Biotech Daily

Wednesday May 9, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRESCIENT UP 14%; OSPREY DOWN 5%**

*** BUDGET QUALIFIED WELCOME: AUSBIOTECH, BIO-MELBOURNE - BIOTECH DAILY, MEDICINES AUSTRALIA, AAMRI, ONEVENTURES**

*** OSPREY: 'HOSPITALS, CLINICAL DATA TO DRIVE DYEVERT SALES'**

*** PAINCHEK (EPAT) FDA REGULATORY GUIDANCE**

*** OPTISCAN EGM; DARREN LURIE CHAIR, ZELKO LENDICH ACTING G-M**

*** MEDIBIO SIGNS ST JOHN OF GOD FOR CHECK-IN**

*** ALCHEMIA PLEADS SCHULZ TO ASX 36% QUERY**

*** PLATINUM TAKES 6% OF ANTISENSE**

*** INVICTUS APPOINTS RICHARD ESTALELLA US ADVISOR**

MARKET REPORT

The Australian stock market was up 0.26 percent on Wednesday May 9, 2018 with the ASX200 up 16.1 points to 6,108.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and two were untraded.

Prescient was the best, up 1.5 cents or 13.6 percent to 12.5 cents with 3.5 million shares traded.

Actinogen climbed 7.1 percent; Volpara was up 6.35 percent; Optiscan and Telix improved more than five percent; LBT, Starpharma and Universal Biosensors climbed four percent or more; Benitec and Cynata were up more than three percent; Polynovo rose two percent; Cyclopharm, Orthocell and Sirtex were up more than one percent with Clinuvel, Cochlear, CSL, Mesoblast and Pro Medicus up by less than one percent.

Osprey led the falls, down one cent or 5.3 percent to 18 cents with 234,377 shares traded, followed by Uscom down 5.1 percent to 18.5 cents with 72,682 shares traded.

Bionomics, Immutep and Impedimed fell four percent or more; Factor Therapeutics shed 2.5 percent; Avita, Compumedics, ITL, Medical Developments , Neuren, Pharmaxis and Reva were down more than one percent; with Nanosonics, Resmed and Viralytics down by less than one percent.

AUSBIOTECH

Ausbiotech says dropping the proposed $40 million lifetime cap on the Research and Development Tax Incentive and the exemption of clinical trials from the $4 million a year cap are “big wins for our sector”.

Ausbiotech said it was “relieved” by the Government’s approach to imposing a much-feared annual cap, with the exemption of clinical trials from the $4 million cap.

Ausbiotech chief executive officer Glenn Cross said that his organization “welcomes the recognition of the critical role that [research and development] expenditure plays in clinical trials for developing life-changing and saving medicines and medical devices”.

“By exempting clinical trials from a $4 million cap and encouraging higher intensity in [research and development], Australia will keep its hard-won momentum in clinical trials and continue its growth in commercialising medical research,” Mr Cross said.

Ausbiotech said that for companies claiming the non-refundable offset, a graduating premium would be introduced to provide incentives for higher research and development intensity and the $100 million cap would be elevated to $150 million

The industry organization said that companies with an intensity above five percent would have a higher tax offset than now available.

Last night, a Federal Government “fact sheet” defined intensity as the amount expended on research and development as a percentage of total expenses.

Ausbiotech said the Government outlined plans for “integrity and affordability” through increased resourcing for administrators and “greater transparency around who is claiming the [Tax Incentive] will promote public accountability”, as well as improved guidance.

“In a sensible and overdue measure, the Government will remove customs tariffs from placebos and clinical trial kits that are imported into Australia from July 1, 2018,” Ausbiotech said.

BIO-MELBOURNE NETWORK

Bio-Melbourne chief executive officer Dr Krystal Evans said the exemption of clinical trials from the $4 million cap “is a win for the sector”.

“It has been terrific to see industry bodies come together to support this advocacy effort on behalf the sector and also a great outcome for Australian patients who benefit from access to novel therapies through clinical trials,” Dr Evans said. “The [National Research Infrastructure] announcement was very good news.”

Last night the Government announced $1.9 billion over 12 years for National Research Infrastructure, along with $1.3 billion for the 21st Century Medical Industry Growth Plan to support medical technology, biotechnology and pharmaceuticals while improving health outcomes, the Bio-Melbourne Network said.

Dr Evans said the announcements were “a strong signal that Australia’s health innovation industry is key to future economic prosperity”.

“This investment will see companies expand the pipeline of medical discoveries and accelerate the development of cures and therapies for the future,” Dr Evans said.

“Melbourne is the capital city of Australia for health innovation and the Budget announcements will see biotechnology and medical technology companies lead the way into the future innovation economy,” Dr Evans said.

“It is terrific news for the sector that the Government has recognized the importance of clinical trials in Australia and excluded these from the cap,” Dr Evans said.

“This allows biotech and medtech companies to accelerate the clinical development of new drugs and medical devices, bring cutting-edge therapies to patients sooner,” Dr Evans said.

BIOTECH DAILY BUDGET EDITORIAL

The biotechnology and medical research communities have broadly welcomed last night's Federal Budget, in part for measures enacted as well as for threats retracted.

Treasurer Scott Morrison said the alleged $20 billion Medical Research Future Fund would provide $500 million over 10 years on genomic research, which is welcome, along with a claimed $1.9 billion over 12 years for National Research Infrastructure.

But $50 million a year is a fraction of the expected $2 billion a year when the MRFF is fully-funded from the original $1 billion Hospitals and Charities Fund and cuts to previous Department of Health budgets. The question of how much is currently in the MRFF since its 2014 initiation and how much is planned to be expended in the 2018-'19 year has been asked, but at the time of publication, not answered.

Health Minister Greg Hunt announced measures including a $240 million Frontier Science Program and $248 million to support clinical trials, as well as $20 million for pre-conception screening for birth disorders. All good measures.

The sector has welcomed the ditching of the $40 million lifetime cap on the already reduced 43.5 percent Research and Development Tax Incentive. It didn't make much sense anyway. What if a company had a second promising drug?

The shifting of the goalposts from the proposed $2 million cap to a $4 million cap is a bureaucratic rather than economic measure, much like the penny-pinching 1.5 percent cut from 45 percent, resulting in no real benefit to the Budget, but causing pain to innovators.

While the change reduces the number of payments outside the cap since 2011 from 40 to 30, the companies affected would have included Alchemia, Benitec, Bionomics, Biota, Kazia, LBT, Mesoblast, Micro-X, Prana, Recce, Starpharma, Universal Biosensors, Viralytics and others on or near the cusp of success.

It is like the dentist telling a patient with a mouthful of rotten teeth that she can extract four teeth instead of two, when the answer is to fluoridate the water and stop eating sugar.

The crackdown on rorting the Tax Incentive is welcome. An Independent Innovation Board is required to approve serious research and define which companies are simply raising funds to lease Maseratis and employ the board and management.

The R&D Tax Incentive should be increased to a maximum of 50 percent and be means-tested. Any company paying a CEO and board more than a reasonable amount would lose one percent for each $100,000 above a stipulated wage and total directors' remuneration.

The intensity off-set is a reasonable idea, but it still requires very close scrutiny of what is claimed under the catch-all of "research and development".

That clinical trials are exempt from the cap is good news, however not for companies conducting serious research and development, but not clinical trials, such as LBT, Osprey (see below) and Universal Biosensors, to name just three.

MEDICINES AUSTRALIA

Medicines Australia welcomed the $1.4 billion for listing innovative medicines on the Pharmaceutical Benefits Scheme (PBS) and a commitment to list all recommended medicines.

“We know that with new highly targeted medicines coming … through the pipeline, continued investment in the PBS is needed,” Medicines Australia said.

“The Government has acknowledged the Budget is in good shape, now it’s time to see some investment in high value areas such as the PBS and the innovative medicines industry,” Medicines Australia said.

Medicines Australia said it was “pleased with the Government’s … exemption of clinical trials under changes to the R&D Tax Incentive and no intensity threshold”.

“The Government has also responded to industry’s pre-Budget submission by budgeting to boost the profile of Australia’s innovative medicines industry internationally through the National Health and Medical Industry Growth Plan,” the industry organization said.

“There are still unanswered questions arising from the Budget, which we will be working through over the coming days,” Medicines Australia said.

ASSOCIATION OF AUSTRALIAN MEDICAL RESEARCH INSTITUTES

The Association of Australian Medical Research Institutes said the $2 billion MRFF investment in the Budget “secures Australia’s future as [a] medical research leader”.

The association said that “multiple funding boosts from the MRFF are being used to innovative medical research fields, including genomics and precision medicine, allowing Australia to be at the forefront of turning new discoveries into the next generation of advanced patient treatments”.

Association president Prof Tony Cunningham said it was “a great Budget for medical research and this is where the Australian medical research sector should be heading”.

“It’s fantastic to see the Government recognize that for Australians to continue to benefit from this work, we need to continue funding it,” Prof Cunningham said.

The Association said that the MRFF was “set to reach $20 billion by 2020-’21”.

ONEVENTURES

Oneventures managing-partner Anne-Marie Birkill said the Research and Development Tax Incentive led to greater revenues and higher tax payments.

“We are strong advocates for the R&D Tax Incentive, believing it provides capital constrained, research intensive companies like those in our portfolio with important funding to ensure they achieve their R&D objectives,” Ms Birkill said.

“We have many examples of companies that have continued to undertake R&D in Australia rather than moving to less expensive jurisdictions because the R&D tax incentive makes undertaking R&D in Australia economically viable,” Ms Birkill said.

“Ideally, we would prefer there was no cap for research intensive companies however, we are realists and understand the Government cannot have an uncapped and ever-expanding obligation,” Ms Birkill said.

“One of the things that seems to have escaped commentary is that the R&D tax refund funds job creation and those new employees pay tax, often at high rates as these are highly skilled roles,” Ms Birkill said.

“This means that the R&D tax refund is significantly offset by [pay as you go] tax and … there are all the other benefits of more R&D being done in Australia, including wealth and asset creation, Ms Birkill said.

OSPREY MEDICAL

Osprey chief executive officer Mike McCormick says that clinical data rather than clinical trials will drive increased sales of Dyevert Plus dye reduction system.

In Melbourne to meet investors and media ahead of the Osprey annual general meeting tomorrow, Mr McCormick said that presentations by three hospitals at the American College of Cardiology and Society for Cardiovascular Angiography and Interventions meetings showed that its Dyevert system reduced the amount of contrast used in cardiac stenting operations and led to a reduction of contrast-induced acute kidney injury.

Mr McCormick said that the presentations by the St Mary's Medical Centre, Houston Methodist Sugar Land Hospital and a multi-centre observational study, covered about 760 patients and showed a 25 percent, 22 percent and three percent, respectively, reduction in acute kidney injury.

Mr McCormick said company would have more definitive data when the presentations were published in peer-reviewed journals.

He said that the take-up of the Osprey Dyevert system by hospital groups showed that physicians understood the benefits of the dye reduction system.

Mr McCormick said that at this stage there was no competitor to the Dyevert system which had US Food and Drug Administration, Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approvals.

Mr McCormick said that the 578-patient, 2015 trial which showed no statistically significant difference between the Avert group and the control arm used the first-generation system which reduced the dye by about 15 percent, compared to the Dyvert Plus which reduced cardiac contrast by 40 percent.

He said that running a larger randomized controlled trial of the Dyevert system would be very expensive for a small company and that hospital-based evidence would drive further sales.

Mr McCormick said that Osprey had 14 consecutive quarters of unit sales growth but, so far, this had not translated into expected revenue.

Last month the company's Appendix 4C quarterly report said that it had received $US502,000 ($A654,000) from customers for the three months to March 31, 2018.

Mr McCormick said that the company started with one sales staff and had increased to 18 sales representatives and five clinical representatives in the US.

He said the company was specifically targeting group purchasing organisations for large hospitals and health care providers and he was expecting a 20 percent increase in unit sales as well as revenue, this quarter rising to 25 percent.

Osprey fell one cent or 5.3 percent to 18 cents.

PAINCHEK (FORMERLY EPAT TECHNOLOGIES)

Painchek says its Painchek pain assessment may be suitable for US Food and Drug Administration 513(f)(2) "risk-based de novo classification".

Painchek said that the FDA's preliminary assessment was that there was no "substantially equivalent product" to its Painchek system making it potentially suitable for de novo classification which covered new devices whose type had not previously been classified.

The company said it would have to provide clinical performance data to support the pre-market submission and might require a clinical trial in the US.

The company said it would develop a revised timeline and costing for regulatory clearance of its Painchek application following the FDA pre-submission process.

Painchek fell 0.6 cents or 8.6 percent to 6.4 cents with 8.2 million shares traded.

OPTISCAN IMAGING

Optiscan says that Darren Lurie has been appointed chairman effective from yesterday and has posted the proxy votes ahead of tomorrow's extraordinary general meeting.
Optiscan said that former chairman Alan Hoffman and directors Peter Francis and Dr Ian Griffiths resigned ahead of the meeting.
In April, Mr Hoffman, Mr Francis and Dr Griffiths resigned and Darren Lurie and Graeme Mutton were appointed to the board (BD: Apr 18, 23, 2018).
In March, the company said the group aligned with director Ian Mann, former chief executive officer Archie Fraser and founder Peter Delaney called for the removal of Phillip Currie as well as Mr Hoffman, Mr Francis and Dr Griffiths and the appointment of Mr Fraser and Ron Grey as directors (BD: Mar 16, 19, 27, 29, 2018).
Optiscan said that a group aligned with Graeme Mutton called for the removal of Ian Mann and the appointment of Darren Lurie and Graeme Mutton.
Biotech Daily understands that Optiscan has appointed Zelko Lendich as acting general-manager of the company.
According to the Australian Competition and Consumer Commission Mr Lendich was a former director of the Australian Egg Corp and the former managing-director of Farm Pride Foods and on May 2, 2016 was ordered to pay $120,000 for "an attempt to induce a cartel arrangement between competing egg producers".
According to the ASX data, Darren Lurie is a former chairman of Farm Pride Foods.
Optiscan was up 0.4 cents or 5.9 percent to 7.2 cents.

MEDIBIO

Medibio says it has an agreement with the Perth-based St John of God Health Care to provide its Check-in corporate health program for its employees.
Medibio said the agreement would provide Check-in access to 14,500 St John of God employees with the online assessment of mental health through its cardiac rate algorithm and provide the option of additional mental healthcare services for those needing it.
The company said its anticipated revenue for an initial four-week program was $58,000 and that mental healthcare services would be billed as they were provided.
Medibio was up 1.5 cents or 9.7 percent to 17 cents.

ALCHEMIA

Alchemia has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 36.4 percent from 1.1 cents on May 7, to a high of 1.5 cents on May 8, 2018 and noted a significant increase in the trading volume.
Alchemia fell 0.1 cents or 7.1 percent to 1.3 cents with 3.1 million shares traded.

ANTISENSE THERAPEUTICS

Platinum Investment Management says it has become a substantial shareholder in Antisense with 20,833,333 shares or 5.68 percent of the company.
The Sydney-based Platinum Investment Management said the registered holder of the shares was the Sydney-based HSBC Custody Nominees.
Platinum Investment Management said the shares were purchased on May 7, 2018 for $500,000 or 2.4 cents a share.
Antisense was unchanged at 2.6 cents.

INVICTUS BIOTECHNOLOGY

Invictus says it has appointed Richard Estalella as advisor for the launch of its food additive products in the US.

Invictus said Mr Estalella would manage the US manufacture, distribution and sales of its NE1-Heart food additive for heart health and its NE1-Elite for muscle recovery.

The company said Mr Estalella would become chief executive officer and president of a US subsidiary that it planned to incorporate by October 2018.

Invictus said that Mr Estalella was previously chief operating officer and president of the Denver, Colorado-based sports nutrition company Musclepharm Corp.

Invictus is a private company.