and] addresses an important unmet clinical need, adopts a novel approach and targets potential global markets."

Biocurate said it would take on more projects in 2018 and would work across different therapeutic areas and modalities including small molecules, biologics and antibodies.

The company said its approach to projects would be "collaboration, cooperation and commercial rigor to achieve scale at the international level" and it was providing on-the-ground expertise and mentoring in drug development and commercialization, funding and project management, "coupled with … extensive international industry experience in drug development and biopharmaceutical and investment networks [to] boost the opportunity for these, and future, projects to undergo successful translation".

The company said it aimed to be a leader in the translation of research into therapeutics.

Prof Begley said the University of Melbourne's head of Pharmacology and Therapeutics Prof Danny Hoyer and the dean of Monash University's Faculty of Pharmacy and Pharmaceutical Sciences Prof Bill Charman were "the architects" of Biocurate.

Prof Charman told the launch that research was about "collaboration, innovation and synergies" and that 60 percent of large pharmaceutical company new drugs were sourced outside the major companies, originating at universities and research institutes.

Prof Charman said that the company was designed "to curate and nurture research to commercialization.

"I don't think the eco-system has ever been more favorable," Prof Charman said. "We have support from universities and government."

"We should make hay while the sun shines and the sun is shining on our sector at the moment," Prof Charman said.

In the media release, Victoria Minister for Innovation Philip Dalidakis said his Government was "proud to support the early-stage drug development research lead by Melbourne and Monash Universities, whose combined expertise in the areas of pharmacology, immunology, neurosciences, and cardiology see them ranked among the world's best".

REDHILL BIOPHARMA

Redhill says its 331-patient, phase III trial of RHB-104 for Crohn's disease showed a superior remission rate at week-26 compared to placebo (p = 0.013).

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, the company said that along with the top-line efficacy results for the intent-to-treat population RHB-104 met its key secondary endpoints.

Redhill said that the proportion of patients meeting the primary endpoint, defined as a Crohn's Disease active index (CDAI) value of less than 150, was significantly greater in the RHB-104 group compared to placebo (37% vs 23%, p = 0.013).

Redhill medical director Dr Ira Kalfus said the "robust results of this study demonstrate that RHB-104 could become a leading therapeutic option in Crohn's disease and bring hope to patients worldwide".

The company said that patients treated with RHB-104 achieved a statistically significant greater response at week-26, defined as a decrease of 100 or more points in the CDAI from baseline, compared to placebo (44% vs 31%, p = 0.028).

Redhill said that at 52 weeks of treatment, remission in the RHB-104 arm continued to be favorable compared to placebo (27% vs 20%, p = 0.155).

The company said that RHB-104 was generally safe and well tolerated, with both the active and placebo treatment groups having similarly low rates of serious adverse events and treatment emergent adverse events leading to study drug discontinuation, indicating a positive safety profile for RHB-104.

Redhill said it would continue to assess additional exploratory endpoints as data became available, including mucosal healing, MAP status, quality of life assessment, sub-population analyses and pharmacokinetics.

The company said RHB-104 was based on the hypothesis that Crohn's disease was caused by Mycobacterium avium subspecies paratuberculosis (MAP) infection in susceptible patients.

"This is the first global, double-blind, placebo-controlled study that demonstrates the efficacy of anti-MAP therapy in Crohn's disease," Dr Kalfus said.

"The availability of antibiotic therapy for treating Crohn's disease could be transformative," Dr Kalfus said.

"The results from the [Redhill] MAP US study are excellent, successfully meeting the primary endpoint at week-26 and demonstrating that treatment with RHB-104 also has an early benefit at week-16, which is persistent though [to] week-52," Dr Kalfus said.

"The study results compare favorably to existing standard-of-care therapies," Dr Kalfus said.

Redhill chief executive officer Dr Dror Ben-Asher said the company looked forward "to discussing the path to approval with the [US Food and Drug Administration] and to accelerating discussions with potential pharma partners."

The company said that an open-label extension phase III study (MAP US2 study) was ongoing to evaluate the safety and efficacy of RHB-104 in subjects who remained with active Crohn's disease (CDAI ≥ 150) after 26 weeks of blinded study therapy in the phase III MAP US study.

Redhill said that additional clinical studies were likely to be required to support a US new drug application for RHB-104, if filed.

The company said that in 2017, about 1.5 million people worldwide had been diagnosed with Crohn's disease, with sales of therapies estimated to exceed $US10 billion in 2018.

On the Nasdaq, Redhill fell 0.68 US cents or 7.21 percent to $US8.75 ($A11.78) with 3.3 million shares traded.

CYNATA THERAPEUTICS

Cynata says a study of its Cymerus mesenchymal stem cells (MSCs) in rats has shown improved cardiac function compared to placebo or bone marrow-derived MSCs.
Cynata said the study, conducted at Sydney's Westmead Institute for Medical Research, induced heart attacks in rats and treated them four days later with the stem cells and assessed them over a 28-day period.
The company said the study compared fractional shortening, which provided an estimate of the heart's ability to contract, between the three treatment groups, with rats in the Cymerus group also showing a lower left ventricular end-systolic diameter than the other groups, which indicated improved cardiac function and reduced risk of further cardiac events.
The company said there was no significant difference in scar size between the groups.
Cynata was up half a cent or 0.4 percent to $1.25.

IMMUTEP

Immutep says the US Food and Drug Administration has approved the investigational new drug application for its phase II trial of IMP321 for cancer.
Immutep said the approval for the trial of IMP321, also known as eftilagimod alpha, allowed the company to begin its US Tacti-002 phase II study to evaluate the combination of IMP321 and anti-PD-1 therapy Keytruda, or pembrolizumab, for non-small cell lung carcinoma, or head and neck carcinoma, subject to the completion of other preparatory steps.
Immutep chief executive officer Mark Voight said the approval was "one more important milestone for the company's pipeline of LAG-3 immunotherapeutic products that aim to transform the treatment of cancer and autoimmune diseases".
Earlier this year, the company said its IMP321 with Keytruda combination trial for melanoma resulted in 11 of 18 patients having an overall response, with two complete responses (BD: May 30, 2018).
Immutep was unchanged at 3.4 cents with 6.6 million shares traded.

RECCE PHARMACEUTICALS

Recce says the Australian Patent Office has "accepted for grant" a patent protecting its synthetic antibiotics.
Recce said the patent, titled 'Copolymer and Method for Treatment of Bacterial Infection', protected its synthetic antibiotics until November 2034.
Recce said the patent was the first of its patent family two, which covered multi-drug applications, with patents in this family in the US and Europe in "late stages of review".
The company said the patent covered the manufacture of Recce antibiotics, their use in the treatment of infections caused by bacteria in the blood, meninges, lungs, urinary tract, sinuses, skin, wounds and abscesses, and the prevention of bacterial infection from surgical procedures, as well as the administration of Recce antibiotics by oral, injection, inhalation and transdermal application.
Recce was up half a cent or 2.8 percent to 18.5 cents.

BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all the significant announcements to the ASX.
Biotechnology companies bleeding money is not news, unless the company involved has less than two quarters of cash.
When companies clearly explain that they expect an R&D Tax Incentive, have equity draw-down facilities or loans or are about to have a capital raising, Biotech Daily will not report their Appendix 4C statement.
Where there is no explanation or it is not clear and the company has less than six months of cash reserves, it will be reported.
We note that of the 130 biotech companies listed on the ASX, 26 had filed their 4Cs by last Friday July 27, with 16 more yesterday and 36 before 4pm today, leaving about 50 companies to file by 10am tomorrow morning.
Companies reporting after the close of business will be reported in the following edition.

David Langsam
Editor

ADMEDUS

Admedus says that receipts from customers for the six months to June 30, 2018 was $14,374,000 compared to $20,150,000 for the 12 months to June 30, 2017.
Last December, Admedus said it would change its reporting year from June 30 to December 31 (BD: Dec 11, 2017).
In its Appendix 4C quarterly report today, Admedus said receipts from customers for the three months to June 30, 2018 were up 67.95 percent to $7,598,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $4,426,000 at June 30, 2018 and $5,000,000 in a loan facility, with an estimated cash outflow for the next three months of $12,573,000.
Admedus fell seven cents or 29.8 percent to 16.5 cents with 11.3 million shares traded.

AVITA MEDICAL

Avita says that receipts from customers for the year to June 30, 2018 rose 21.6 percent to $9,584,000.
In its Appendix 4C quarterly report, Avita said that receipts for its Recell wound product was up 52.3 percent to $1,811,000 compared to the previous corresponding period, with revenue from its US Biomedical Advanced Research and Development Authority contract up 16.15 percent to $7,773,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $14,825,000 at June 30, 2018 and an estimated cash outflow for the next three months of $8,050,000.
Avita was unchanged at 8.1 cents with 1.4 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says that receipts from customers for the year to June 30, 2018 was up 13.5 percent to $9,544,000 compared to the previous corresponding period.
In its Appendix 4C quarterly report Mach7 said that receipts from customers for the three months to June 30, 2018 fell 20.1 percent to $2,344,000 compared to the previous period.
The company said it had cash and cash equivalents of $2,505,000 at June 30, 2018 and an estimated cash outflow for the next three months of $3,347,000.
Mach7 was up one cent or five percent to 21 cents.

MESOBLAST

Mesoblast says that receipts from customers for the year to June 30, 2018 was up 207.0 percent to $US5,625,000 ($A7,584,000) compared to the previous corresponding period.
Mesoblast said it had cash and cash equivalents of $US77.8 million at July 10, 2018, along with loan facilities and an estimated three-month cash outflow of $US22,467,000.
Mesoblast was up 4.5 cents or 2.45 percent to $1.885 with 1.8 million shares traded.

CELLMID

Cellmid says that revenue for the year to June 30, 2018 was up 21.2 percent to $6.74 million compared to the previous corresponding period.
In its Appendix 4C quarterly report, Cellmid said that receipts from customers for the year to June 30, 2018 were up 15.8 percent to $5,382,000 compared to the previous period.
Today, the company said it had raised $9 million in a placement and expected to raise a further $1 million through a share purchase plan (see above).
Cellmid said it had cash and cash equivalents of $1,601,000 at June 30, 2018 and an estimated cash outflow for the next three months of $2,430,000.

ADHERIUM

Adherium says that receipts from customers for the year to June 30, 2018 was up 127.0 percent to $5,363,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $12,118,000 at June 30, 2018 and an estimated cash outflow for the next three months of $5,886,000.
Adherium fell 1.7 cents or 15.45 percent to 9.3 cents.

IQ3 CORP

IQ3 says that receipts from customers for the year to June 30, 2018 was up 36.15 percent to $4,860,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $166,000 at June 30, 2018 and an estimated cash outflow for the next three months of $1,465,000, and revenue for the three months to June 30, 2018 of $1,680,000.
IQ3 was untraded at 25 cents.

MEDLAB CLINICAL

Medlab says that receipts from customers for the year to June 30, 2018 was up 47.45 percent to $4,708,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $20,333,000 at June 30, 2018 and an estimated cash outflow for the next three months of $2,485,000.
Medlab fell one cent or 2.1 percent to 46.5 cents.

NUHEARA

Nuheara says that receipts from customers for the year to June 30, 2018 was up 113.69 percent to $4,058,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $8,346,000 at June 30, 2018 and an estimated cash outflow for the next three months of $4,700,000.
Nuheara fell 0.4 cents or 4.3 percent to nine cents with 6.1 million shares traded.

IMMUTEP (FORMERLY PRIMA BIOMED)

Immutep says that receipts from customers for the year to June 30, 2018 rose 312.49 percent to $3,535,000 compared to the previous corresponding period.
Earlier this year, Immutep said it received payments from Novartis for IMP701, EOC for a trial approval, and $1.3 million from the French Government (BD: Feb 23, 2018).
The company said it had cash and cash equivalents of $23,476,000 at June 30, 2018 and an estimated cash outflow for the next three months of $5,261,000.

RHINOMED

Rhinomed says that unaudited revenue for the year to June 30, 2018 rose 23.98 percent to $2,130,000 compared to the previous corresponding period.
In its Appendix 4C quarterly report Rhinomed said that receipts from customers for the year to June 30, 2018 fell 12.65 percent to $1,768,000 compared to the previous corresponding period, with trade receivables of about $1.04 million yet to be recognized.
Rhinomed said it had cash and cash equivalents of $1,263,000 at June 30, 2018 and an estimated cash outflow for the next three months of $1,150,000.
Rhinomed was up half a cent or 2.5 percent to 20.5 cents.

USCOM

Uscom says that receipts from customers for the year to June 30, 2018 fell 25.83 percent to $2,082,922 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $2,492,575 at June 30, 2018 and an estimated cash outflow for the next three months of $1,078,000.
Uscom fell 1.5 cents or 8.1 percent to 17 cents.

THE HYDROPONICS COMPANY

Hydroponics says that receipts from customers for the six months to June 30, 2018 was up 316.2 percent to $1,365,000 compared to the previous corresponding period.
Hydroponics said it had cash and cash equivalents of $8,606,000 at June 30, 2018 and an estimated cash outflow for the next three months of $1,550,000.
Hydroponics fell two cents or 3.7 percent to 52 cents.

MICRO-X

Micro-X says that receipts from customers for the year to June 30, 2018 was up 114.2 percent to $1,311,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $4,062,000 at June 30, 2018 and an estimated cash outflow for the next three months of $4,881,000.
Micro-X fell 2.5 cents or 6.6 percent to 35.5 cents.

OBJ

OBJ says that receipts from customers for the year to June 30, 2018 was up 339.15 percent to $1,234,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $4,170,000 at June 30, 2018 and an estimated cash outflow for the next three months of $750,000.
OBJ fell 0.9 cents or 24.3 percent to 2.8 cents with 13.0 million shares traded.

G (GEVA) MEDICAL

G Medical says its net operating cash burn for the three months to June 30, 2018 was $US4,979,000 with cash at the end of the quarter of $US3,204,000.
G Medical said it had revenue of $US356,000 in the three months to June 30 and expected to spend $US4,950,000 in the three months to September 30, 2018, with loan facilities from Israel's Bank Mizrahi Tfahot of $US2,008,000, a loan of $US1,497,000 and a loan from controlling shareholder and chief executive officer Dr Yacov Geva of $US1.5 million.
G Medical fell half a cent or 2.6 percent to 19 cents.

HYDROPONICS

Hydroponics says that Australian patients can now access Endoca medicinal cannabis through the Medicinal Cannabis Medicines Portal.
Hydroponics said the cannabidiol products were available through the approved prescriber and special access schemes.
The company said its wholly owned subsidiary, Canndeo, had released its first medicinal cannabis products, imported from European partner, Endoca.

MGC (MEDICAL GRADE CANNABIS) PHARMA

MGC says Prof Wendyl D'Souza has been appointed to its medical advisory board to lead research and development into medicinal cannabis for neurological disorders.
MGC said that Prof D'Souza was a consultant neurologist and epileptologist with more than 15 years' clinical experience researching new and emerging treatments for common neurological disorders and was currently a University of Melbourne professor in neuro-epidemiology and health services research and the head of epilepsy services at Melbourne's St Vincent's Hospital.
The company said that Prof D'Souza was an authorised prescriber of medicinal cannabis and had treated more than 3,000 patients with drug-resistant epilepsy from currently available treatments in Australia.
MGC fell 0.3 cents or 5.3 percent to 5.4 cents with 4.9 million shares traded.