Biotech Daily

Monday December 7, 2015

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: NEUREN UP 33%, OPTISCAN DOWN 9%**

*** PM MALCOLM TURNBULL LAUNCHES $1b INNOVATION, SCIENCE AGENDA**

*** BIO-MELBOURNE WELCOMES AGENDA 'INFLECTION POINT'**

*** NEUREN TROFINETIDE SHOWS 'BENEFICIAL EFFECTS' FOR FRAGILE X**

*** BENITEC IN-VITRO DATA BACKS BB-HB-331 FOR HEPATITIS B**

*** PROGEN MEETING BACKS MEDIGEN TBG BACKDOOR, SUSPENSION**

*** STARPHARMA REQUESTS CAPITAL RAISING TRADING HALT**

*** MACH7 WAIVES $10m MINIMUM FOR 3D MERGER**

*** SUDA PLEADS SCHULTZ TO ASX 17% QUERY**

*** UP TO 37% OF PSIVIDA OPPOSE 500k DIRECTOR OPTIONS**

*** GOLDMAN SACHS BELOW 5% OF NANOSONICS**

*** UBS AG BUYS, SELLS, BORROWS, RETURNS TO 5% MAYNE**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Monday December 7, 2015 with the ASX200 up 4.1 points to 5,155.7 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and four were untraded.

Neuren was the best, up three cents or 33.3 percent to 12 cents with 20.3 million shares traded, followed by Benitec up 25.8 percent to 39 cents with 1.2 million shares traded. Ellex climbed 7.35 percent; Biotron and Compumedics were up more than five percent; Admedus and Pro Medicus were up more than four percent; Pharmaxis and Universal Biosensors were up more than three percent; Nanosonics rose 2.5 percent; with CSL up 0.3 percent.

Optiscan led the falls, down 0.3 cents or 9.1 percent to three cents with 130,000 shares traded. Circadian lost 8.8 percent; Prima and Tissue Therapies fell more than seven percent; Osprey was down 6.7 percent; Atcor retreated 5.4 percent; Clinuvel, Medical Developments and Orthocell fell more than four percent; Polynovo and Sirtex were down more than three percent; Anteo, Living Cell and Mesoblast shed more than two percent; IDT, Psivida, Resmed and Reva lost more than one percent; with Cochlear down 0.03 percent.

FEDERAL GOVERNMENT

Prime Minister Malcolm Turnbull has launched a four-year $1.1 billion 'National Innovation and Science Agenda' including funding for research and commercialization.

According to the Government's Innovation website, the measures include a $250 million Biomedical Translation Fund and a $200 million "co-investment" in the Commonwealth Scientific and Industrial Research Organisation.

The website said the Biomedical Translation Fund would invest in biomedical innovation and commercialization, drawing on fund managers "selected through a competitive process to bring at least matching funding from the private sector for investment".

The website said that the fund would "receive its funding by reducing the capital contributions to the proposed $20 billion Medical Research Future Fund by $125 million in 2015-'16 and 2016-'17, while the MRFF would be fully capitalized in 2019-'20 "meaning that investment will be available for medical innovation almost immediately" rather than when the MRFF was fully capitalized.

The Biotech and Related Industries Leadership Group has called for 25 percent of the proposed $20 billion MRFF to be set aside for commercialization (BD: Jul 30, 2014).

A spokesperson for the Minister for Industry, Innovation and Science Christopher Pyne told Biotech Daily that the proposed 1.5 percent cut to the 45 percent Research and Development Tax Incentive, currently before the Senate, remained Government policy.

The Innovation website said that the CSIRO Innovation fund would include a $200 million early stage innovation fund to support co-investment in new companies comprising $70 million from the Government, as well as private sector investment and new revenue from CSIRO's wireless local area network (WLAN) program.

The Government said it would fund a $20 million expansion to CSIRO's accelerator program to include other publicly-funded research organisations, beginning in 2016-'17 with the early stage innovation fund to be implemented in 2016.

The website said that from July 1, 2016 Venture Capital Limited Partnerships would be changed to make them more internationally competitive and attract greater levels of investment through a 10 percent non-refundable tax offset on investments in start-ups, an increase in maximum size from $100 million to $200 million and removal of the need to divest when a company exceeded $250 million.

The Government said it would increase access to prior-year tax losses, with the 'same business test' being relaxed to a more flexible 'predominantly similar business test' and would make employee share schemes more user-friendly for innovative companies.

The Government said that investors in start-ups would gain a 20 percent non-refundable tax offset on their investment capped at $200,000 per investor, per year, as well as a 10-year capital gains tax exemption for investments held for three years, for companies incorporated in the last three income years, not listed on any stock exchange and had expenditure of less than $1 million and income less than $200,000 in the previous year.

The Government said it would invest $18 million in an Innovation Connections program to "expand and refocus the existing Research Connections program to drive new industry-led collaborations between researchers and small and medium enterprises".

The Government said that an $8 million Incubator Support Program would offer competitive matched funding to support development of new incubators and accelerators.

Mr Pyne said the Agenda would "transform Australia's economy" with an additional $127 million for research collaboration, and over the next 10 years, the Government would provide $520 million to the Australian Synchrotron, $294 million for the Square Kilometre Array, $1.5 billion to the National Collaborative Research Infrastructure Strategy, with a $36 million Global Innovation Strategy supporting businesses and researchers to collaborate with counterparts in Tel Aviv, Silicon Valley and three other key locations.

BIO-MELBOURNE NETWORK

Bio-Melbourne Network says the Federal Government National Innovation and Science Agenda “is the inflection point for innovation in Australia”.

Bio-Melbourne Network chief executive officer Dr Krystal Evans told Biotech Daily that “innovation is an idea whose time has come, finally”.

“The National Innovation and Science Agenda positions Australia for growth,” Dr Evans said.

“It is a good start, and building on this platform will allow Australia to deliver on our innovation potential,” Dr Evans said. “It is an important step in the right direction.”

Dr Evans said that “the important thing from a policy perspective will be how the major parties can use this Agenda as a platform to build Australia’s future, leading into the 2016 election”.

“Too often our sector has suffered from stop-start program cycles and a lack of long term, stable, strategic planning,” Dr Evans said.

“We want to see a continuation of the positive vision that Prime Minister Turnbull has put forward, to continue to deliver life-changing health innovation to Australia and to the world,” Dr Evans said.

Dr Evans said that the $250 million Biomedical Translational Fund was a key recommendation from the 2013 McKeon Review of Health and Medical Research and she welcomed its enactment.

Dr Evans said that “building the right team around technology” was key for biotechnology so the new Entrepreneur Visas would attract and retain talent in Australia.

Dr Evans also welcomed a proposed boost to science, technology, engineering and mathematics skills “to foster our own talent pipeline here, with a focus on women in science and entrepreneurial skills in schools”.

In terms of access to capital, Dr Evans said the new incentives would “invigorate our angel investor community, with a 20 percent non-refundable tax offset and capital gains offsets, but it was “not as generous as the UK Seed Enterprise Investment Scheme on which is it based, which provides a 50 percent non-refundable tax offset”.

Dr Evans said the Agenda included “real incentives to enhance industry and academic engagement, particularly supporting [small and medium sized enterprize] research connections, these relationships are critical for our innovation future”.

Dr Evans said it was “disappointing not to see any incentives to secure downstream activities that will secure the manufacture of innovation outputs in Australia”.

“Once companies move from start-up to scale-up we want to make sure Australia has a competitive business environment to keep Australian innovation Australian,” Dr Evans said.

Dr Evans said that the absence of changes to the R&D tax incentive were “a relief as this program provides significant support that enables companies to undertake, develop and extend their R&D programs”.

“This highly successful policy program has helped many Australian biotechnology and medical technology businesses to do more R&D and to successfully create innovative health care products for the global market,” Dr Evans said.

“The National Innovation and Science Agenda provides a solid platform on which to build,” Dr Evans said.

Further comment will be published in tomorrow’s edition.

NEUREN PHARMACEUTICALS

Neuren says that its 70 patient phase II trial of trofinetide has shown safety and “beneficial effects” for Fragile X syndrome and it will trial higher doses.

Neuren said that male patients aged 12 to 45 years were randomized to placebo (25 subjects), 35mg/kg of trofinetide (NNZ-2566) twice a day (24 subjects) and 70mg/kg trofinetide twice a day (21 subjects).

The company said that the effects observed following treatment with the 35mg/kg low dose were “less consistent and the magnitude of improvement did not meet pre-specified targets, but there was evidence of a dose response”.

Neuren said that the trial established proof-of-concept and provided “a strong rationale …to move forward with developing trofinetide for Fragile X syndrome”.

The company said that the small trial had a short treatment period, but trofinetide “was very well tolerated, with the high dose, 70mg/kg twice daily, demonstrating a consistent pattern of clinical improvement, observed in both clinician and caregiver assessments”.

Neuren said that after 28 days of treatment, improvements were seen across core Fragile X syndrome symptoms, including higher sensory tolerance, reduced anxiety, better self-regulation and more social engagement.

The company said that beneficial effects of trofinetide had been observed in two different neuro-developmental disorders, Fragile X syndrome and Rett syndrome, which was consistent with the known actions of trofinetide, expected to normalize a number of biological processes in the brain that impacted by each syndrome.

Neuren said that given the tolerability profile and the observed dose response profile, there was “a clear rationale to study higher doses” and the company expected to conduct a study in younger children with Fragile X syndrome, possibly with longer treatment duration at higher doses.

The company said that the next study would refine the outcome measures that might be used in a phase III study and it intended to discuss the trial results and drug development plan with the US Food and Drug Administration in early 2016.

University of California Davis MIND Institute and Fragile X Research and Treatment Center director Dr Randi Hagerman said that trofinetide had “a unique mechanism of action very different from any other molecule … tested before in Fragile X syndrome”.

“Its derivation from a naturally occurring neurotrophic factor makes it a promising candidate to treat a wide range of the core symptoms of Fragile X syndrome and potentially other neurological disorders,” Dr Hagerman said. “The results of this trial and the clinical improvements that investigators observed are an exciting first step.”

Neuren executive chairman Dr Richard Treagus said the results “further underscore the value of trofinetide as a potential treatment for complex neurodevelopmental disorders”.

Neuren said that the primary objective was safety and tolerability of the two dose levels compared to placebo, along with a number of secondary and exploratory outcome measures for efficacy, including two rating scales.

The company said that no serious adverse events were reported and no subject discontinued due to adverse events during the double-blind treatment period, dose-dependent and time-dependent patterns were not observed in the adverse events reported during the trial, and there was no pattern of adverse events evident with initiation or cessation of treatment, with no consistent dose-dependent trends in objective safety assessments or laboratory measurements detected.

Neuren said the trial design anticipated a potential placebo response and the data was subjected to permutation testing to estimate whether the observed clinical improvement was observed purely by chance, with the probability estimated as 4.5 percent ($p = 0.045$).

Neuren climbed three cents or 33.3 percent to 12 cents with 20.3 million shares traded.

BENITEC BIOPHARMA

Benitec says that initial in-vitro data shows efficacy for BB-HB-331, a DNA directed RNA interference (ddRNAi) therapeutic to cure hepatitis B with a single injection.
Benitec said that the data was presented at the 'Hep Dart' hepatitis conference in Hawaii on December 6, 2015 and showed that BB-HB-331 could effectively suppress multiple aspects of the hepatitis B virus in infected human liver cells.
The company said that treatment with BB-HB-331 saw a 90 percent reduction in the levels of hepatitis B surface antigen and e-antigen as compared to untreated controls or liver cells treated with a construct that produced unrelated short hairpin RNA, the core antigen was decreased by about one logarithmic interval and treated cells showed at least an 85 percent reduction of intracellular hepatitis B DNA after 23 days.
Benitec said that the data "strongly supports progression of BB-HB-331 into in vivo testing".
Benitec chief scientific officer Dr David Suhy said the data showed that BB-HB-331 produced "robust knock-down" of many of the parameters of active hepatitis B infection.
Benitec was up eight cents or 25.8 percent to 39 cents with 1.2 million shares traded.

PROGEN PHARMACEUTICALS

Progen has requested a voluntary suspension pending following receipt of security holder approval for the acquisition of TBG from Medigen (BD: May 1, Oct 16, Nov 11, 2015).
All resolutions at the Progen annual general meeting and subsequent extraordinary general meeting were passed overwhelmingly.
Progen last traded at 22.5 cents.

STARPHARMA

Starpharma has requested a trading halt "pending an announcement to the market regarding the completion of an equity capital raising".
Trading will resume on December 9, 2015 or on an earlier announcement.
Starpharma last traded at 78 cents.

3D MEDICAL

3D Medical says that Mach7 Technologies has waived the $10 million minimum raising condition of the proposed merger (BD: Oct 26, 28, 2015).
3D said it raised $3,984,080 in a placement, had binding commitments to raise $2.5 million through the exercise of 40,857,405 options and had a share plan underway.
The company said that it had extended its share plan to December 21, 2015.
3D was up 0.4 cents or 5.8 percent to 7.3 cents.

SUDA

Suda 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 16.7 percent from 3.0 cents on December 4 to 3.5 cents today, December 7, 2015 and noted an increase in trading volume.
Suda was unchanged at three cents with 9.9 million shares traded.

PSIVIDA

Up to 36.9 percent of Psivida's annual general meeting voted against the grant to chief executive officer Dr Paul Ashton and five directors stock options over 500,000 shares.
Psivida it proposed to grant Dr Ashton 290,000 options, vesting in four equal tranches from July 23, 2016 and exercisable at $US4.09 ($A5.64) a share, within 10 years of grant, with chairman Dr David Mazzo to receive, 30,000 options, and 20,000 options each for Douglas Godshall, Michael Rogers, Peter Savas and Dr James Barry, all vesting on July 23, 2016, exercisable at $US4.09 and within 10 years of grant.
The strongest opposition was to Mr Savas with 4,039,847 votes (36.9%) against and 6,903,427 votes (63.1%) in favor, while the other options grants were passed by wider margins.
The vote to approve executive compensation passed with 8.1 million votes in favor and 2.8 million votes against, while all directors were re-elected overwhelmingly.
The company's most recent Appendix 3B new issue announcement said that Psivida had 29,417,365 shares on issue, meaning that the vote against Mr Savas options amounted to 13.7 percent of the company, sufficient to requisition extraordinary general meetings.
Psivida fell 10 cents or 1.85 percent to $5.30.

NANOSONICS

The Delaware-based Goldman Sachs Group says it has ceased its substantial shareholding in Nanosonics, yet again.
Following the notice on Friday December 4, 2015 that it had become substantial in Nanosonics with 14,874,308 shares or 5.25 percent, Goldman Sachs said after the market closed on Friday that it had reduced its holding below the five percent substantial threshold (BD: Oct 2, 5, 15, 16, 20, 21, 23, 27, 28, Nov 5, 6, 9, Dec 2, 4, 2015).
Goldman Sachs said that subsidiary Rothesay Life returned 1,253,160 shares "to the counterparty under a repurchase agreement" for no applicable consideration.
Previously, under a counterparty agreement, Goldman Sachs said it had returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australia, HSBC Custody Nominees and the Bank of New York Mellon (BD: Apr 13, 2015).
Nanosonics was up four cents or 2.5 percent to $1.655.

MAYNE PHARMA

The Singapore-based UBS AG and related bodies corporate says they have become substantial in Mayne Pharma with 40,366,577 shares or 5.02 percent.
UBS AG said that between August 3 and December 2, 2105 in more than 600 trades it bought, sold, borrowed and returned Mayne Pharma shares for institutions, including Citibank, Citigroup, BNP Paribas, Warbont Nominees JP Morgan Chase Bank, National Australia Bank, State Street Bank & Trust Co, Regal Funs Management, Paragon Funds and Blue Lake Partners.
Mayne fell one cent or 0.7 percent to $1.35 with 2.4 million shares traded.