

Biotech Daily

Wednesday May 4, 2016

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: BIONOMICS UP 9%, USCOM DOWN 9%
- * EARLY INVESTOR TAX BREAK, VENTURE CAPITAL PASS SENATE
- * AVCAL DETAILS EARLY STAGE INVESTOR, VENTURE CAPITAL CHANGES
- * RESEARCH AUSTRALIA: BUDGET CUTS TO ARC, CRCS, MRFF
- * COMMENT: BIOTECH DAILY, ALP OPPOSITION, MELBOURNE UNIVERSITY
- * MGC RAISES \$5m, RIGHTS OFFER FOR MORE
- * ST VINCENT'S APPROVES ORTHOCELL CELGRO HIP TRIAL
- * AIRXPANDERS 1m DIRECTORS OPTIONS, ELECTION AGM
 - GREG LICHTWARDT, ZITA PEACH IN; ALBERT CHA, BRIGITTE SMITH OUT
- * PHARMAXIS SELLS 1,103 UNMARKETABLE PARCELS
- * GENETIC TECHNOLOGIES RINGS THE NASDAQ BELL, AGAIN

MARKET REPORT

The Australian stock market fell 1.54 percent on Wednesday May 4, 2016 with the ASX200 down 82.7 points to 5,271.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and two were untraded.

Bionomics was best, up three cents or 9.1 percent to 36 cents with 1.5 million shares traded. Antisense, Opthea and Osprey climbed more than five percent; Viralytics was up 4.1 percent; Admedus, Avita, Biotron, Impedimed, Oncosil, Orthocell and Sirtex were up more than three percent; Acrux, Anteo, Clinuvel, CSL and Pro Medicus rose more than one percent; with Psivida and Resmed up by less than one percent.

Uscom led the falls, down two cents or 9.1 percent to 20 cents with 50,000 shares traded. Tissue Therapies lost 7.5 percent; Mesoblast and Prana fell five percent or more; Medical Developments and Prima shed four percent or more; Living Cell and Polynovo were down more than three percent; Airxpanders and Neuren shed more than two percent; Compumedics, Ellex, Reva and Starpharma were down more than one percent; with Cochlear and Nanosonics down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says the Tax Incentive For Early Stage Investors and New Arrangements For Venture Capital Limited Partnerships have passed the Senate.

A media release from the Minister for Industry, Innovation and Science Christopher Pyne said that the two initiatives were designed to make investment in Australian start-ups more attractive and would be in place for the 2016-'17 financial year.

Mr Pyne said the measures were part of the Government's National Innovation and Science Agenda, and were "designed to broaden and diversify the economy through economic policies that build growth and productivity".

"The Tax Incentive For Early Stage Investors and New Arrangements For Venture Capital Limited Partnerships will promote investment in innovative high-growth potential start-up companies and improve businesses' access to venture capital," Mr Pyne said.

Mr Pyne said that more than 4,500 start-ups were missing out on equity finance each year and the measures would help them obtain access to funding.

The media release said that the Tax Incentive for Early Stage Investors gave tax concessions to eligible early stage investors who invested in qualifying companies, including a capped 20 percent non-refundable tax offset and 10 year capital gains tax exemption for investments, while the New Arrangements for Venture Capital Limited Partnerships provided changes that would "improve access to capital and make investing in venture capital more user-friendly and internationally competitive".

AUSTRALIAN PRIVATE EQUITY AND VENTURE CAPITAL ASSOCIATION

The Australian Private Equity and Venture Capital Association (Avcal) said that apart from the small business tax cuts, the Budget included previously announced tax incentives for early stage investors and expanded arrangements for venture capital limited partnerships and early stage venture capital limited partnerships.

Avcal said that the Government had: amended tax incentives for angel investors to reduce the holding period from three years to 12 months to access the 10 year capital gains tax exemption; included in the definition of eligible start-ups a time limit on incorporation and the criteria for determining an innovation company; required that the investor and company are not affiliated; and limit non-sophisticated investors to \$50,000 per income year to receive a tax offset.

Avcal said that the Government introduced arrangements for venture capital limited partnerships (VCLPs) and early stage venture capital limited partnerships (ESVCLPs) that would: add a transitional arrangement that allowed conditionally registered funds that become unconditionally registered after December 7, 2015 to access the tax offset if the criteria were met; relax the requirement for very small entities to provide an auditors' statement of assets; extend the increase in fund size from \$100 million to \$200 million for new ESVCLPs to also apply to existing ESVCLPs; and ensure that the venture capital tax concessions were available for financial technology, banking and insurance related activities.

RESEARCH AUSTRALIA

Research Australia says the Budget includes cuts to the Australian Research Council and the Co-operative Research Centres, and delays the Medical Research Future Fund.

Research Australia said that the Budget made no provision for a payment from the Medical Research Future Fund, despite a \$10 million provision in last year's Budget and the MRFF was not expected to reach full funding until 2020-21, "a year later than first projected in the Budget in 2014".

The industry organization said that National Health and Medical Research Council (NHMRC) funding was \$797 million for 2016-'17 with "estimates for the following three years ... remaining virtually stable with increases of roughly 1.5 percent each year".

Research Australia said that funding for the Australian Research Council Discovery and Linkage programs "declines compared to the 2015-'16 expenditure with a \$7.4 million reduction for 2016-'17, increasing to a \$19.9 million reduction by 2018-'19".

"The Linkage Program was singled out in the Government's National Innovation and Science Agenda as an important component of Australia's innovation system, and it was announced that from July 1, 2016 the Program would be open to continuous applications and decision making would be fast tracked," Research Australia said.

"There is, however, no additional funding for the Linkage program, Research Australia said. "Funding for the next financial year will be \$26 million less than the current year and will only increase again slightly in each subsequent year [and] the estimates for the financial years 2017-'18 and 2018-'19 are slightly lower than in last year's Budget."

The industry organization said that the Co-operative Research Centre program was "important to health and medical research, with 10 existing health-related CRCs receiving funding under this program".

"In last year's Budget, the Government announced that \$26.8 million would be taken from the CRC program over four years from 2015-'16, with the Government providing \$732.4 million over the forward estimates [to June 30, 2019] pending the outcome of the CRC Review." Research Australia said.

"The Review concluded that the program should continue with some changes, and the Government accepted this recommendation [but] this year's Budget provides for only \$652 million over the forward estimates [to June 30, 2020]," Research Australia said.

Research Australia said that the \$248 million commitment to the six industry growth centres, one of which is medical technologies and pharmaceuticals, was maintained in the Budget.

The organization said that the Biomedical Translation Fund was announced as part of the Innovation Statement, would be funded with \$250 million from contributions earmarked for the MRFF, and would use existing commercial investment managers for co-investment between July 2015 and July 2017, and while it was not specified there were references to the Fund to be established in 2016, in the Budget Papers.

Biotech Daily Budget Comment

The Federal Budget is the implementation of the Government's philosophy and policies and despite all the talk about innovation, the funding appears to be elsewhere.

The first thing to say is that there is no proven link between corporate and business tax cuts and the Federal Treasurer's mantra of "jobs and growth".

Few small companies move countries, as the Federal Government claims, on the basis of a one or two percent taxation differential. Major corporations might use a foreign domicile to minimize tax, but companies generally stay where they are created.

In any case, most of the 130 or so listed biotechnology companies are burning money, or are under the previous threshold, or do sufficient research and development to earn a Rudd-Gillard Government 45 percent Tax Incentive.

What was startlingly absent was the lack of incentive of any sort for innovation in general and biotechnology in particular.

After all the promises last year that there was never a better time to be an innovator, Biotech Daily gave Christopher Pyne a clean slate and watched as the media releases rolled in from the Turnbull-Pyne Department of Innovation: a couple on landing pads and start-ups in California and many on the steel industry and decisions to build the wrong submarines in Mr Pyne's state of South Australia.

Worse, the Prime Minister Tony Abbott-appointed chief executive officer of the Commonwealth Scientific and Industrial Research Organisation Dr Larry Marshall took an innovative slash-and-burn approach to his institute and the Abbott-appointed chief executive officer of the National Health and Medical Research Council, Prof Anne Kelso made her indelible debut wasting \$3.3 million on two long-term laboratory-based sleep studies to prove the harm (or possibly not) of near-silent turbines on hill tops.

The mechanism for investment in long term research and development and pivotal trials is absent. Funding from the Abbott-Hockey \$20 billion Medical Research Future Fund is absent, although the Biomedical Translation Fund is being created from funds diverted from the MRFF. With a couple of exceptions, those running the overseeing body have little if any commercialization experience.

The proposed cuts to the Entrepreneurs Program and the Co-operative Research Centres are a snip in the wrong direction. The previous Abbott, Gillard and Rudd Governments had already cut the Commercial Ready Program, the Innovation Investment Funds and the lacklustre Commercialisation Australia.

Despite the overall 5.1 percent cut to general research over the two years to June 30, 2017, I suppose we should be grateful that the Government for Innovation hasn't touched the R&D Tax Incentive nor cut the NHMRC and ARC budgets by very much.

Federal Opposition

The Australian Labor Party Opposition says the Budget is "an attack on Australia's innovation system, an attack that undermines growth, jobs and Australia's future".

In a media release, Labor's Shadow Minister for Higher Education, Research, Innovation and Industry Senator Kim Carr said the Liberal Party was "hiding behind a smoke screen, claiming that this Budget is about innovation when it will only mean more cuts for students, more cuts for researchers and more cuts for industry".

"The first two Liberal Budgets saw more than \$3 billion ripped from innovation, science and research – all with Malcolm Turnbull's full support – and this Budget does nothing to reverse those cuts," Senator Carr said.

In an email, Senator Carr told Biotech Daily that it was "an anti-innovation Budget, from an anti-innovation government".

"Malcolm Turnbull uses words like agile, creative and innovative, as though just to mention them is to be doing something," Senator Carr said.

"The measures Mr Turnbull announced in the so-called National Innovation and Science Agenda are at best pale imitations of the programs that Labor developed in Government, under our 10-year national innovation strategy, Powering Ideas," Senator Carr said. "Now, what we have instead of that coherent, long-term strategy is a mish-mash of half-baked ideas and desperate election gambits."

University of Melbourne

Melbourne University Faculty of Business and Economics' Prof Danny Samson, said that Australia had "a risk averse, structure-centric approach to innovation, in which government thinks it can set some economic conditions, stand back and wait for it to happen".

"We tweak tax rates, and other incentives, based on dry economic thinking only," Prof Samson said. "We have not invested in human capital to nearly the extent that has occurred in the countries that outperform us in innovation rates, such as Singapore, Israel, the US, Taiwan and South Korea."

Prof Samson said the bold initiative promised by Prime Minister Malcolm Turnbull in the December 2015 innovation strategy was not in the Budget.

"It's simple - people do innovation," Prof Samson said. "The Prime Minister's innovation strategy needs to build our widespread human capital."

Prof Samson said the Government needed to fund Technical and Further Education institutes and universities "to deliver the core innovation skills as part of the curriculum, as well as training for early career professionals within the workplace".

"They have the energy to drive innovation. They need only the knowledge and capability of how to do it," Prof Samson said.

"This is how we will build a real innovation boom," Prof Samson said. "We need to build human capital on a widespread basis, not just tweak the financials."

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says its \$5.0 million placement at 4.4 cents a share has closed, "multiple times oversubscribed" and it will offer a priority rights offer.

MGC said that the offer included one free attaching listed option for every three new shares, exercisable at 6.5 cents by June 30, 2019.

The company said it would offer shareholders the opportunity to participate on the same terms, with a record date of May 10, 2016.

MGC said the funds would be used for the construction of its Slovenian cannabis growing facility, research laboratory and cannabinoid extraction facility, genetics and breeding research operations, roll-out its Derma cosmetics line and implement its Australian medical cannabis strategy.

The company said that Sanlam Private Wealth was the lead manager for the placement. MGC fell 0.3 cents or 5.6 percent to 5.1 cents with 22.1 million shares traded before being placed in a suspension.

ORTHOCELL

Orthocell says that Melbourne's St Vincent's Hospital has given ethics approval for a 25-patients study of its Celgro collagen scaffold for osteochondral defects in the hip. Orthocell said that the primary objective was to demonstrate the safety and tolerability of Celgro when used as the collagen matrix for osteochondral defects in the hip.

The company said the treatment was known as autologous matrix induced chondrocyte and was an enhanced version of the original micro fracture technique, in which a type I/III collagen matrix was placed over the cartilage defect to stabilize the fragile bone marrow cell infiltrate and provide infrastructure for tissue repair and regeneration.

Orthocell managing director Paul Anderson said the approval showed that Celgro had applicability across a number of clinical indications.

The study's principal investigator Dr John O'Donnell said that the Celgro scaffold matrix for regenerative therapy (SMRT) Graft was "a novel biological device that had the potential to augment autologous matrix induced chondrocyte treatment for osteochondral defects within the hip.

"The unique properties of Celgro SMRT Graft may provide a more effective repair than currently available treatments," Dr O'Donnell said.

Orthocell said the study was due to start by July 2016.

Orthocell was up 1.5 cents or 3.6 percent to 43 cents.

AIRXPANDERS

Airxpanders will vote to grant chief executive officer Scott Dodson and five directors options over the equivalent of 1,092,600 Chess depository instruments (CDIs). Airxpanders proposed that Mr Dodson be granted options over 228,500 US shares equivalent to 685,500 CDIs, exercisable at the price on the date of the grant, vesting in equal monthly installments over four years and expiring after 10 years.

The company said that it proposed to issue options over shares equivalent to 128,700 CDIs to chairman Barry Sheskin, 105,000 CDIs to each of Gregory Lichtwardt and Zita Peach and 34,200 CDIs each to Dennis Condon and Tadmor Shalon, all exercisable at the price on the date of the grant, vesting over three years and expiring after 10 years. The meeting will be held at Johnson Winter & Slattery, Level 25, 20 Bond Street, Sydney, on May 17, 2016 at 9am (AEST).

Airxpanders fell 2.5 cents or 2.9 percent to 84 cents.

AIRXPANDERS

Airxpanders says it proposes that Gregory Lichtwardt and Zita Peach replace directors Dr Albert Cha and Dr Brigitte Smith at the May 17, 2016 annual general meeting.

Airxpanders said that Mr Lichtwardt previously held senior finance positions at Allergan, Ocular Sciences and Conceptus, and most recently was Accuray Inc's head of operations and chief executive officer.

The company said that Ms Peach had more than 20 years' experience, most recently as Fresenius Kabi's managing director for Australia and New Zealand and was currently a director at Starpharma, the Vision Eye Institute, 4DX, Bionic Vision Technologies and Mt Buller and Mt Sterling Alpine Resorts management board.

PHARMAXIS

Pharmaxis says that a total of 1,103 shareholders with an aggregate of 844,375 shares participated in the unmarketable parcel share sale facility.

Pharmaxis said that the shares were sold on-market and the proceeds would be distributed to the participants on or about May 6, 2016.

The company said that the decrease in the number of shareholders would reduce administrative costs associated with maintaining the share register including printing and mailing costs and other registry related expenses.

Pharmaxis said that as a result of the share sale facility its shareholder base was reduced to about 5,150 investors.

Pharmaxis was unchanged at 28 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says that chief executive officer Eutillio Buccilli and racing car driver Pippa Mann will ring the Nasdaq closing bell on May 6, 2016.

Genetic Technologies last rang the Nasdaq bell in 2005 when founder and then executive chairman Dr Mervyn Jacobson marked the company's Nasdaq listing (BD: Nov 8, 2005). Dr Jacobson is no longer associated with Genetic Technologies and was believed to have been released from prison in November 2015 following his conviction for conspiracy and market manipulation (BD: Nov 28, 2014).

Genetic Technologies said that Ms Mann was a Brevagenplus spokesperson and the bell-ringing would be televised on US finance and business networks.

Mr Buccilli said the company was "extremely pleased to be invited to the Nasdaq Market Site for the ceremonial bell ringing at this exciting time for the Company as we ramp-up commercial activities for Brevagenplus".

Genetic Technologies said that Ms Mann was one of nine women to compete in the Indianapolis 500 and the only female driver to start in the race over the past three consecutive years.

The company said that the Brevagenplus logo would feature on Ms Mann's racing and promotional apparel as well as the racing car.

Genetic Technologies said that the Indianapolis 500 would be held on May 29, 2016. Genetic Technologies was untraded at two cents.