

Biotech Daily

Wednesday April 3, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.68 percent on Wednesday April 3, 2019, with the ASX200 up 42.6 points to 6,285.0 points.

Ten of the Biotech Daily Top 40 stocks were up, 12 fell, 13 traded unchanged and five were untraded.

Starpharma was the best on an investor presentation to Goldman Sachs, up 9.5 cents or 9.6 percent to \$1.08, with 710,654 shares traded.

Pro Medicus climbed 7.8 percent; Neuren was up 6.2 percent; Medical Developments improved 4.4 percent; Antisense and Impedimed rose more than two percent; Avita, Clinuvel, CSL, Opthea and Paradigm were up more than one percent; with Cochlear up 0.8 percent.

Oncosil led the falls, down 0.3 cents or 5.6 percent to 5.1 cents, with 2.3 million shares traded.

Cynata, Patrys and Prescient fell more than four percent; Genetic Signatures, Mesoblast and Proteomics lost more than three percent; Universal Biosensors shed 2.4 percent; Kazia and Pharmaxis were down more than one percent; with Nanosonics, Resmed and Volpara down by less than one percent.

BUDGET COMMENT AND ANALYSIS

BIOTECH DAILY

Last night's budget has removed \$1,316 million or 10.55 percent from the five-year estimates for the Federal Research and Development Tax Incentive.

Instead of underpinning innovation, the Federal Liberal National Party Coalition Government has again cut funding to innovation.

Instead of cracking down on rorts in the research and development claims, it has chosen the blunt instrument of a \$4 million cap on Tax Incentives, despite the biotechnology companies claiming the larger amounts often being on the cusp of success.

Last year's Budget allowed for \$12,471 million in Treasury expenses for the Tax Incentive from 2017 to 2022. This year's Budget has \$11,155 million for 2018 to 2023.

This follows the penny-pinching Joe Hockey 1.5 percent cut to the original Gillard Government's 45 percent Tax Incentive, which was enacted under the Prime Minister for Innovation Malcolm Turnbull and delivered by now Prime Minister Scott Morrison.

The Budget Papers said the Government would achieve "efficiencies" of \$48.9 million over five years from 2018-'19 from within the uncommitted funds from the Entrepreneurs' Programme and the Industry Growth Centres Initiative.

In exchange, Federal Treasurer Joshua Frydenberg said that there would be a further \$60 million for export market development grants, a \$525 million skills package for 80,000 new apprenticeships, a tax write-off for capital expenditure up to \$30,000 per item and incentives for women in science, technology, engineering and mathematics (STEM).

It is increasingly hard to believe this Government is interested in innovation or jobs in future industries. There were promises of funds to farmers to ameliorate the impacts of climate change, but nothing allocated to create industries that would prevent global warming.

Indeed, the words "innovation", "biotechnology" and information technology" did not appear in Mr Frydenberg's Budget speech, at all; with the sole reference to "climate change" in relation to subsidies for farmers, with "Indigenous communities" tacked on for better marketing.

The promise of generational tax cuts - mirroring the previous Liberal Party Treasurer Peter Costello's middle-class welfare - means that there will be less money for core infrastructure in the years to come, including hospitals, schools and universities.

The only bright spot is that none of this will be implemented unless the Liberal National Party Coalition is re-elected, and even then, they may be non-core promises.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation has welcomed continued funding from the Government.

CSIRO manager media liaison Huw Morgan said, "the government's investment in CSIRO across this period remains consistent with previous levels, increasing by over \$6 million, in line with indexation".

"This funding will continue to be directed towards innovative science and technology to solve Australia's greatest challenges," Mr Morgan said.

AUSTRALIAN MEDICAL RESEARCH ADVISORY BOARD

The Australian Medical Research Advisory Board chair Prof Ian Frazer says that the Government's 10-year commitment to the \$20 billion Medical Research Future Fund "will have a positive outcome for health in Australia and will also ensure that Australian continues to contribute to improving health across the globe".

"While it is pleasing that the funding for the National Health and Medical Research Council is maintained in the budget, I am disappointed to note a reduction in funding for universities and for the Australian Research Council, as these organizations are essential to drive the basic research that enables the clinical research that translates into practical outcomes for patients," Prof Frazer said.

ASSOCIATION OF AUSTRALIAN MEDICAL RESEARCH INSTITUTES

The Association of Australian Medical Research Institutes says it welcomes full funding for the \$20 billion Medical Research Future Fund by 2020-'21.

AAMRI said that about \$5 billion would be invested in medical research into chronic and debilitating diseases such as diabetes, cardiovascular disease, mental health, dementia and brain cancer.

The association said that the fund was "at the half way mark, with the Government committed to it being fully funded within the next two years, making it the largest sovereign wealth fund for medical research in the world".

AAMRI president Prof Vlado Perkovic said, "the 10-year plan for the fund will provide long-term stability and allow investments in projects with longer time frames, allowing projects to deliver significant health and economic benefits for the nation".

"We look forward to seeing competitive processes put in place to make sure we get most from this funding opportunity," Prof Perkovic said.

MEDICINES AUSTRALIA

Medicines Australia has welcomed the Federal Government promised subsidy of \$331 for medicines listed on the Pharmaceutical Benefits Scheme.

Medicines Australia said the Government's Health portfolio would increase overall spending by \$20 billion to \$115 billion by 2022-'23, with a forward estimate of \$40 billion for the Pharmaceutical Benefits Scheme (PBS).

Medicines Australia chief executive officer Elizabeth de Somer said, "the Morrison Government has recognized that medicines matter and confirmed their commitment to the uncapped PBS and overall health expenditure".

"This will help ensure all Australians have access to new innovative medicines they need when they need them," Ms de Somer said.

AUSBIOTECH

Ausbiotech chair Julie Phillips says the organization is "pleased that additional cuts to the [Research and Development Tax Incentive] are not explicitly mentioned in the 2019 Federal Budget" but the organization was "curious to understand the Government's intent for future plans, particularly given the lack of detail and certainty around how they will obtain the \$1.35 billion savings from the RDTI outlined in the forward estimates". "The RDTI is absolutely critical to the life sciences industry ... [and] should be maintained in its current form to ensure stability and maximize its economic benefits," Ms Phillips said.

NANOSONICS

Nanosonics says it welcomes French Ministry of Health increased disinfection standards for endocavitary ultrasound probes.

Nanosonics said that guidance from the Ministry of Health would require intermediatelevel disinfection for endocavitary ultrasound probes, even with the use of a sheath, and discussed the benefits of automated disinfection.

The company said intermediate disinfection in France was equivalent to high level disinfection in other countries and its Trophon2 automated disinfection technology met the requirements for both intermediate and high-level disinfection in France.

Nanosonics chief executive officer Michael Kavanagh said the guidance was "the latest in a growing number of European guidelines requiring the appropriate level of disinfection for ultrasound probes and further supports our growth plans in the European region".

"Our latest Trophon2 technology is now available in France delivering the highest standard of automated ultrasound probe disinfection," Mr Kavanagh said.

"Indeed, in France, Trophon meets the requirements of both intermediate level disinfection and high-level disinfection as it is additionally sporicidal, thus delivering the highest level of patient protection," Mr Kavanagh said.

Nanosonics fell one cent or 0.2 percent to \$4.46 with 715,921 shares traded.

ACRUX

Acrux says it has settled Valeant Pharmaceuticals-initiated patent litigation for its generic equivalent to Jublia or efinaconazole topical solution for onychomycosis.

Last year, Acrux said that the Bridgewater, New Jersey-based Valeant Pharmaceuticals North America had begun patent litigation in the US District Court for the District of New Jersey against it and 13 other companies relating to its lead program for generic Jublia topical solution 10 percent (BD: Sep 24, 2018).

The company said at that time that Valeant began proceedings regarding their paragraph IV abbreviated new drug applications for a generic version of Jublia, asserting patents listed in the Orange Book and said the legal action was "expected and formally initiates the litigation process under the Hatch-Waxman Act".

In August, Acrux said it had submitted a first-to-file application to the US Food and Drug Administration for generic Jublia, or efinaconazole, for the fungal toe and finger nail infection onychomycosis (BD: Aug 2, 2018).

Today, the company said the settlement terms were "confidential" and would have no financial impact on the company.

Acrux chief executive officer Michael Kotsanis said, "this product is one of 14 generic topical products in our pipeline which are progressing to commercialization".

The company said that its generic Jublia was under review by the FDA.

Acrux was up 0.75 cents or 4.1 percent to 19 cents.

ANATARA LIFESCIENCES

Last night's article on Anatara referred to a mouse model study of irritable bowel syndrome.

The mouse study is for inflammatory bowel disease, while a human clinical trial is planned in irritable bowel syndrome.

The error was made by the mouse sub-editor who has been enrolled in a trial of warfarin for irritable publisher syndrome.

Anatara was untraded at 49 cents.

OSPREY MEDICAL

Osprey says Allan Gray Australia has increased its holding from 64,516,130 Chess depository instruments (CDIs) (14.94%) to 73,705,840 CDIs (17.07%).

Last year, Allan Gray said its 64,516,130 holding in Osprey was diluted from 15.97 percent to 14.94 percent in a non-renounceable entitlement offer (BD: Dec 10, 2018).

Today, Osprey has told the ASX that in March 2019, Allan Gray acquired 9,189,710 CDIs but did not disclose the price paid.

Osprev was unchanged at 14.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it has appointed chief operating officer Dr Collin Biggin as acting chief executive officer, replacing Dr Matt Harris.

Clarity said Dr Harris would remain on its board as chief scientific officer.

The company said it would look for a replacement chief executive officer over the next six to nine months.

Clarity said Dr Biggin had more than 15 years' experience, including eight years at the Oslo, Norway-based Algeta ASA.

The company said Dr Biggin had regulatory and quality assurance experience and held a Bachelor of Science and Doctor of Philosophy from the University of Glasgow.

Clarity said changes to its senior executive team would help in its move from an early to later stage clinical development company.

Clarity is a public unlisted company.