Biotech Daily

Daily news on ASX-listed biotechnology companies

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Budget Special Edition

Wednesday May 9, 2018

Qualified Welcome:

Ausbiotech, Bio-Melbourne

Biotech Daily, Medicines Australia

AAMRI, Oneventures

BUDGET 2018

The Federal Government says it will "cap" the R&D Tax Incentive at $4 million a year and provide $500 million over 10 years for genomic research.

In his Budget address to the House of Representatives, Treasurer Scott Morrison said that "to support companies genuinely investing in R&D we are refocusing the R&D Tax Incentive to give more support to companies that invest a higher proportion of what they spend in R&D, over and above what others would just do anyway".

"We are cracking down to ensure that R&D tax incentives are used for their proper purpose, with enhanced integrity, enforcement and transparency arrangements, saving taxpayers $2 billion over the next four years," Mr Morrison said.

A Budget "fact sheet" titled 'Tax Integrity' and 'Reforming the R&D Tax Incentive' said that from July 1, 2018 the Government would "introduce a $4 million annual cap on cash refunds for R&D claimants with aggregated annual turnover less than $20 million".

Jobs and Innovation Minister Senator Michaelia Cash told Biotech Daily that “clinical trials would be exempt from the $4 million cap and the proposed lifetime $40 million cap had been rejected”.

Senator Cash said “a range of integrity measures introduced”.

“Amounts that are in excess of the cap will become a non-refundable tax offset and can be carried forward into future income years,” the fact sheet said.

The fact sheet said that from July 1, 2018, the Government would introduce a research and development “intensity” system evaluating research and development expenditure as a proportion of total expenditure, providing a tax offset of the claimant’s tax rate, plus 4.0 percentage points for R&D expenditure between 0 percent and 2 percent R&D intensity rising through four tiers to 12.5 percentage points for expenditure above 10 percent R&D intensity.

The fact sheet said the refundable research and development tax offset for companies with a turnover of less than $20 million, would be the claimant’s tax rate for the year plus 13.5 percentage points.

The Government said that from July 1, 2018 it would increase the $100 million research and development expenditure threshold to $150 million.

Mr Morrison said the Medical Research Future Fund would provide $500 million over 10 years “for Australia to become a world leader in genomic research”.

A media release from Senator Cash said the Government would “ensure that taxpayer support for the [R&D Tax Incentive] is fiscally affordable and crack down on R&D tax claims that push the boundaries of the R&DTI, with enhanced integrity, enforcement and transparency arrangements”.

The media release said that the Government would invest about “$2.4 billion in growing Australia’s research, science and technology capabilities … [through] additional funding for national research infrastructure [and] the Australian Technology and Science Growth Plan”.

The Senator Cash media release said that $20.0 million would “help Australian small-to-medium enterprises form local and regional business hubs”, the Government would extend funding for the Industry Growth Centres by two years, provide $20.0 million to support opportunities for Australian business, entrepreneurs and researchers in Asia and further abroad, as well as extending the Australia-India Strategic Research Fund and allocate $29.9 million to develop the artificial intelligence and machine learning capabilities of Australian businesses and workers, including for Cooperative Research Centre Projects.

A media release from Health Minister Greg Hunt said the Government would “deliver $6 billion in record funding for Australia’s health and medical research sector, including $3.5 billion for the National Health and Medical Research Council, $2 billion in disbursements from the Medical Research Future Fund and $500 million from the Biomedical Translation Fund”.

The Government said the $1.3 billion National Health and Medical Industry Growth Plan would “improve health outcomes for hundreds of thousands of Australians, create tens of thousands of new jobs, and develop the next generation of Australia’s global leading industries”.

Mr Hunt’s media release said that the first genomics project would be Mackenzie’s Mission, with $20 million for a pre-conception screening trial for rare and debilitating birth disorders including spinal muscular atrophy, Fragile X and cystic fibrosis.

The Government said it would establish a new $240 million Frontier Science Program to develop innovative medical ideas, research, devices and treatments.

The media release said the Government would provide $248 million to support clinical trial activity through the rare cancer, rare diseases and unmet need clinical trials and registries program and establish a $125 million chronic disease fund, the Targeted Translation Research Accelerator, with a focus on diabetes and cardiac disease.

Further reports, comment and analysis in tomorrow’s edition.

Wednesday May 9, 2018

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,” Dr Evans said.

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. [On May 10, the Finance Department said the MRFF had $7,055,724,000 at June 30, 2018, with $214,913,000 to be expended in 2018-'19.]

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.