Biotech Daily

Wednesday February 26, 2014

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: MEDICAL DEVEL UP 12%, BENETIC DOWN 19%**

*** MESOBLAST H1 REVENUE UP 41% TO $21m, LOSS UP 11% TO $31m**

*** IMMURON SECURES $1.8m OF $9.7m, UNDERWRITTEN $7.8m TO GO**

*** MAYNE H1 REVENUE UP 158% TO $71m, LOSS TO $11m PROFIT**

*** COMPUMEDICS H1 REVENUE UP 10% TO $14.5m, LOSS TO $402k PROFIT**

*** IMPEDIMED H1 REVENUE UP 18% to $1.65m, LOSS DOWN 31% TO $3.6m**

*** EMA FURTHER DELAY FOR TISSUE THERAPIES VITROGRO**

*** INVION DETAILS 20-FOR-1 RIGHTS ISSUE**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Wednesday February 26, 2014 with the S&P ASX 200 up 3.2 points to 5,437.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and two were untraded.

Medical Developments was the best, up 12 cents or 12 percent to $1.12 with 29,021 shares traded.

Universal Biosensors climbed 8.8 percent; Impedimed was up 6.8 percent; Prana was up 5.6 percent; Anteo and QRX were up three percent or more; Admedus, Bionomics, Ellex and Tissue Therapies rose more than two percent; with Cochlear, CSL, GI Dynamics and Mesoblast up more than one percent.

Benitec's run paused today, leading the falls, down 43 cents or 19.2 percent to $1.81 with 2.2 million shares traded, followed by Optiscan down 12.5 percent to seven cents with 171,000 shares traded and Uscom down 11.1 percent to 20 cents with 34,651 shares traded.

Antisense lost 6.25 percent; Compumedics, Genetic Technologies, IDT and Living Cell fell five percent or more; Avita, Patrys, Phosphagenics and Prima were down four percent or more; Atcor, Neuren and Psivida lost more than three percent; Resmed shed 2.75 percent; Clinuvel and Reva were down more than one percent; with Acrux, Sirtex and Starpharma down by less than one percent.

MESOBLAST

Mesoblast says that revenue for the six months to December 31, 2013, was up 41 percent to $20,774,000 with net loss after tax up 11 percent to $30,859,000.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that the Osiris mesenchymal stem cell product Prochymal for graft versus host disease could be approved in Japan by the end of 2014 and the company was expecting further discussions with the US Food and Drug Administration in April or May this year (BD: Oct 11, 2013).

“We have three times the data compared to when we acquired Prochymal and the data is as compelling,” Prof Itescu said.

Prof Itescu said that Mesoblast was aiming to file for approval in the US by the end of 2014, but was also hoping for Breakthrough Therapy status.

Prof Itescu said that Prochymal was approved in both Canada and New Zealand and was being supplied under special access schemes to as many as 10 patients per month, in Canada and the US, but a commercial launch would be dependent on US approval.

Prof Itescu said that Mesoblast had four phase III trials underway including the Teva Pharmaceuticals-funded trial of mesenchymal precursor cells for congestive heart failure, a 300 to 400 patient trial for disc repair, a three-quarters recruited trial for Crohn’s disease inherited from Osiris and a small study of stem cells for cord blood expansion.

Prof Itescu said that the early look at the 1,700-patient congestive heart failure trial was expected after 120 patients had been treated and followed up and that was expected in about 12 months time.

“We are well cashed-up for the programs,” Prof Itescu said. “The question is do we bring in partners to share costs and undertake distribution?”

“We’re not going to be a sales and marketing company,” Prof Itescu said.

Mesoblast said that research and development expenditure fell 3.9 percent to $20,736,000 for the six months to December 31, 2013.

The company said the increased loss was due to increased operations expenses of $9,104,000, offset by an increase in other income of $6,854,000 of which $5,795,000 was the Federal Government Research and Development Tax Incentive revenue.

Mesoblast said that manufacturing commercialization costs increased 44.5 percent to $13,212,000, with management and administration costs up 49.8 percent to $17,678,000.

Mesoblast said that diluted loss per share was almost unchanged up 0.03 cents to 9.72 cents for the six months to December 31, 2013.

The company said it had cash and cash equivalents of $250,262,000 at December 31, 2013, compared to $178,651,000 at June 30, 2013.

Mesoblast said that net tangible assets per share fell 25 percent to 25.02 cents at December 31, 2013 compared to 33.36 cents at December 31, 2012.

Mesoblast was up six cents or 1.02 percent to $5.97 with 464,268 shares traded.

IMMURON

Immuron says it has received acceptances $1,840,641 of the $9.66 million it hopes to raise through its fully-underwritten rights issue at 0.5 cents a share (BD: Jan 22, 2014).

Immuron said it received acceptances for 368,128,158 shares, leaving a shortfall of 1,563,617,244 shares to be placed by Patersons Securities amounting to $7,818,086.

Immuron chief executive officer Amos Meltzer said that the company had the funds for its strategy including the phase II trials for non-alcoholic steato hepatitis.

“A successful outcome in our [non-alcoholic steato hepatitis] trials is expected to focus many pharmaceutical companies and investors on Immuron,” Mr Meltzer said.

Immuron was unchanged at 0.5 cents with 5.3 million shares traded.

MAYNE PHARMA

Mayne Pharma says revenue for the six months to December 31, 2013, was up 158 percent to $70,748,000 with a turnaround net profit after tax of $10,913,000.
Mayne said that it acquired US generics company Libertas Inc on July 2, 2013 and the results for the six months to December 31, 2013 include the revenue and expenses for Metrics and Libertas for the six month period, whereas the comparison period includes Metrics trading for the period from November 14, 2012 to December 31, 2012.
Mayne said that net tangible asset backing per share fell 30 percent from 0.01 cents to 0.007 cents.
The company said diluted earnings per share was 1.45 cents compared to a loss of 1.0 cents in the previous corresponding period.
Mayne said that cash and cash equivalents at December 31, 2013 was $19,807,000 compared to $18,938,000 at June 30, 2013.
Mayne fell four cents or 4.35 percent to 88 cents with 1.4 million shares traded.

COMPUMEDICS

Compumedics says revenue for the six months to December 31, 2013, was up 9.9 percent to $14,479,000 with a turnaround net profit after tax of $402,000.
Compumedics said the result “reflects greater shipments as a result of the additional funding received by the business in June 2013, improved margins … and the depreciation of the Australian dollar against the US dollar and the Euro”.
The company said it carried $7.2 million of sales orders into the second half of the year and expected to make significant inroads into shipping these sales-orders.
Compumedics said that net tangible asset backing per share was up 13.8 percent from 2.9 cents to 3.3 cents.
The company said diluted earnings per share was 0.2 cents compared to a loss of 0.5 cents in the previous corresponding period.
Compumedics said that cash and cash equivalents at December 31, 2013 was $1,285,000 compared to $1,292,000 at June 30, 2013.
Compumedics fell 0.4 cents or five percent to 7.6 cents.

IMPEDIMED

Impedimed says that revenue for the six months to December 31, 2013, was up 18 percent to $1,645,000 reducing net loss after tax 31 percent to $3,586,000.
Impedimed said that the sale of goods and services was up 28 percent to $1.6 million due primarily to lymphoedema products within the medical segment up 38 percent and test and measurement segment up 22 percent.
The company said that the increased revenue in the lymphoedema market was mainly due to an increase in placements of devices and growth in ordering of our electrodes from new and existing customers.
Impedimed said that diluted loss per share decreased 33.3 percent from 3.0 cents in the previous year to 2.0 cents for the six months to December 31, 2013.
The company said it had cash and cash equivalents of $4,535,000 at December 31, 2013, compared to $7,316,000 at June 30, 2013.
Impedimed said that net tangible assets per share fell 50 percent to 3.0 cents at December 31, 2013 compared to 6.0 cents at December 31, 2012.
Impedimed was up 1.5 cents or 6.8 percent to 23.5 cents.

TISSUE THERAPIES

Tissue Therapies says its final review for Conformité Européenne (CE) mark approval by the European Medicines Agency has been delayed a further four months.
Tissue Therapies said the EMA review was defined process with a maximum duration of 210 calendar days, which did not include the time taken to respond to questions.
The company said it received a series of questions which required data from its contract manufacturers.
Tissue Therapies said that assembling the data would take a few months and during this time the EMA 210 day clock has stopped.
Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that he expected approval from the EMA by October 2014 with sales to start shortl after.
The company said that the US Food and Drug Administration the application for a clinical trial of Vitrogro ECM for venous ulcers would be approved subject to one more piece of information, a plan for an additional quality control test.
Tissue Therapies was up one cent or 2.8 percent to 37 percent.

INVION

Invion has published the key dates and details of its 20-for-one non-renounceable rights issue at 7.5 cents a share to raise about $2 million.
Last week, Invion said it had raised $5.0 million in a private placement at 7.5 cents a share to institutional and sophisticated investors for "the collaboration with 3M Drug Delivery Systems to develop Invion's inhaled respiratory drugs franchise and continuing development of Invion's three drug assets" INV102 or nadolol, INV103 or chaperonin-10 and INV104 or zafirulkast (BD: Feb 21, 2014).
Today Invion said that the record date for the rights issue would be March 6, the offer would open on March 11 and close on March 25, 2014.
Invion said that Patersons Securities and Morgans Corporate were joint lead managers to the capital raise.
Invion fell 1.2 cents or 13.5 percent to 7.7 cents with 5.5 million shares traded.