Biotech Daily

Thursday August 30, 2018

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: COMPUMEDICS UP 12%; MEDICAL DEV DOWN 6%**

*** CYNATA CYP-001 STEM CELLS PHASE I SAFETY, EFFICACY FOR GvHD**

*** PRESCIENT: 2 PTX-200 AML COMPLETE RESPONSES; EXTENSION STUDY**

*** SIENNA, RMH STUDY HTERT FOR INDETERMINATE THYROID CANCER**

*** DSMB OKAYS MEDICAL DEVELOPMENTS YOUTH PENTHROX TRIAL**

*** COMPUMEDICS REVENUE UP 7.5% TO $37m, PROFIT UP 113% TO $2.8m**

*** CLINUVEL REVENUE UP 52% to $26m, PROFIT UP 86% TO $13m**

*** MESOBLAST REVENUE UP 619% TO $17m, LOSS DOWN 54% TO $48m**

*** LBT 'REBATE REVENUE' UP 0.6% TO $6m, LOSS DOWN 47.7% TO $2.7m**

*** CRYOSITE REVENUE $5.9m, LOSS $1.2m**

*** IMPEDIMED REVENUE DOWN 15% TO $5.2m, LOSS DOWN 1.4% TO $27m**

*** RESONANCE REVENUE UP 15% TO $2.9m, LOSS TO $225k PROFIT**

*** IMMURON REVENUE UP 32% TO $1.8m, LOSS DOWN 55.5% TO $3m**

*** MICRO-X REVENUE UP 144% TO $1.6m, LOSS UP 28% TO $16.6m**

*** G MEDICAL H1 REVENUE $1.4m, LOSS UP 61% TO $11.7m**

*** MMJ 'LOSS OF CONTROL' REVENUE UP 40,034% TO $49m, PROFIT $34m**

*** BOTANIX: FDA 'CONFIRMS' CANNABIDIOL BTX1204 ECZEMA TRIAL**

*** MEDADVISOR, EBOS, HPS WORK ON HOSPITAL DRUG MANAGEMENT**

*** ONCOSIL APPOINTS IQVIA MARKET ADVISOR FOR THE EU**

*** CELLMID NEIMAN MARCUS, SOFT SURROUNDINGS ÉVOLIS LAUNCH**

*** INNATE TO RENAME AS AMPLIA**

*** DIRECTOR NIALL CAIRNS, C2, CARNETHY TAKE 15% OF CARDIEX**

MARKET REPORT

The Australian stock market slipped 0.01 percent on Thursday August 30, 2018 with the ASX200 down 0.4 points to 6,351.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and four were untraded. All three Big Caps rose.

Compumedics was the best, up 5.5 cents or 11.7 percent to 52.5 cents with 257,099 shares traded. Prescient climbed 10 percent; Clinuvel, Factor, Mesoblast and Oncosil improved more than four percent; Ellex and Pro Medicus were up three percent or more; Immutep and Neuren rose more than two percent; Cochlear, CSL, Cyclopharm, Orthocell, Polynovo, Resmed and Telix were up more than one percent; with Opthea and Sirtex up by less than one percent.

Medical Developments led the falls, down 29 cents or 6.4 percent to $4.22 with 274,179 shares traded. Airxpanders and Bionomics fell more than four percent; Actinogen, Avita and Cynata were down three percent or more; Osprey shed 2.3 percent; Genetic Signatures, Optiscan and Pharmaxis were down one percent or more; with Starpharma and Volpara down by less than one percent.

CYNATA THERAPEUTICS

Cynata says that high dose CYP-001 demonstrated safety and efficacy in its 15-patient phase I trial for steroid-resistant acute graft-versus-host disease

Cynata said that 100-day data showed that the mesenchymal stem cell CYP-001 met all clinical endpoints in the trial, “consistent with day-100 data from the lower-dose cohort A and a day-28 evaluation of cohort B”.

The company said that patients in cohort A received 1,000,000 cells per kilogram of bodyweight, to a maximum of 100 million cells per infusion and cohort B received 2,000,000 cells per kg, to maximum of 200 million cells per infusion.

Cynata said that 14 of the 15 patients (93.3%) had an overall response, measured as an improvement in GvHD severity by at least one grade compared to baseline.

The company said eight of the 15 patients (53.3%) had a complete response with GvHD signs and symptoms completely resolved and 13 patients (86.7%) survived to day-100.

The company said there were no treatment-related serious adverse events or safety concerns identified.

Cynata head of product development Dr Kilian Kelly said that CYP-001 “met all clinical endpoints in the first trial of a product based on our Cymerus stem cell technology”.

“The clinical results from patients in cohorts A and B are highly encouraging, as all of the patients had failed to respond to corticosteroid therapy, the only approved treatment for GvHD,” Dr Kelly said.

Cynata said one cohort B patient withdrew on day-22 to begin palliative care, but all other patients remained alive at day-100.

The company said it would provide a formal clinical study report to its partner Fujifilm which would then have 90 days to exercise its licence option.

Cynata said the data supported “the advancement of additional Cymerus [mesenchymal stem cell] product candidates directly to phase II trials in other indications” and it was planning a phase II trial for critical limb ischemia.

Cynata chief executive officer Dr Ross Macdonald said the completion of the trial “marks a major achievement not only for Cynata but also as a world-first for [induced pluripotent stem cell]-derived therapeutic products”.

Cynata fell five cents or 3.7 percent to $1.30.

PRESCIENT THERAPEUTICS

Prescient says two of 13 patients have had a complete response in its combination trial of PTX-200 with cytarabine for relapsed or refractory acute myeloid leukemia.
Prescient said the results were encouraging and it would reduce to dose of cytarabine to optimize Akt inhibition for a nine to 12 patient extension study at Florida's H Lee Moffitt Cancer Centre, the Yale Cancer Center and Kansas University Medical Center.
The company said that given the "very difficult to treat patient population, it was "delighted to report that two patients had a complete response to treatment, meaning total eradication of disease" which was an improvement on single agent activity of PTX-200 in the phase I monotherapy study.
Prescient said that "some peculiar toxicities" were observed in three patients, including stomatitis, appendicitis and a small bowel obstruction, which were not seen in the phase I study of PTX-200 as a monotherapy, nor in the other PTX-200 trials, with transaminase elevation observed in three subjects, but only one was dose limiting.
The company said that it would lower the cytarabine dose to optimize PTX-200 and better inhibit Akt, with a similar modification made in the PTX-200 ovarian cancer, trial which reduced the amount of carboplatin.
Prescient said the extension study would increase the number of samples for analysis.
Prescient was up 0.9 cents or 10 percent to 9.9 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says that with the Royal Melbourne Hospital it will investigate the use of its telomerase diagnostic for thyroid cancer.
Sienna said the study would investigate its human telomerase reverse transcriptase (hTERT) in-vitro diagnostic on fine needle aspirate samples from thyroid glands.
In March, Sienna announced the first sale of its hTERT-based adjunct test for bladder cancer in Europe (BD: Mar 13, 2018).
Today, the company said that hTERT was upregulated in about 85 percent of tissue-based cancers, giving the test potential application in a range of cancers.
Royal Melbourne specialist endocrine surgeon Dr Julie Miller said that thyroid nodules were "very common, but usually harmless [and] a needle biopsy can usually tell doctors if a nodule is benign or cancerous".
Dr Miller said that about 10 percent of thyroid needle biopsies were indeterminate and had a 20 to 30 percent chance of harboring cancer, with those patients typically having surgery "to remove half the thyroid to make the diagnosis".
"Sienna's test may help resolve indeterminate needle biopsies limiting the number of patients that require surgical intervention," Dr Miller said.
Dr Miller said the study would compare Sienna's hTERT test on needle biopsies with matched thyroid nodules after removal to determine whether the test was accurate enough to make a correct diagnosis and spare patients from unnecessary surgery.
"If successful, this technique will represent a major breakthrough in care for patients with indeterminate thyroid nodules, as patients with benign disease can avoid surgery altogether, while patients with cancer can have the correct operation the first time, rather than undergoing a two-stage procedure," Dr Miller said.
Sienna was untraded at eight cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says a data and safety monitoring board has approved continuation of trial of Penthrox in children and adolescents from six to 18 years of age.
Medical Developments said the randomized, double-blind, multi-centre, placebo controlled study of the Penthrox inhaled methoxyflurane analgesic for the treatment of acute pain would evaluate the safety and efficacy of children and adolescents presenting to an emergency department with minor trauma.
The company said that 2,051 patients were screened, 94 were randomized of which 12 were not treated and no serious adverse events had been noted.
Medical Developments said the data and safety monitoring board approved the trial to continue as planned without modifications to its target of 220 patients.
Medical Developments fell 29 cents or 6.4 percent to $4.22.

COMPUMEDICS

Compumedics says that revenue for the 12 months to June 30, 2018 increased 7.5 percent to $37,002,000 with net profit after tax up 113.33 percent to $2,784,000.
The company said that sales of its sleep and brain blood flow diagnostic systems in Europe increased 108 percent compared to the previous year with Germany's DWL business was up two percent, Chinese sales were up 28 percent and US sales up 6.3 percent.
The company said that net tangible asset backing per share was up 13.7 percent from 9.5 cents to 10.8 cents, with diluted earnings per share up 128.6 percent to 1.6 cents compared to the previous year's 0.7 cents a share.
Compumedics said it had cash and cash equivalents of $3,906,000 at June 30, 2018, compared to $4,102,000 at June 30, 2017.
Compumedics was up 5.5 cents or 11.7 percent to 52.5 cents.

CLINUVEL

Clinuvel says revenue for the year to June 30, 2017, was up 51.6 percent to $25,750,125 with net profit after tax up 85.9 percent to $13,224,185.
Clinuvel declared a maiden unfranked two cents a share dividend for shareholders at the record date of September 24, 2018.
The company said it was the first time it had announced two consecutive net profits after tax, and followed its decision to charge a uniform price for Scenesse for erythropoietic protoporphyria.
Clinuvel said that commercial European sales were up 79.7 percent to $21,359,000, including the first full 12 months of sales in Germany.
The company said that total sales in Italy and Switzerland under special access schemes fell 14.6 percent to $4,126,000, with Italian sales since August 31, 2016 recorded as commercial, and the previous July and August of 2016-'17 year having a higher demand.
Clinuvel said that diluted earnings per share was up 86.7 percent to 26.7 cents at June 30, 2018, with tangible assets per share increased 54.7 percent to 82 cents,
The company said it had $36,198,451 in cash and cash equivalents at June 30, 2018, compared to $23,752,312 at June 30, 2017.
Clinuvel climbed 55 cents or 4.3 percent to $13.26.

MESOBLAST

Mesoblast says that revenue for the 12 months to June 30, 2017 was up 618.9 percent to $US17,341,000 ($A23,732,680), with net loss after tax down 54.1 percent to $US35,290,000 ($A48,297,460).

Mesoblast said that revenue was primarily $US11.8 million from its licence agreement for the fat-derived stem cell product Alofisel, or Cx601, for fistulae with the Leuven, Belgium-based Tigenix, which was now fully owned by Takeda, in December 2017.

The company said it received $US5.1 million in royalties and milestones from sales of Temcell for graft versus host disease by Japan licencee JCR Pharmaceuticals Co, with Temcell royalties up 157.1 percent to $3.6 million.

Mesoblast said that research and development expenditure climbed 11.9 percent to $US65,927,000, with manufacturing costs down 54.3 percent to $US5,508,000 and administration costs down 4.8 percent to $21,907,000.

The company said that net tangible assets backing per security fell 51.7 percent to 4.88 US cents, with diluted loss per share down 60.6 percent to 7.58 US cents.

Mesoblast said it had cash and cash equivalents of $US37,763,000 at June 30, 2018 compared to $US45,761,000 at June 30, 2017.

Mesoblast was up 7.5 cents or 4.8 percent to $1.63 with 1.5 million shares traded.

LBT INNOVATIONS

LBT says revenue for the year to June 30, 2018 was up 0.6 percent to $5,958,000 with net loss after tax down 47.7 percent to $2,683,000.

LBT said that $4.75 million in revenue was a reimbursement for its research and development expenses for its APAS automated plate assessment system by its 50 percent owned joint venture Clever Cell Culture.

LBT said that diluted loss per share fell 57.7 percent to 1.7 cents at June 30, 2018, net tangible assets per share rose 19.3 percent to 7.65 cents and that it had $7,572,000 in cash and cash equivalents at June 30, 2018 compared to $3,498,000 at June 30, 2017.

LBT was unchanged at 11.5 cents.

CRYOSITE

Cryosite says revenue for the 12 months to June 30, 2018 was $5,923,000 with net loss after tax of $1,240,439.

Last year, Cryosite said it would close its cord blood banking service and operate a long-term storage facility for blood and tissue samples previously deposited by past customers as well as the continuing operations of clinical trials and biorepository (BD: Jun 23, 2017).

In 2017, the company said it had revenue of $10,163,000 with a net profit after tax of $225,000 (BD: Aug 24, 2018).

Cryosite said that trials and biorepository revenue was up 2.4 percent to $5,310,826, with revenue from the long-term consumer contracts down 11.7 percent to $553,313.

The company said that no final dividend would be paid this year, following an unfranked dividend of 0.5 cents a share in 2017.

The company said that diluted loss a share was 2.61 cents at June 30, 2018 after posting net earnings per share of 0.48 cents a share in the previous corresponding period, with net tangible asset backing per share down 27.3 percent to four cents.

Cryosite said that it had cash and cash equivalents of $4,688,104 compared to $5,089,110 at June 30, 2017.

Cryosite was untraded at 6.4 cents.

IMPEDIMED

Impedimed says revenue for the year to June 30, 2017, was down 14.8 percent to $5,225,000 with net loss after tax down 1.4 percent to $27,174,000.
Impedimed said medical revenue fell 27.1 percent to $3.5 million, consisting of revenue from its Sozo bio-impedance body composition systems, up 800 percent to $900,000, and revenue from its legacy L-Dex bio-impedance spectroscopy devices for post cancer surgery lymphoedema, which was down 80.7 percent to $2.6 million.
The company said the decrease in medical revenue was caused by a change from revenue recognized on the shipment of products to subscription-based services.
Impedimed company said that diluted loss per share was unchanged at seven cents with net tangible assets per share down 40.0 percent to nine cents and it had cash and cash equivalents of $31,345,000 at June 30, 2018 compared to $54,884,000 at June 30, 2017.
Impedimed was unchanged at 50 cents.

RESONANCE HEALTH

Resonance says revenue for the year to June 30, 2018 was up 14.9 percent to $2,911,615 turning the previous $304,217 loss to a net profit after tax of $224,619.
Resonance said sales of its magnetic resonance imaging-based Ferriscan and other products was up 16.5 percent to $2,896,395.
The company said that diluted earnings per share was 0.06 cents compared to a loss of 0.08 cents in the previous corresponding period and net tangible assets per share rose 7.5 percent to 0.43 cents,
Resonance said it had $1,549,088 in cash and cash equivalents at June 30, 2018 compared to $1,685,375 at June 30, 2017.
Resonance was unchanged at 2.3 cents.

IMMURON

Immuron says revenue for the year to June 30, 2018 was up 32.0 percent to $1,842,909 with net loss after tax down 55.5 percent to $3,010,929.
Immuron said that sales of the travellers' diarrhoea preventative product Travelan had increased in Australia and New Zealand but decreased in Canada and the US.
The company said that diluted loss per share fell 64.1 percent to 2.3 cents at June 30, 2018 and net tangible assets per share rose 16.8 percent to 5.91 cents and that it had $4,727,430 in cash and cash equivalents at June 30, 2018 compared to $3,994,924 at June 30, 2017.
Immuron was up half a cent or 1.5 percent to 34.5 cents.

MICRO-X

Micro-X says revenue for the year to June 30, 2018 was up 143.9 percent to $1,607,000 with net loss after tax up 28.4 percent to $16,595,000.
The company said most of the loss was due to spending $15.2 million on research and development for the its DRX Revolution Nano miniature x-ray system (BD: Oct 4, 2017).
The company said that diluted loss per share rose 10.2 percent to 11.5 cents at June 30, 2018 and net tangible assets per share fell from 9.14 cents to negative 2.05 cents and it had $4,068,000 in cash and cash equivalents at June 30, 2018 compared to $5,573,000 at June 30, 2017.
Micro-X was unchanged at 35 cents.

G MEDICAL

G Medical says its inaugural revenue for the six months to June 30, 2018 was $US1,001,000 ($A1,375,348) with net loss after tax up 60.9 percent to $US8,509,000 ($A11,685,367).

G Medical said it received $US985,000 revenue for Its electro-cardiogram diagnostic services and $US16,000 for sales of its mobile technology health monitoring products.

G Medical said that basic loss per share fell 79.5 percent to 0.025 US cents at June 30, 2018 and net tangible assets per share fell from 0.035 US cents to 0.002 US cents and it had $US3,204,000 in cash and cash equivalents at June 30, 2018 compared to $US14,158,000 at June 30, 2017.

G Medical fell half a cent or 1.4 percent to 35.5 cents.

MMJ PHYTOTECH

MMJ says that revenue for the 12 months to June 30, 2018 increased 40,034 percent to $48,963,000 with net profit after tax of $34,119,000 compared to a net loss of $12,725,000 in the previous corresponding period.

MMJ said $48,324,000 came from the “loss of control” of its now 30.7 percent-owned subsidiary Harvest One Cannabis, and it had “deconsolidated” its 100 percent-owned Phytotech Therapeutics which it would sell to Harvest One (BD: Jun 25, 2018).

The company said the sale of Phytotech Therapeutics was a part of its “strategic intent to operate as a global cannabis investment company with a portfolio of minority investments, rather than having control over its investments”.

The company said that net tangible asset backing per share was up 71.9 percent to 27.47 cents, with diluted earnings per share 15.9 cents compared to the previous year’s 6.71 cent loss per share.

MMJ said it had cash and cash equivalents of $1,347,000 at June 30, 2018, compared to $23,801,000 at June 30, 2017.

MMJ was up 1.5 cents or 6.4 percent to 25 cents.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has confirmed its plans for a phase II trial of its synthetic cannabidiol BTX1204 for atopic dermatitis, or eczema.

Botanix said the pre-investigational new drug meeting with the FDA Division of Dermatology and Dental Products provided an opportunity to seek clarification and support from the FDA on the development plan and data package required to begin phase II studies in the US and Australia and enabled the company “to gain consensus from the FDA on the overall drug development plan required for BTX1204 to support a new drug application”.

The company said it provided data from its phase Ib, randomized, double blinded, vehicle-controlled patient study, the proposed phase II study for moderate atopic dermatitis, the scientific rationale to support the drug’s therapeutic potential, manufacturing standards and details of the human and animal safety data.

Botanix said the FDA “confirmed that the proposed development plan and data package was adequate to support the commencement of the proposed phase II clinical study in the US”.

Botanix was unchanged at 10.5 cents with 1.8 million shares traded.

MEDADVISOR

Medadvisor says it has signed an initial 12-month agreement with Ebos subsidiary HPS to pilot medication management in hospitals.
Last year, Medadvisor said the Melbourne and Christchurch, New Zealand-based Ebos group invested $10.5 million in the company or 14.1 percent (BD: Oct 24, 2018).
Today the company said that HPS was “Australia’s largest provider of outsourced pharmacy services to private hospitals”.
Medadvisor said it had been working with the Ebos Zest division to develop an integrated medication management system for hospitals, which would give Medadvisor patients “full control and oversight to expressly authorize and permit hospital pharmacists to electronically request and retrieve the patient’s … medication history from Medadvisor at the time of admission”.
Medadvisor chief executive officer Robert Read said the collaboration with HPS would “simplify the admission process for patients and potentially make hospital pharmacies more productive and efficient”.
Medadvisor was untraded at 4.2 cents.

ONCOSIL MEDICAL

Oncosil says it has appointed North Carolina’s Iqvia as its market access and reimbursement advisor for its pancreatic cancer treatment in the European Union.
Oncosil said it would collaborate with Iqvia to “develop a strategic and effective approach to commercialization” for the treatment in the European Union.
Oncosil was up one cent or 4.8 percent to 22 cents with 2.3 million shares traded.

CELLMID

Cellmid says it will launch its Évolis hair loss treatment at Neiman Marcus and Soft Surroundings shops in the US on August 31, 2018.
Cellmid said Évolis would be launched at Neiman Marcus shops in Hawaii, California, Florida and Texas and at Soft Surroundings stores from “Arizona to Texas”.
Cellmid was up half a cent or 1.3 percent to 39 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says that all resolutions to its annual general meeting were passed overwhelmingly including the name change to Amplia Therapeutics (BD: Jul 26, 2018).
Innate said the meeting approved the remuneration report, the re-election of director Dr Robert Peach and the grant of 2,330,000 options exercisable at 60 cents each to chief executive officer Simon Wilkinson, Dr Peach and company secretary Andrew Cooke.
The meeting results notice said the greatest dissent was from 77,485 proxy votes (0.7%) opposed to Mr Wilkinson’s options, with 10,432,187 proxy votes (99.3%) in favor.
An Innate executive told Biotech Daily the company expected the name change to Amplia and the change of ASX code to ATX was expected to be formalized next week.
Innate was up one cent or 2.7 percent to 38 cents.

CARDIEX GROUP

The Sydney-based C2 Ventures says it has become a substantial shareholder in Cardiex with 78,000,000 shares (14.68%).

The substantial shareholder notice, signed by Cardiex director Niall Cairns, said that C2 held 75,000,000 and Carnethy Evergreen Pty Ltd was a related party as its sole director, Mr Cairns, was a director of C2 and held 3,000,000 shares.

The notice said that on December 21, 2017 Carnethy bought 3,000,000 shares for $93,340 or 3.1 cents a share and on May 31, 2018 C2 bought 75,000,000 shares for $1,500,000 or two cents a share.

Cardiex was up 0.2 cents or 5.7 percent to 3.7 cents.