Biotech Daily

Friday February 26, 2016

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: USCOM UP 18%, BENITEC DOWN 52%**

*** BENITEC FALLS ON CLOSING TT-034 FOR HEP C TRIAL**

*** BRISBANE WESLEY HOSPITAL JOINS RESAPP 400 PATIENT TRIAL**

*** HEARTWARE 2015 REVENUE DOWN 1% to $382m, LOSS UP 73% TO $73m**

*** ELLEX H1 REVENUE UP 13% TO $35m, PROFIT UP 43% TO $1m**

*** PHARMAXIS REVENUE DOWN 25% to $9m, LOSS UP 70% TO $11m**

*** ADMEDUS H1 REVENUE UP 37% to $6.6m, LOSS UP 19% TO $14m**

*** AVITA H1 REVENUE UP 49% TO $2m, LOSS UP 45% TO $5m**

*** MAYNE H1 REVENUE UP 114% TO $127m, PROFIT UP 349% TO $18m**

*** RESONANCE H1 REVENUE UP 1% TO $1.3m, PROFIT TO $22k LOSS**

*** GI DYNAMICS REVENUE DOWN 54% TO $2m, LOSS DOWN 27% TO $49m**

*** GENETIC SIGNATURES REVENUE UP 101% TO $890k**

*** ORTHOCELL SALES REVENUE UP 17% TO $451k**

*** RHINOMED POSTS FIRST SIGNIFICANT REVENUE OF $522k**

*** OPTHEA H1 REVENUE UP 41% TO $515k, LOSS DOWN 43% TO $1.7m**

*** CORRECTION: ALLEGRA**

*** MMJ REQUESTS 'CAPITAL RAISING' TRADING HALT**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Friday February 26, 2016 with the ASX200 down 1.2 points to 4,880.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and two were untraded.

Uscom was the best, up 2.5 cents or 17.9 percent to 16.5 cents with 57,600 shares traded. Avita climbed 11.7 percent; Oncosil was up 10.3 percent; Prana rose 8.6 percent; Atcor and Compumedics were up more than seven percent; Cellmid was up 5.6 percent; Universal Biosensors climbed four percent; Antisense, Bionomics and Biotron were up more than three percent; with Opthea and Medical Developments up more than two percent.

Benitec led the falls, down 14 cents or 51.85 percent to 13 cents with 5.7 million shares traded. Admedus lost 9.7 percent; Osprey fell 8.3 percent; Pharmaxis was down 5.6 percent; Actinogen and IDT lost more than three percent; Clinuvel, Orthocell, Tissue Therapies and Viralytics shed more than two percent; with Ellex, Polynovo and Psivida down more than one percent

BENITEC BIOPHARMA

Benitec says competition from other hepatitis C treatments has forced the termination of its phase I/IIa trial of DNA-directed RNA interference (ddRNAi) drug TT-034.

In 2013, when Benitec said it was preparing to begin the trial of the once-only infusion of TT-034, the standard of care was daily injections for six to 12 months of interferon and ribavirin, but today there are several drugs on the market for most genotypes that are daily tablets for three months, expected to be listed on the Australian Pharmaceutical Benefits Scheme in the immediate future (BD: Mar 22, 2013).

Benitec faced several separate delays in having the first-in-human trial approved, and then enrolments were slower than expected with the first patient dosed in May 2014 and the second patient dosed in November 2014 (BD: May 29, Nov 13, 2014).

The sixth and first "potentially therapeutic" patient did not receive the drug until June 2015 and the trial is yet to be completed (BD: Jun25, 2015).

Last December, Benitec said that the chief executive officer who supervised the ddRNAi program Dr Peter French would "step down" and chief financial officer Greg West was appointed interim chief executive officer (BD: Dec 9, 16, 2015).

A permanent chief executive officer has not been announced.

Today, Benitec said it would "wind-down its hepatitis C program and terminate it upon completion of patients in cohort four".

Benitec said that the decision to discontinue the hepatitis C program followed a review of the commercial opportunities for TT-034.

The company said that "a number of effective therapies have become available for the treatment of hepatitis C since Benitec commenced its clinical trial in January 2014".

"In recent months, several competitors have made improvements in the efficacy, delivery and success rates of their product treatments while continuing to reduce pricing and treatment duration," Benitec said.

"As a result of this increasing competitive landscape and the time required to get TT-034 to market, TT-034 has generated limited and diminishing partnering interest from pharmaceutical companies," the company said.

Benitec said that the hepatitis C program did not offer the commercial value necessary to attract a worthwhile partnership deal and did not warrant additional expenditure or focus of company resources beyond completion of patients in the fourth cohort.

The company said that completing the work with patients in the fourth cohort could provide valuable data on the ddRNAi technology platform and other pipeline programs and it would complete the collection of trial data and monitor patients through the required long-term safety follow-up period, with final data to be reported by the end of 2016.

The company said that no significant financial obligation would arise from terminating the hepatitis C program.

Benitec said that TT-034 had been shown to be safe and well tolerated, meeting the primary endpoint of the study and, as such, will assist in other programs.

Benitec chief scientific officer Dr David Suhy said that the TT-034 hepatitis C trial data "presented to date shows that TT-034 transduces hepatic tissues, expresses the anti-[hepatitis C short-hairpin] RNA and has a favorable safety profile with no significant adverse events reported relating to the administration of the study drug".

"Considering the novel characteristics of the drug, administered in a manner that cannot be withdrawn, we are pleased with the validity that TT-034 has shown in this trial," Dr Suhy said. "It has provided solid proof-of-concept for our ddRNAi platform and our other pipeline programs, particularly our hepatitis B program."

Benitec fell as much as 61.1 percent to 10.5 cents, closing down 14 cents or 51.85 percent at 13 cents with 5.7 million shares traded.

RESAPP HEALTH

Resapp says the Brisbane-based Wesley Hospital has joined the 400 adult patient trial of its respiratory diagnostic.

The trial began last year at Western Australia's Joondalup Health Campus to demonstrate that the technology, which had been shown "to be highly accurate for diagnosis of childhood respiratory conditions, can be extended to adults" (BD: Dec14, 2015).

Resapp fell half a cent or 3.6 percent to 13.5 cents with 4.5 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says revenue for the year to December 31, 2015, fell 0.6 percent to $US276,843,000 ($A382,452,130) with net loss after tax up 73.4 percent to $US72,780,000 ($A100,542,800).

Heartware chief executive officer Doug Godshall said the company "made substantial progress in expanding our commercial footprint in the past year, adding 55 new hospital centers … [and] with a presence in 47 countries, and more than 300 commercial centers".

Mr Godshall said that Heartware began enrolment in the 'Lateral' 145-patient trial to evaluate the thoracotomy implant technique, presented 'Endurance' destination therapy trial results showing the Heartware ventricular assist device (HVAD) system achieved the primary endpoint, and completed enrolment in the 'Endurance 2' supplemental destination therapy cohort, and initiated the first human implants of the miniaturized ventricular assist device (MVAD) system, and upgraded the quality system.

"In 2016, our priorities include fortifying our HVAD system … and seeking an expanded [destination therapy] indication; completing our remediation efforts related to the warning letter from the FDA; and understanding and resolving the early clinical challenges experienced with our next-generation MVAD system," Mr Godshall said.

Heartware said research and development costs were up 0.8 percent to $US120,769,000 or 43.6 percent of revenue, diluted loss per share increased 269.3 percent to $US4.21 and it had cash and cash equivalents of $US175,047,000 at December 31, 2015.

Last night on the Nasdaq, Heartware fell $US2.30 or 7.09 percent to $US30.13 ($A41.64) with 1,139,329 shares traded.

ELLEX MEDICAL LASERS

Ellex says revenue for the six months to December 31, 2015, was up 13.4 percent to $34,809,000 with net profit after tax up 43.2 percent to $1,167,000.

Ellex said that the revenue increase was due to "organic growth in sales of Ellex-branded product in the US, Europe and Japan of 11 percent … [the] positive impact of [the] lower Australian dollar … [and] discontinuation of contract manufacturing and lower margin third party product sales along with reduction in other third party product sales that has reduced revenue by 11 percent".

Ellex chief executive officer Tom Spurling said it was "very pleasing that our growth has been driven by contributions from our in-house developed Ellex branded products not just the lowering of the value of the Australian dollar".

The company said that net tangible assets per share was up 11.8 percent to 19 cents and diluted earnings per share was up 44.0 percent to 1.08 cents at December 31, 2015 compared to 0.75 cents for the previous period.

Ellex said that cash and cash equivalents at December 31, 2015 was $4,215,000 compared to $3,899,000 at December 31, 2014.

Ellex fell one cent or 1.4 percent to 69 cents.

PHARMAXIS

Pharmaxis says that revenue for the six months to December 31, 2014, fell 25.25 percent to $9,372,000 with net loss after tax up 70.2 percent to $11,185,000.
Pharmaxis said Bronchitol for cystic fibrosis sales increased 34 percent to $2.8 million with Aridol sales up nine percent to $960,000, and other income including the reimbursement of research and development costs under the agreements with Chiesi and Synairgen.
Pharmaxis said that diluted loss per share was up 100 percent from 0.02 cents in the previous year to 0.04 cents for the six months to December 31, 2015, with net tangible assets per share up 119.4 percent to 7.9 cents and cash and cash equivalents of $45,936,000 at December 31, 2015, compared to $54,138,000 at June 30, 2015.
Pharmaxis fell 1.5 cents or 5.6 percent to 25.5 cents.

ADMEDUS

Admedus says that revenue for the six months to December 31, 2015, was up 37.0 percent to $6,568,000 with net loss after tax up 19.3 percent to $13,598,520.
Admedus said that it had “a strong sales period compared to the corresponding period … [with] sales for Cardiocel up 130 percent” to $2.3 million.
The company said that its infusion products portfolio contributed $4.3 million to sales for the six months and it continued its investment in its immunotherapies program.
Admedus said that basic loss per share fell 6.3 percent to 6.94 cents for the six months to December 31, 2015, with net tangible assets per share up 6.0 percent to 12.4 cents.
The company said it held cash and cash equivalents of $19,152,186 at December 31, 2015, compared to $24,025,859 at June 30, 2015.
Admedus fell 5.5 cents or 9.7 percent to 51 cents.

AVITA MEDICAL

Avita says total revenue for the six months to December 31, 2015 was up 49.1 percent to $2,038,200 with net loss after tax up 45.2 percent to $4,929,299.
Avita said that sales of goods fell 32.8 percent from $852,071 in the previous corresponding period to $572,542 for the six months to December 31, 2015 and received a BARDA payment of $643,466.
The company said that total sales of its Recell wound treatment was up 17 percent compared to the six months to December 31, 2014.
Avita said it sold its respiratory business to Medical Developments (BD: Jan 25, 2016).
The company said its net tangible assets per share increased 128.6 percent to 1.6 cents, diluted loss per share fell 17.3 percent to 0.86 cents, with cash and cash equivalents of $7,715,644 at December 31 compared to $2,966,555 at June 30, 2015.
Avita was up 1.1 cents or 11.7 percent to 10.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says its revenue for the six months to December 31, 2015 rose 113.7 percent to $127,261,000 taking net profit after tax up 348.6 percent to $17,905,000.
Mayne said that diluted earnings per share was up 262.1 percent to 2.39 cents for the six months to December 31, 2015, with net tangible assets per share rising from negative 0.8 cents to four cents, and cash and cash equivalents of $49,735,000 at December 31, 2015 compared to $59,201,000 at June 30, 2015.
Mayne was up five cents or 4.3 percent to $1.225 cents with 3.8 million shares traded.

RESONANCE HEALTH

Resonance says revenue for the six months to December 31, 2014, was up 0.9 percent to $1,300,000, turning the previous period's net profit after tax of $448,000 to a loss of $22,000.

Resonance said that sales revenue increased by 17 percent to $1,300,403 with the number of scans up by six percent, but other income was reduced in the absence of government grants compared to $135,000 in the previous corresponding half-year. The company said that operating expenses were up by 25 percent or $290,500 higher compared to the previous corresponding half year due to increased marketing and travel activities and increased research and development spending on Fibrosis, Ferriscan and Hepafat.

Resonance said that net tangible asset backing per share fell 2.9 percent from 0.70 cents to 0.68 cents.

The company said diluted earnings per share was 0.12 cents compared to a loss of 0.04 cents in the previous corresponding period.

Resonance said that cash and cash equivalents at December 31, 2014 was $2,584,226 compared to $2,097,607 at June 30, 2014.

Resonance was untraded at 2.1 cents.

GI DYNAMICS

GI Dynamics says that revenue for the year to December 31, 2013, fell 53.5 percent to $US1,316,000 ($A1,820,270) with net loss after tax down 27.1 percent to $US35,161,000 ($A48,634,070).

GI Dynamics said that the decrease in sales across all markets "was a result of the termination of the Endo trial in the third quarter of 2015 … [and] we decided to focus sales activity on a limited number of countries while disengaging from others".

On Tuesday, GI Dynamics chief executive officer Michael Dale resigned, having been appointed shortly before European Union shipments of the Endobarrier duodenal liner for obesity and type 2 diabetes were halted and the US Food and Drug Administration halted the Endobarrier trial (BD: Aug 25, Oct 6,7, Dec 1, 2014; Mar 6 2015; Feb 24, 2016).

The company said that net tangible assets per Chess depositary interests (CDIs) fell 63.6 percent to 0.04 Australian cents, with diluted loss per common share down 30.8 percent to $US3.71 cents.

GI Dynamics said that it had cash and cash equivalents of $US19,590,000 at December 31, 2015 compared to $US51,191,000 at December 31, 2014.

GI Dynamics was unchanged at two cents.

GENETIC SIGNATURES

Genetic Signatures says that revenue for the six months to December 31, 2015 was up 100.7 percent to $890,224 with net loss after tax down 18.8 percent to $1,612,844.

Genetic Signatures said that domestic diagnostic kit sales were up 100.7 percent to $847,294.

The company said that net tangible assets per security was down 19.3 percent to 7.81 cents with diluted loss per share down 19.3 percent to 2.21 cents.

Genetic Signatures said it had cash and cash equivalents of $4,315,181 at December 31, 2015 compared to $5,461,686 at June 30, 2015.

Genetic Signatures was up six cents or 9.5 percent to 69 cents.

ORTHOCELL

Orthocell says that sale of goods for the six months to December 31, 2015 was up 17.3 percent to $450,832, with total revenue down 19.8 percent to $627,834.
Orthocell said that its net loss after tax was down 14.4 percent to $2,349,626.
The company said that net tangible assets per security was constant at 0.05 cents with diluted loss per share down 20 percent to 2.8 cents.
Orthocell said it had cash and cash equivalents of $6,105,324 at December 31, 2015 compared to $4,774,108 at June 30, 2015.
Orthocell fell one cent or 2.7 percent to 36.5 cents.

RHINOMED

Rhinomed says that revenue for the six months to December 31, 2015 rose 303.0 percent to $522,165 with net loss after tax up 18.7 percent to $2,784,085.
Rhinomed company secretary Phillip Hains told Biotech Daily that the revenue was primarily from sales of the company's Mute and Turbine nasal plugs for snoring and improved respiration in sport, respectively.
The company said that net tangible asset per security was down 70.9 percent to 0.23 cents with diluted loss per share down 9.4 percent to 0.48 cents.
Rhinomed said it had cash and cash equivalents of $1,085,772 at December 31, 2015 compared to $1,368,621 at June 30, 2015.
Rhinomed fell 0.1 cents or four percent to 2.4 cents with 1.8 million shares traded.

OPTHEA (FORMERLY CIRCADIAN TECHNOLOGIES)

Opthea says revenue for the six months to December 31, 2015 was up 40.7 percent to $515,156, with a net loss after tax down 42.6 percent to $1,731,722.
Opthea said the reduced loss was "mainly due to the decrease in research and development spending … attributed to the expenditure incurred in 2014 for the manufacture of clinical grade OPT-302 and … toxicology studies".
The company previously said it received income from its VGX-100 cancer and VGX-300 eye disease programs, and licences to Imclone and Healthscope (BD: Feb 19, 2013).
Opthea said its net tangible assets per share fell 18.75 percent from 16 cents at December 31, 2014 to 13 cents at December 31, 2015, with diluted loss per share down 75.1 percent to 1.14 cents and cash and cash equivalents of $17,757,769 at December 31, compared to $18,435,637 at June 30, 2015.
Opthea was up one cent or 2.6 percent to 39 cents.

ALLEGRA ORTHOPAEDICS (FORMERLY ADVANCED SURGICAL DESIGN)

Last night's headline said that Allegra's H1 revenue was "up 1% to $4m, loss up 194% to $262k".
As correctly reported in the text, Allegra said that revenue for the six months to December 31, 2015, fell 26.6 percent to $3,422,654 with net loss after tax up 340.1 percent to $1,151,285.
The headline editor apologizes for any confusion and her pay has been docked.
Allegra was untraded at 25 cents.

MMJ PHYTOTECH

MMJ Phytotech has requested a trading halt “pending an announcement regarding a proposed capital raising”.
Trading will resume on March 1, 2016 or on an earlier announcement.
MMJ last traded at 34 cents.