Biotech Daily

Wednesday February 28, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: USCOM UP 12%; ORTHOCELL DOWN 6%**

*** PATRYS UP 100%: 'PAT-DX1 BLOOD TO BRAIN, TUMOR SHRINK IN MICE'**

*** ONCOSIL: 'PANCREATIC CANCER TUMOR REDUCTION'**

*** RCH OKAYS ANTISENSE DUCHENNE MUSCULAR DYSTROPHY TRIAL**

*** EDITORIAL: YOUR R&D TAX INCENTIVE IS NOT REVENUE**

*** MESOBLAST H1 REVENUE UP 1442% TO $19m, LOSS TO $8.6m PROFIT**

*** TPI REVENUE UP 111% TO $22m, LOSS UP 19% TO $17m**

*** ADMEDUS H1 REVENUE DOWN 8% TO $11m, LOSS UP 38% TO $9m**

*** CLINUVEL H1 REVENUE UP 3% TO $7m, PROFIT DOWN 44% TO $1.4m**

*** AIRXPANDERS REVENUE UP 585% TO $5m, LOSS UP 33% TO $37m**

*** TBG H1 REVENUE UP 198% TO $4m, LOSS UP 150% TO $6.5m**

*** CRYOSITE H1 REVENUE DOWN 4% TO $3m, PROFIT TO $895k LOSS**

*** MEDLAB H1 REVENUE UP 30% TO $2m, LOSS UP 33% TO $2.4m**

*** ATCOR H1 REVENUE UP 7% TO $2m, LOSS DOWN 42% TO $1m**

*** GENETIC SIGS H1 REVENUE UP 44% TO $1.6m, LOSS UP 28% TO $1.3m**

*** PHOSPHAGENICS REVENUE DOWN 28% TO $1m, LOSS DOWN 51%**

*** RHINOMED H1 REVENUE DOWN 37% TO $762k, LOSS UP 37% TO $1.8m**

*** PHARMAUST RECEIVES $354k FEDERAL R&D TAX INCENTIVE**

*** HYDROPONICS MARIJUANA IMPORT LICENCE, TOURETTE'S TRIAL**

*** LAZARD TAKES 5% OF MAYNE PHARMA**

*** DR DAX MARCUS CALDER, STAFFWEAR TAKE 13% OF PATRYS**

*** RESONANCE APPOINTS MITCHELL WELLS DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.68 percent on Wednesday February 28, 2018 with the ASX200 down 40.9 points to 6,016.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and two were untraded.

Uscom was the best, up three cents or 12.0 percent to 28 cents with 647,494 shares traded. LBT climbed 8.3 percent; Genetic Signatures and Opthea were up more than seven percent; Medical Developments was up five percent; Mesoblast improved 4.1 percent; Bionomics, Factor Therapeutics, Immutep (Prima) and Polynovo rose more than two percent; ITL, Optiscan, Telix and Universal Biosensors were up more than one percent; with Cochlear, Pro Medicus and Resmed up by less than one percent.

Orthocell led the falls, down two cents or 6.1 percent to 31 cents with 28,920 shares traded. Admedus, Airxpanders and Compumedics lost more than five percent; Actinogen, Acrux and Impedimed were down more than three percent; Ellex, Neuren and Viralytics shed more than two percent; Clinuvel, Nanosonics, Osprey, Pharmaxis and Starpharma were down more than one percent; with CSL and Volpara down by less than one percent.

PATRYS

Patrys says a Yale University study has shown PAT-DX1 crosses the blood-brain barrier, significantly reducing glioblastoma tumor in the brains of mice.

Patrys said that PAT-DX1, a humanized version of the 3E10 anti-DNA antibody, was administered through a tail vein injection into mice previously injected with human glioblastoma tumor explants, by the New Haven, Connecticut-based Yale's Dr James Hansen and Dr Jiangbing Zhou.

The company said that evaluation of brain sections showed that the glioblastoma tumors in three mice treated with PAT-DX1 were more than 40 percent smaller than the comparable tumours in three control mice.

Patrys said that the blood-brain barrier was a protective layer of endothelial cells that only allowed certain molecules to transit from the blood into the cerebrospinal fluid that surrounds the brain.

The company said that the blood-brain barrier was a significant challenge to the delivery of therapeutics, as only a very limited number of molecular classes could cross into the brain.

Patrys said that to date, very few proteins or antibodies had been shown to transit across the barrier from the blood to the brain.

The company said that glioblastoma was a particularly aggressive, highly malignant form of brain cancer characterized by very fast cellular reproduction, constituted about 15 percent of all primary brain cancers and were a significant unmet therapeutic need, with a median survival period of 18 months, depending on disease severity.

Patrys chief executive officer Dr James Campbell said the company was "delighted with this significant discovery".

"The blood-brain barrier is one of the major limitations in the development of neuro-therapeutics and the observation that PAT-DX1 can cross the barrier and reduce glioblastoma tumor size is very positive," Dr Campbell said.

"With our collaborators at Yale we are currently undertaking a parallel study to evaluate the comparative survival of mice with glioblastoma that have been treated with PAT-DX1 versus untreated mice, and will report on this in the coming month," Dr Campbell said.

Patrys closed up 2.2 cents or 100 percent at 4.4 cents with 249.0 million shares traded.

ONCOSIL MEDICAL

Oncosil says 27 patients have been implanted in its 300-patient pivotal Brachysil localized radiation trial for pancreatic cancer (BD: Oct 23, Dec 21, 2017).
Oncosil said 20 patients had reached week-8 and 14 had reached week-16 evaluations, with 100 percent local disease control rate at week-8 and 87 percent at week-16.
The company said that "so far four of the first 20 patients implanted have achieved a partial response" or a reduction in tumor longest diameter of at least 30 percent from baseline and three were being considered for surgical resection.
Oncosil said the reduction of tumor size raised "the possibility of demonstrating improved outcomes in a patient group deemed inoperable at study entry".
The company said that "substantial tumour volumetric reduction continued to be observed in participants at week-8 and [week]-16", with no serious adverse events attributed to device or the implantation procedure and no evidence of radiation toxicities.
Oncosil said that it had recruited 35 patients in Australia, the UK and Belgium and the US.
Oncosil was unchanged at 14.5 cents with 4.4 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says that Melbourne's Royal Children's Hospital has given ethics approval for its phase II trial of ATL1102 in patients with Duchenne muscular dystrophy.
Antisense said that Duchenne muscular dystrophy was an incurable muscle wasting disease of children and the trial was expected to begin by July 2018.
The company said that the study was a single dose investigation of 25mg of ATL1102 administered weekly in wheel-chair bound boys with Duchenne muscular dystrophy aged 10 to 18 years and weighing between 25kg and 60kg.
Antisense said the primary goal was to establish safety and tolerability in the patient population at the 25mg dose along with potential efficacy assessed by changes to blood and imaging markers of inflammation and muscle damage associated with Duchenne muscular dystrophy.
Last year, Antisense said the US Food and Drug Administration had lifted a clinical hold on its phase IIb trial of ATL1102 for multiple sclerosis, approving the trial at a 25mg/week dose for six months (BD: Apr 24, Jul 27, Oct 2, 2017).
Antisense managing-director Mark Diamond told Biotech Daily last year that the company had expected trials of ATL1102 be at a dose of 200mg or lower per week.
The company said that in parallel with the FDA process for the multiple sclerosis trial, it had Melbourne's Royal Children's Hospital ethics approval for a trial of ATL1102 for Duchenne muscular dystrophy, subject to FDA clearance of the ATL1102 for multiple sclerosis investigational new drug application (BD: Sep 12, 2017).
Today, Antisense said the extended six-month dosing period might allow for ATL1102 to show an improvement in clinical endpoints relevant to Duchenne muscular dystrophy disease progression, such as upper limb function, required for product registration.
Principal investigator Dr Ian Woodcock said that Duchenne muscular dystrophy was "a common, debilitating and ultimately terminal degenerative condition causing muscle inflammation and wasting".
"There is a dire need for more effective therapies than those we have already," Dr Woodcock said.
"The approach of using ATL1102 to inhibit CD49d+ T-cells to treat this inflammation is consistent with observations of international researchers and published studies," Dr Woodcock said.
Antisense was untraded at 4.1 cents.

BIOTECH DAILY EDITORIAL

A number of companies have been claiming the Federal Research and Development Tax Incentive as "revenue" when in fact they have little or no real revenue at all.

The Tax Incentive is similar to a tax rebate and is not taxable, so it should not be called revenue; just as one's tax payment in one year is not an allowed tax deductible expense in the following year.

In this reporting season, one company claimed more than $3 million in revenue but it was nearly all Tax Incentive, with some cash deposit interest. Another had about $1.2 million in actual revenue from sale of product and a further expected (but not received) $400,000 in R&D Tax Incentive and claimed $1.7 million in revenue.

Unless one goes to the fine detail (and some companies do not provide it) an investor could think the company has money when it doesn't.

Revenue does not include the Tax Incentive or grants. It does include sale of product, licence fees, milestone payments, royalties and bank interest.

All these sub-units of revenue should be made clear in the Appendix 4E and investors should not need to go searching for the truth, buried deep in the notes or have to call the company to find out what they have not announced clearly.

David Langsam, Editor

MESOBLAST

Mesoblast says that revenue for the six months to December 31, 2017 climbed 1441.9 percent to $US14,571,000 ($A18,693,390), with last year's $US39,849,000 net loss after tax turned to a $US6,681,000 ($A8,572,680) profit.

Mesoblast said that revenue period included $US11.8 million in connection with the patent licence agreement with Tigenix, including the upfront receipt of $US5.9 million and $US5.9 million recognized in the period but due within 12 months, as well as milestone and royalties of $US2.6 million in connection with sales of Temcell for graft versus host disease in Japan by licencee JCR Pharmaceuticals Co.

The company said that net cash outflows were reduced by $US11.2 million, primarily as a result of a reduction in payments to suppliers and employees and increased inflows of $US6.5 million relating to the receipts from Tigenix and JCR.

Mesoblast said that research and development spending increased 8.8 percent to $US31,590,000, manufacturing commercialization were costs down 76.3 percent to $US1,678,000, with management and administration expenses up 3.1 percent to $US10,655,000.

The company said that its net tangible liability per ordinary security increased 10.7 percent to 11.16 US cents.

Mesoblast said that the diluted loss per share of 10.41 US cents for the six months to December 31, 2016 turned to a diluted earnings per share of 1.46 US cents for the six months to December 31, 2017.

The company said that it had cash and cash equivalents of $US47,386,000 at December 31, 2017, compared to $US33,902,000 at December 31, 2016.

Mesoblast climbed seven cents or 4.1 percent to $1.78 with 2,1 million shares traded.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says revenue for the year to December 31, 2017, increased 110.9 percent to $22,263,174 with net loss after tax up 19.1 percent to $16,692,689.
TPI said it supplied narcotic raw material, or opium, to pharmaceutical companies and poppy seeds for food, and had a medicinal cannabis licence (BD: Sep 29, 2017).
The company said that net tangible assets per share was up 152.9 percent to 0.43 cents, diluted loss per share fell 13.3 percent to 23.38 cents, with cash and cash equivalents of $3,644,547 at December 31, 2017 compared to $662,548 at December 31, 2016.
TPI fell 50 cents or 25.6 percent to $1.45 with 1.6 million shares traded.

ADMEDUS

Admedus says revenue for the six months to December 31, 2017, decreased 7.7 percent to $11,305,079 with net loss after tax up 38.0 percent to $8,828,576.
Admedus said it had record sales of its Cardiocel Adapt-treated bovine cardiac tissue due to product range expansion and a targeted sales strategy, and growth of its infusion business due to higher demand from the Royal Adelaide Hospital.
The company said it also had regulatory approval to launch Cardiocel in India and had launched in January, 2018.
Admedus said that net tangible assets per share was down 61.3 percent to 3.5 cents, basic loss per share was up 26.5 percent to 3.39 cents, with cash and cash equivalents of $8,254,823 at December 31, 2017 compared to $14,343,543 at December 31, 2016.
Admedus fell 1.5 cents or 5.6 percent to 25.5 cents.

CLINUVEL

Clinuvel says revenue for the six months to December 31, 2017, was up 2.9 percent to $7,193,183 with net profit after tax down 44.1 percent to $1,410,947.
Clinuvel said that as commercial sales of Scenesse continued, expenses for marketing sponsorship and listing fees increased 20 percent; along with a 111 percent increase in intellectual property fees; clinical, regulatory and commercial overheads were up 30 percent to $1.1 million; and general operations expenses rose 27 percent to $2.7 million.
The company said diluted earnings per share fell 45.1 percent to 2.8 cents, net tangible assets per share rose 32.6 percent to 57 cents and it had cash and cash equivalents of $27,938,889 at December 31, 2017, compared $19,550,345 at December 31, 2016.
Clinuvel fell 17 cents or 1.9 percent to $8.73.

AIRXPANDERS

Airxpanders says revenue for the year to December 31, 2017, increased 585.3 percent to $US3,906,000 ($A5,009,140), with net loss after tax up 33.0 percent to $US28,983,000 ($A37,182,290).
Airxpanders said 80 percent of revenue was from sales in the US of its breast reconstruction technology for post-mastectomy patients, with 20 percent in Australia.
The company said that net tangible assets per Chess depository instruments (CDIs) were up 20 percent to 0.06 US cents, with diluted loss per US share up 19.2 percent to 31 US cents at December 31, 2017 and it had cash and cash equivalents of $US4,162,000 at December 31, 2017 compared to $US11,477,000 at December 31, 2016.
Airxpanders fell three cents or 5.8 percent to 49 cents.

TBG DIAGNOSTICS

TBG says that revenue for the six months to December 31, 2017, was up 197.8 percent to $4,024,000 with net loss after tax up 149.5 percent to $6,540,000.
TBG said that sales were principally of its two diagnostics for bone marrow transplants, as well as technical services.
The company said that net tangible assets per share fell 27.7 percent to 6.5 cents, with diluted loss per share up 150.0 percent to 3.0 cents.
TBG said that it had cash and cash equivalents of $7,918,213 at December 31, 2017 compared to $10,642,000 at December 31, 2016.
TBG was untraded at 8.5 cents.

CRYOSITE

Cryosite says revenue for the six months to December 31, 2017, fell 4.3 percent to $2,909,814 with net profit after tax turned to a loss of $895,467.
Cryosite said its principal activities for the period were the provision of protocol management for supply chain logistics management of clinical trial pharmaceuticals and biological materials.
The company said it had ceased processing, collecting and banking of cord blood and tissue for clients, due to the market stagnating.
Cryosite said that net tangible assets per share was down 29.5 percent to 4.3 cents, while diluted earnings per share turned to a diluted loss per share of 1.902 cents, with cash and cash equivalents of $4,361,549 at December 31, 2017 compared to $4,073,192 at December 31, 2016.
Cryosite was untraded at 10 cents.

MEDLAB CLINICAL

Medlab says revenue for the six months to December 31, 2017, increased 30.4 percent to $1,972,236 with net loss after tax up 33.1 percent to $2,374,914.
Medlab said it had increased its sales of food additives and had been granted licences to supply and manufacture its Nanabis medicinal cannabis for cancer pain.
Medlab said that diluted loss per share was up 28.4 percent to 1.22 cents at December 31, 2017.
The company said that cash and cash equivalents of $789,691 at December 31, 2017 compared to $4,309,132 at December 31, 2016.
Medlab fell one cent or 1.3 percent to 76.5 cents.

ATCOR MEDICAL

Atcor says its revenue for the six months to December 31, 2017 was up 6.8 percent to $1,964,189 reducing net loss after tax by 42.1 percent to $1,081,420.
Atcor said that along with a 43 percent increase in sales of its Sphygmocor central blood pressure systems to clinicians to had increased sales to pharmaceutical companies and reduced expenses from $4.24 million to $2.83 million.
The company said that its net tangible asset backing per share fell 58.3 percent from 1.2 cents at December 31, 2016 to 0.5 cents at December 31, 2017, diluted loss per share fell 53.9 percent to 0.41 cents and it had cash and cash equivalents of $724,671 at December 31, 2017 compared to $1,747,247 at December 31, 2016.
Atcor fell 0.2 cents or 6.25 percent to three cents.

GENETIC SIGNATURES

Genetic Signatures says revenue for the six months to December 31, 2017, was up 43.6 percent to $1,557,807, with net loss after tax up 27.5 percent to $1,342,713.
Genetic Signatures said it had increased its foreign client base for its molecular diagnostics for infectious diseases and was seeking approvals for existing and new products in development.
Genetic Signatures said that net tangible assets per share fell 18.2 percent to 13.82 cents, while diluted loss per share was up 7.9 percent to 1.64 cents at December 31, 2017.
The company said that it had cash and cash equivalents of $11,722,393 at December 31, 2017 compared to $16,008,374 at December 31, 2016.
Genetic Signatures was up two cents or seven percent to 30.5 cents.

PHOSPHAGENICS

Phosphagenics says revenue for the year to December 31, 2017, decreased 27.6 percent to $1,150,356 with net loss after tax down 50.7 percent to $8,545,358.
Phosphagenics said that while revenue was down, royalties and licence fees were slightly increased, offset by lower sales of goods and services.
The company said sales of its Vital ET (vitamin E) to Ashland were down on prior years, as Ashland exhausted its existing stock, but new orders had been received.
Phosphagenics said that net tangible assets per share was down 72.6 percent to 0.28 cents, while diluted loss per share was down 51.8 percent to 0.66 cents at December 31, 2017.
The company said that it had cash and cash equivalents of $2,898,596 at December 31, 2017 compared to $6,091,508 at December 31, 2016.
Phosphagenics fell 0.1 cents or 6.25 percent to 1.5 cents.

RHINOMED

Rhinomed says revenue for the six months to December 31, 2017, fell 37.3 percent to $761,852 with net loss after tax up 36.6 percent to $1,846,888.
Rhinomed said it had recorded revenue of its Mute and Turbine nasal dilators of $1,478,956 in the six months to December 31, 2017, of which $761,852 was recognised during the period while $717,104 was recognised as deferred revenue.
The company said that net tangible assets per share was up 19.1 percent to 2.74 cents, while diluted loss per share was up 12.4 percent to 1.91 cents at December 31, 2017.
Rhinomed said that cash and cash equivalents of $3,075,561 at December 31, 2017 compared to $800,086 at December 31, 2016.
Rhinomed fell half cent or 4.35 percent to 11 cents.

PHARMAUST

Pharmaust says it has received $354,300 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Pharmaust said the rebate related to research and development activities for its monepantel for cancer in dogs and humans for the year to June 30, 2017.
Pharmaust was up 0.1 cents or 1.8 percent to 5.7 cents.

THE HYDROPONICS COMPANY

Hydroponics says the Department of Health has approved the import of medicinal cannabis products from its European partner, Endoca.
Hydroponics said it had been allowed to import 10ml quantities of three and 15 percent raw cannabidiol oil and three and 15 percent heated and decarboxylated cannabidiol oil.
The company said that the products had been "used successfully in Europe in the treatment of epilepsy and associated neurological disorders".
Hydroponics said it the products would be available through its own clinics, as well as by direct order for patients on the special access scheme or through an approved prescriber.
The company said that the Revadim, Israel-based medical marijuana company Breath Of Life Pharma would supply sublingual tablets containing tetrahydrocannabinol and cannabidiol for research into the potential benefits of medicinal cannabis in Tourette's syndrome to be conducted by Brisbane's Wesley Medical Research by July 2018.
Hydroponics was up one cent or 1.3 percent to 77 cents with 1.1 million shares traded.

MAYNE PHARMA

The Sydney-based Lazard Asset Management Pacific Co says it has become a substantial holder in Mayne Pharma with 79,563,230 shares or 5.22 percent.
Lazard said that the registered holders included the Bank of New York Melon, BNP Paribas, Citibank, JP Morgan Chase, Northern Trust and State Street Australia.
Lazard said it acquired shares between October 23, 2017 and February 23, 2018 with the single largest purchase on December 15, 2017 of 27,286,198 shares for $17,410,259 or 63.8 cents a share.
Mayne was up one cent or 1.4 percent to 73 cents with 6.1 million shares traded.

PATRYS

Dr Dax Marcus Calder has increased his substantial shareholding in Patrys from 87,026,226 shares (11.16%) to 118,000,004 shares (12.67%).
The substantial shareholder notice said that the West Perth, Western Australia-based Dr Calder sold 3,026,226 shares directly and with Staffwear Pty Ltd on December 12 and 13, 2017 for $66,298 or an average price of 2.2 cents a share.
The notice said that Dr Calder and Staffwear acquired 34,000,004 shares between February 16 and 26, 2018 for $584,258 or 1.7 cents a share.

RESONANCE HEALTH

Resonance says that Mitchell Wells has been appointed as a non-executive director replacing Dr Jason Loveridge who resigned last year (BD: Jun 29, 2017).
Resonance said that Mr Wells was an experienced executive and a lawyer with commercial and legal experience in Australia, the US and the UK and had been a company director of, and worked as an executive with, listed-public and private companies.
Resonance was unchanged at 2.5 cents.