Biotech Daily

Wednesday May 13, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: USCOM UP 25%, TISSUE THERAPIES DOWN 22%**

*** WEHI, RESEARCH AUSTRALIA WELCOME MRFF**

*** GRANT THORNTON: 'BUDGET OVERLOOKS BIOTECH, R&D SLY CUT'**

*** AUSBIOTECH: 'BUDGET UNDERWHELMING, FEW BRIGHT SPOTS'**

*** BIO-MELBOURNE CALLS FOR TRANSLATION ELEMENT TO MRFF**

*** DIMERIX BACKDOOR INTO SUN FOR KIDNEY DISEASE, RAISE $1.6m**

*** PSIVIDA SIGNS 2 EVALUATION DEALS WITH UNNAMED COMPANY**

*** TISSUE THERAPIES NEW EU CLINICAL, PRE-CLINICAL VITROGRO TRIALS**

*** AVITA GRANTED US RECELL METHODS PATENT**

*** AMP TAKES 5% OF MEDICAL DEVELOPMENTS**

MARKET REPORT

The Australian stock market climbed 0.71 percent on Wednesday May 13, 2015 with the S&P ASX 200 up 40.4 points to 5,715.1 points. Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell and 13 traded unchanged.

Yesterday's worst, Uscom, was today's best, up four cents or 25 percent to 20 cents with 25,000 shares traded.

Pharmaxis climbed 9.4 percent; Compumedics was up 7.1 percent; Mesoblast, Oncosil, Osprey and Universal Biosensors rose five percent or more; Avita and Neuren were up four percent or more; IDT was up 3.7 percent; Bionomics, Clinuvel and Viralytics rose more than two percent; Ellex and Sirtex were up more than one percent; with Acrux and CSL up by less than one percent.

Tissue Therapies led the falls, down 1.9 cents or 22.35 percent to 6.6 cents with 2.1 million shares, followed by Analytica down 15.8 percent to 1.6 cents with 9.9 million shares traded. Psivida lost 8.8 percent; Optiscan fell 4.35 percent; Benitec and Biotron were down more than three percent; Actinogen, Anteo and Medical Developments shed more than two percent; Cochlear fell 1.4 percent; with Impedimed, Nanosonics and Resmed down less than one percent.

Medical Research Future Fund

WALTER AND ELIZA HALL INSTITUTE, RESEARCH AUSTRALIAN
Both the Walter and Eliza Hall Institute and Research Australian have welcomed the establishment of the Medical Research Future Fund, but again its funding is uncertain.
In media releases, WEHI and Research Australia said that along with the $1 billion in the Health and Hospitals Fund it would have about $3.5 billion at June 30, 2016.
But to fund the MRFF, the Federal Budget papers refer to savings in the Health budget, saying: “The savings from [these measures] will be redirected by the Government to fund other Health policy priorities or will be reinvested into the Medical Research Future Fund”.
http://www.budget.gov.au/2015-16/content/bp2/html/bp2_expense-14.htm.
The Budget papers said the Government “will not proceed with measures originally announced ... to redefine the time requirements for Level A and B GP consultation items and to reduce rebates by $5 for common GP consultations and after hours services to non-concessional patients aged 16 and over”.
The Budget papers said that the savings included $125.6 million from the Child Dental Benefit Schedule; $144.6 million by removing duplication between health assessments under the Medicare Benefits Schedule and State and Territory assessments; $214.1 million from the Electronic Health Records program; $5.1 million in 2018-’19 by extending increases to the Pharmaceutical Benefits Scheme safety net thresholds by one year; $252.2 million over five years for drug price amendments for the Pharmaceutical Benefits Scheme and the Repatriation Pharmaceutical Benefits Scheme; $962.8 million over five years by rationalizing and streamlining Health programs; $113.1 million over five years through operational efficiencies in the delivery of corporate services of the Therapeutic Goods Administration, ceasing activities that mirror the work of specialist agencies, ceasing the National Lead Clinicians Group and rationalizing the structure of the Department; $7.6 million over four years from the Stoma Appliance Scheme; and $72.5 million over four years by reducing nine health workforce scholarships to a single program.
These savings total $1,897.6 million with no guarantee that they will all go to the MRFF, but Budget Paper No 1, Statement 6 said the Government “will establish the Medical Research Future Fund on August 1, 2015 to provide additional funding for medical research from 2015-’16” with $1 billion from the Health and Hospitals Fund and savings from the Health portfolio until the Fund reaches a target of $20 billion in 2019-’20.
http://www.budget.gov.au/2015-16/content/bp1/html/bp1_bs6-02.htm.
WEHI director Prof Doug Hilton said the Fund was “an important start to securing a healthier future for all Australians”.
“The initial $3.4 billion deposit into the MRFF should provide some certainty for the medical research community, which has been seeking long-term security in funding for many years,” Prof Hilton said. “It is integral, however, that the fund attain its full capitalization of $20 billion to ensure Australian medical researchers, who have a strong track record of delivering health benefits for Australians, can maintain that momentum for years to come.”
Research Australia said the fund was expected to provide $10 million in 2015-’16, with $53 million in 2016-’17, $130 million 2017-’18 and $224 million in 2018-’19.
Research Australia chair Prof Christine Bennett said that “making the MRFF a reality at the scope and pace proposed will guarantee that we can build on our strong track record in discovery and invention and secure Australia’s position as a leading research nation”.
Research Australia said that every $1 from the MRFF invested in medical research returns $3.39 in future health and productivity gains and the MRFF had the potential to improve lives, benefit the economy and reduce future health expenditure.

R&D Tax Incentive

Budget Paper No 2 said that the Government had introduced a cap of $100 million on the R&D Tax Incentive and expenditure beyond the cap would receive a lower offset at the company tax rate, with changes apply in relation to assessments for income years commencing on or after July 1, 2014 and to be reviewed five years following Royal Assent and to sunset 10 years following the July 1, 2014 start date.
The Budget papers said that under the R&D Tax Incentive, companies could claim a refundable tax offset of 43.5 percent if their turnover was less than $20 million or a non-refundable tax offset of 38.5 percent.
http://www.budget.gov.au/2015-16/content/bp2/html/bp2_revenue-07.htm.

GRANT THORNTON AUSTRALIA
Grant Thornton says the Federal Budget "overlooked" life sciences and it was disappointed by the "sly cut" to the R&D Tax Incentive.
Ina media release, the Sydney-based accounting and advisory firm said that "Australia's biotechnology and life sciences sector is crying out for further support on innovation and commercialization if it wants to remain a corner stone of an economy operating in a post mining boom environment".
"Unfortunately this was overlooked in the 2015 Federal Budget," Grant Thornton said.
Grant Thornton life sciences national leader Michael Cunningham said the firm was "disappointed we didn't see any incentives encouraging commercialization that we've seen work so well in other parts of the world, like the patent box schemes introduced in the UK".
"There was unfortunately an unexpected and sly cut to the R&D Incentive," Mr Cunningham said. "The Government has signaled that it will continue to make cuts of 1.5 percent to both the R&D refundable tax offset (43.5%) and the non-refundable tax offset (38.5%) despite not going forward with its intended 1.5 percent corporate tax rate".
"As most people are aware, the R&D Incentive is a cornerstone underpinning Australian innovation and it is extremely disappointing to see the incentive still being under attack despite being an extremely successful policy to date," Mr Cunningham said.
"This Budget does little to soothe the unease amongst the local Australian biotech industry, who believe the Government can be doing more to encourage innovation and commercialization in Australia," Mr Cunningham said.
Grant Thornton said it supported an Ausbiotech survey that showed the need for local companies to work globally "and, sadly, fight to keep their operations in Australia as the international environment gets more competitive and Australia's policy environment fails to adequately respond".
"This budget was a missed opportunity to increase confidence in the sector by creating an environment that supports innovation and encourage biotechnology companies to operate in Australia," Mr Cunnigham said. "Let's not risk seeing our ideas commercialized in other parts of the world for the global economy to enjoy at our expense," Mr Cunningham said.
Grant Thornton R&D Tax national leader Sukvinder Heyer said that when the rate cut was first flagged in the previous budget, it was linked to the reduction in the rate of company income tax but "the company tax rate is only being dropped for small business with an aggregate turnover of less than $2 million".
"For companies in tax losses, the reduction in rate represents a loss of cash, which could be used to fund further investment in innovation," Ms Heyer said. "Stable support is needed at all levels and this continued changing of the rules leads to uncertainty, the antithesis for encouraging investment."

AUSBIOTECH

Ausbiotech says that following “last year’s savage Budget cuts to industry support and science programs, biotech can be relieved it was not again targeted for direct savings”.
Ausbiotech chief executive officer Dr Anna Lavelle said the Federal Budget 2015-’16 “is underwhelming apart from a few bright spots”.
“Australia’s biotech companies are doing great work in growing jobs and revenue sources for the post-mining boom economy, but this Budget delivers no significant measures to encourage the commercialization of life sciences innovation,” Dr Lavelle said.
Ausbiotech said the Medical Research Future Fund was delayed due to its linking to unpopular savings and more than $400 million would be distributed for research.
“While this is welcome news, there remains no articulation of a specific portion to be set aside for commercialization of Australia’s world-class research,” Dr Lavelle said.
Ausbiotech said that regulation for crowd-sourced equity funding would be improved, which would help small businesses access finance by increasing the availability of innovative sources of funding and biotechnology companies would welcome another form of access to capital to assist research and development.
Dr Lavelle said “the reversal of the [employee share schemes], altered in 2009, is a big win for common sense ... Australian companies have for many years been frustrated by an inability to incentivize innovation employees with shares and options.”
Ausbiotech said that the reduction in the company tax rate to 28.5 percent for businesses with revenue of less than $2 million a year was a boost of $3,000 a year, and a number of other measures would allow deductions for business purchases and start up costs, and the abolition of Fringe Benefits Tax on mobile phones, laptops and computers.
Ausbiotech said that if the Federal Government was successful in reducing the R&D Tax Incentive by the proposed 1.5 percent small businesses with a turnover of more than $2 million which can claim the R&D Tax Incentive will lose the benefit of the 1.5 percent corporate tax cut and small and medium sized enterprises with turnover over $2 million would be disadvantaged by the 1.5 percent reduction in potential claims under the R&D Tax Incentive, without the benefit of the new 28.5% corporate tax rate.
Ausbiotech said that the Government announced four-year savings of $26.8 million from the Cooperative Research Centres program, but would continue to provide $732.4 million over the forward estimates for the program pending the outcome of a review.
“Australia has excellent potential to be a nation driven by bio-innovation,” Dr Lavelle said.
“We have a strong education system, stable government, good regulatory, intellectual property and legal environment and a proven track record in innovation,” Dr Lavelle said.
“However, we have unstable public policy supporting innovation, constantly changing programs and a handful of critical gaps, notably a tax regime to support our international competitiveness,” Dr Lavelle said.
“If we as a nation are serious about innovation, we must address the gaps and leaks, as outlined in this submission, to create the right environment for innovation to thrive and the coming Tax White Paper provides a not-to-be-missed opportunity,” Dr Lavelle said.

BIO-MELBOURNE NETWORK

Bio-Melbourne Network chief executive officer Dr Krystal Evans says the Medical Research Future Fund “creates an enormous opportunity to innovate ... [but it] should focus on the translation of the benefits of health and medical research into better patient outcomes for Australia”.
“The MRFF must commit the distributions to translating health and medical research into real world outcomes,” Dr Evans said.

DIMERIX BIOSCIENCE, SUN BIOMEDICAL

Sun Biomedical says it will acquire Dimerix Bioscience for 750,000,041 Sun shares and has places 160,000,000 shares at one cent each to raise $1.6 million.

Sun said that the placement was to sophisticated and professional investor clients of Forrest Capital and was in part subject to approvals.

The company said 60,000,000 options would be issued to Forrest Capital exercisable at one cent each by June 30, 2017, and the acquisition included 30,851,592 management options exercisable at two cents by June 30, 2017, and 225,000,120 performance shares in three tranches, pending a patent allowance, an investment decision to file an investigational new drug application with the US Food and Drug Administration, and receipt of ethics approval allowing commencement of a second clinical trial.

The Melbourne-based Dimerix currently has a phase II study of its combination therapy DMX200 for chronic kidney disease.

Last year, Dimerix shelved its intended initial public offer to raise $9 million and said it expected to treat its first phase II proof-of-concept chronic kidney disease patient with its DMX200 combination drug by the end of 2014 (BD: Jun 4, Sep 29, Nov 25, 2014).

Dimerix executive chairman Dr James Williams said at that time that the company was proceeding with a two-part trial, initially treating 10 to 15 patients for nephrotic syndrome, and evaluating them prior to approaching the US Food and Drug Administration to discuss an investigational new drug application for the second part of the trial.

Dr Williams said that the DMX200 combination of irbesartan and propagermanium was synergistic, with the combination more effective than the component parts.

Irbesartan has been marketed as Avapro and propagermanium as Serocion.

Dr Williams said that the mechanism of action was to block two separate receptors, but the two molecules also interacted positively with each other.

Sun said that following the acquisition James Williams would be appointed as executive chairman and Dr Sonia Poli as a non-executive director replacing non-executive directors Evan Cross and Peter Webse.

The company said that Dr Anton Uvarov would remain as an executive director and former executive chairman Howard Digby would remain as a non-executive director and Mr Webse would continue as company secretary.

Sun has been attempting to commercialize workplace saliva-based drug tests and said it was collaborating with the Telethon Kids Institute in Subiaco Western Australia on a genetic diagnostic for asthma.

Sun last traded at 1.1 cents with 13.2 million shares traded.

Dimerix Bioscience a public unlisted company

PSIVIDA

Psivida it has signed two funded technology evaluation agreements with an unnamed pharmaceutical company.

Psivida said that the agreements would each evaluate the use of its Durasert technology “to deliver a specific compound to treat a significant ophthalmic disease”.

Psivida chief executive officer Dr Paul Ashton said Psivida was “very pleased to be working with this leading global pharmaceutical company”.

“Our strategy includes partnering product development with market leaders in appropriate circumstances, allowing us to expand our reach beyond our own product development,” Dr Ashton said. “This opportunity fits that criteria and we are excited about the potential products.”

Psivida fell 48 cents or 8.8 percent to $5.00.

TISSUE THERAPIES

Tissue Therapies says it has proposed further clinical and pre-clinical studies to earn European approval for its Vitrogro wound treatment.

In March, the UK Committee for Medical Products for Human Use said it wanted additional data regarding the insulin-like growth factor-1 components of Vitrogro (BD: Mar 26, 2015).

In 2011, Tissue Therapies said it expected European sales of Vitrogro to begin by July 2012, but has had a long series of regulatory delays, culminating in the request for data on insulin-like growth factor-1 (IGF-1) (BD: Sep 30, 2011).

Tissue Therapies said it had met with the European Medicines Agency's Scientific Advice Working Party and submitted a comprehensive written response to a list of questions provided by the Working Party ahead of a May 6, 2015 meeting with an additional question answered on May 12, 2015.

The company said the primary purpose of the meeting was to agree on an appropriate disease model and further in-vitro studies to provide pre-clinical data demonstrating the utility of IGF-1 in a chronic disease setting and supplement further clinical trial data, as well as an appropriate clinical study designed to assess comparative safety.

Tissue Therapies said the next step was for the Working Party to forward an integrated view to the UK Committee for Medicinal Products for Human Use, which was expected to be tabled at the next meeting, scheduled for May 18 to 21, 2015.

The company said that "in the weeks following the CHMP meeting [it] expects to receive either a written confirmation that the company's proposed changes are acceptable, recommendations for further changes to the plan, or alternatively another list of questions for the company to address".

Tissue Therapies said it had filed a submission to the Working Party to obtain advice on whether the proposed changes were effective, compliant and able to provide adequate data that was more likely to support a favorable benefit-risk assessment, but the Committee would "not be bound by scientific advice recommendations" when forming an opinion for the purpose of Conformité Européenne (CE) marking.

The company said it would need to implement the changes to the development plan, and subsequently undergo another 210-day ancillary medicinal product consultation for the IGF-1 component of its Vitrogro ECM wound treatment.

Tissue Therapies fell 1.9 cents or 22.35 percent to 6.6 cents with 2.1 million shares traded.

AVITA MEDICAL

Avita says the US Patent and Trademark Office has issued a patent for methods of making and using an epithelial cell suspension, part of the Recell wound therapy.

The USPTO website said that the patent, entitled 'Cell suspension preparation technique and device' said the inventors were Prof Fiona Wood and Marie Stoner.

Avita chief executive officer Adam Kelliher said that the patent "continues to strengthen and expand our overall patent coverage for Recell".

"We are continuing to focus on the prosecution of additional patents that support our entire regenerative medicine franchise," Mr Kelliher. "This patent is a key milestone towards our commercialization effort in the US."

Avita said that the patent provided protection for methods for producing and using a transplantable cellular suspension of living tissue suitable for grafting to a patient.

The company said that its regenerative technology platform including Recell, Regenercell and Renovacell were protected by a family of patents and patent applications.

Avita was up 0.3 cents or four percent to 7.8 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

The Sydney-based AMP says it has become a substantial shareholder in Medical Developments with the acquisition of 3,000,000 shares (5.20%).

Yesterday, Medical Developments chairman David Williams said he had sold 7,000,000 shares to institutional investors at $2.40 a share to increase liquidity in the company.

The substantial shareholder notice said that the holders of the relevant interest in the shares included AMP Life and AMP Capital Investors, with registered holders including AMP Life, Citicorp Nominees, HSBC Custody Nominees, JP Morgan Nominees and National Nominees.

Medical Developments fell six cents or 2.4 percent to $2.41 with 751,880 shares traded.