Biotech Daily

Tuesday March 16, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 15%; USCOM DOWN 3%**

*** BARD1, MINOMIC WORK ON PANCREATIC CANCER BLOOD TEST**

*** STARPHARMA: 'DEP-HER2-LU BEATS HERCEPTIN FOR BREAST CANCER IN MICE'**

*** MICRO-X TERMINATES THALES IED DEAL**

*** IMMUTEP STARTS IMP321-KEYTRUDA HEAD, NECK CANCER TRIAL**

*** AZURE MANUFACTURES NE1-ELITE, NE1-HEART FOOD ADDITIVES**

*** RHYTHM COLOSTAT BLOOD TEST 84% SENSITIVITY, 95% SPECIFICITY**

*** INCANNEX: IHL-675A BEATS CBD, HCQ FOR ARTHRITIS IN RATS**

*** IMEX: 54 AQUILA DEALS, $1.2m ANNUAL RECURRING REVENUE**

*** IMAGION RECEIVES FEDERAL $50k GRANT**

*** BLUECHIIP RECEIVES $1.6m R&D TAX INCENTIVE**

*** ADHERIUM REQUESTS 'PLACEMENT' TRADING HALT**

*** EUROPEAN PATENT FOR REGENEUS PROGENZA STEM CELLS**

*** BRANDON, MRCF, HESTA HOLD 27% OF OSPREY**

*** NAOS TAKES 29.5% OF BTC**

*** FIL REDUCES TO 8.4% OF RESAPP**

*** REGAL REDUCES TO 6.6% OF ALTERITY**

*** ELIXINOL APPOINTS KIM BRADLEY-WARE CO-CO SEC**

MARKET REPORT

The Australian stock market was up 0.8 percent on Tuesday March 16, 2021, with the ASX200 up 54.1 points to 6,827.1 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 10 fell and seven traded unchanged. All three Big Caps were up.

Actinogen was the best, up 0.4 cents or 14.8 percent to 3.1 cents, with 50.7 million shares traded. Optiscan climbed 14.6 percent; Immutep was up 10.45 percent; Amplia, Polynovo and Proteomics were up more than six percent; Antisense and Starpharma rose more than five percent; Genetic Signatures, Nanosonics, Pharmaxis and Pro Medicus improved more than three percent; Compumedics, CSL, Mesoblast, Paradigm and Resonance rose more than two percent; Cochlear, Cynata, Kazia, Medical Developments, Neuren, Prescient, Resmed and Telix were up one percent or more; with Clinuvel up 0.9 percent.

Uscom led the falls, down 0.5 cents or 3.1 percent to 15.5 cents, with 25,000 shares traded. Next Science, Oncosil, Universal Biosensors and Volpara fell two percent or more; Cyclopharm, LBT, Nova and Opthea were down one percent or more; with Avita down by 0.5 percent.

BARD1 LIFE SCIENCES

Bard1 says that working with Sydney's Minomic International it has been able to differentiate pancreatic cancer from healthy control samples using a blood test.

Bard1 said there were no blood tests for the early detection of pancreatic cancer but its Exo-Net exosome capture technology was shown to isolate exosomes from 10 pancreatic cancer patients and five healthy control plasma samples.

The company said that Minomic's proprietary antibody MIL-38 bound to the protein glypican-1 (GPC-1) and the antibody "was shown to specifically bind Exo-Net isolated pancreatic cancer exosomes and not bind to healthy non-cancer exosomes".

Bard1 said it isolated exosomes from plasma in samples from 10 pancreatic cancer patients and five healthy controls, and probed them with Minomic's MIL-38.

The company said independent studies reported that GPC-1 was present on exosomes from pancreatic cancer patients, with high-levels associated with poor prognosis.

Bard1 said that the study found that Exo-Net was "highly effective at isolating exosomes from both pancreatic cancer and healthy control samples, and the anti-GPC-1 antibody was specific for exosomes from pancreatic cancer patients".

Bard1 chief scientific officer Dr Peter French said it was "a pleasing result, as it highlights two key outcomes for Bard1".

"Firstly, the results demonstrated that the company's proprietary exosome-capture technology, Exo-Net, is extremely efficient at capturing exosomes from patient samples with a high specificity, yield and speed [of 15 minutes] which compares well with competitive exosome isolation technologies," Dr French said.

"Secondly, although only a small number of patient samples were tested, exosomes from pancreatic cancer patients displayed significant levels of GPC-1 protein compared to non-cancer patients, as indicated by binding of Minomic's MIL-38 antibody," Dr French said.

"This finding supports the previously reported association by several independent researchers that GPC-1 is a potential marker of pancreatic cancer exosomes," Dr French said.

"Whilst further studies are needed to confirm sensitivity and specificity of an exosome-based GPC-1 test for pancreatic cancer detection, the data support the ongoing development of this technology," Dr French said.

Minomic head of research and development Dr Douglas Campbell said: it was "exciting that this pilot study indicated that our anti-GPC-1 antibody, MIL-38, appears to specifically bind pancreatic cancer exosomes".

"This opens up new applications for MIL-38 which we are eager to explore," Dr Campbell said. "The ease of use of Exo-Net means that an exosome-based diagnostic test is commercially viable, overcoming many of the barriers of current exosome isolation technologies in terms of scalability, isolation speed and high yield".

Bard1 chief executive officer Dr Leearne Hinch said the "encouraging result … clearly demonstrates the commercial potential of our soon-to-be launched research-use-only Exo-Net product for capturing exosomes and the feasibility of using GPC-1 [with] exosomes for detection of pancreatic cancer," Dr Hinch said.

"Bard1 and Minomic are extremely pleased by this outcome and will discuss how to advance the project towards development of an exosome-based GPC-1 test for early detection of pancreatic cancer to improve patient outcomes and survival for this important unmet need," Dr Hinch said.

Minomic chief executive officer Dr Brad Walsh told Biotech Daily that his company was currently undertaking a capital raising for up to $15 million.

Bard1 climbed 26 cents or 6.8 percent to $4.10 with 3.7 million shares traded.

Minomic is a public unlisted company.

STARPHARMA

Starpharma says its second radio-pharmaceutical candidate, DEP-HER2-lutetium, outperforms Herceptin, labelled with lutetium, for human breast cancer in mice.
Starpharma said the dendrimer enhanced product (DEP) human epidermal growth factor receptor-2 (HER2) lutetium "achieved potent and durable anti-cancer activity, with complete tumor regression" compared with Herceptin labelled with lutetium.
The company said that HER2 was a growth-promoting protein on the outside of all breast cells and breast cancer cells with higher-than-normal levels of HER2 were called HER2-positive, and these cancers tend to grow and spread faster than other breast cancers but were more likely to respond to treatments with drugs that target the HER2 protein such as Herceptin, or trastuzumab.
Starpharma said the HER2 receptor existed in some other cancers such as gastric, colon, bladder and biliary cancers.
The company said that its DEP-HER2-lutetium was a dendrimer incorporating the radioisotope lutetium-177 (177Lu) and a HER2-targeting moiety, or nanobody.
Starpharma said the study, at the University of Queensland's Centre for Advanced Imaging, evaluated the anti-cancer activity of different doses of DEP HER2-lutetium and DEP-lutetium compared to Herceptin labelled with lutetium
The company said that mice were dosed intravenously with vehicle, 177Lu-labelled Herceptin at 15 mega-becquerels (MBq) 177Lu; DEP HER2-lutetium (15 MBq 177Lu); or DEP-lutetium (15 MBq 177Lu).
Starpharma said there was statistically significant benefit ($p < 0.0001$) for the company's DEP-HER2-lutetium over Herceptin labelled with lutetium and the control, as well as for DEP-lutetium over Herceptin labelled with lutetium and the control.
The company said all DEP-HER2-lutetium doses were "extremely well tolerated .. [with] no deaths due to treatment or as a result of tumor growth in any treatment group".
Starpharma said the data showed that DEP dendrimer without HER2 targeting had "a potent anticancer effect which is greater than with Herceptin, while the targeted DEP HER2-lutetium provides even greater efficacy".
Starpharma said the company had multiple potential radio-pharmaceutical and radio-diagnostic DEP products and its DEP radio-pharmaceutical conjugates selectively penetrated and accumulated within tumors to more effectively deliver radiation to kill tumor cells, that mighty be unreachable by conventional therapies.
The company said that the addition of targeting groups such as HER2 onto the DEP radio-pharmaceutical could further enhance efficacy.
Starpharma was up 10 cents or 5.35 percent to $1.97 with 1.6 million shares traded.

MICRO-X

Micro-X says it has terminated its agreement with Thales AVS France SAS for x-ray tubes for its improvised explosive device (IED) imaging product.
Last month, Micro-X it had raised $30.5 million in a placement and some of the funds would be used to insource x-ray tubes (BD: Feb 1, 2021)
Today, the company said it would repay a $5 million convertible loan to the Le Cannet-des-Maures, France-based Thales.
Micro-X said the x-ray tube would be designed and produced at its Tonsley, South Australia facility and it had appointed Shaun Graham manager for the IED product line.
The company said Mr Graham previously worked as a Royal Australian Navy clearance diver and had experience in explosive ordnance disposal.
Micro-X was up 2.5 cents or 7.25 percent to 37 cents.

IMMUTEP

Immutep says it will begin a 160-patient, phase IIb combination trial to investigate IMP321 with Keytruda in first-line head and neck squamous cell carcinoma patients.

Immutep said the randomized, controlled trial would evaluate the safety and efficacy of its IMP321, or eftilagimod alpha, in combination with Merck Sharp & Dohme's Keytruda (pembrolizumab) and compared to pembrolizumab alone.

The company said the 'two active immunotherapies' Tacti-003 trial would be conducted at more than 20 sites in the US, Australia and Europe and the first patient was expected to be enrolled in mid-2021.

Immutep said that the combination of IMP321 and Keytruda was being evaluated in its phase II TACTI-002 study and "the promising clinical results generated to date" had prompted the new TACTI-003 trial.

Immutep chief executive officer Marc Voigt said the company was "excited to be deepening our collaboration with [Merck Sharp & Dohme] through this second agreement and the Tacti-003 clinical trial."

"Advancing to this later stage phase IIb trial will allow us to explore the combination therapy in the commercially relevant first-line therapy setting which has a high unmet medical need," Mr Voigt said.

Immutep was up 3.5 cents or 10.45 percent to 37 cents with 4.2 million shares traded.

AZURE HEALTH TECHNOLOGY

Azure says it has completed its first US manufacturing run for its NE1-Elite and NE1-Heart food additives.

Azure said the US production would supply the products for sale in the US, Australia and China.

The company said that NE1-Elite and NE1-Heart were "based on annatto-derived delta tocotrienols delivered using [its] MELT3, melt then swallow, platform.

Azure said that NE1-Elite was "clinically-proven to reduce delayed onset muscle soreness, improve muscle recovery after exercise and improve maintenance of peak muscle power", while NE1-Heart was "a strong antioxidant … and maintains heart health".

The company's wholly-owned US subsidiary Invictus Nutraceuticals chief executive officer Richard Estalella said that people who tried NE1-Elite were "unanimously positive and surprising in a very good way".

"We have had reports from a range of sportspeople including champion marathon runners, grid-iron football players and long-distance bike riders and they all say that NE1-Elite has completely transformed the way that they enjoy their sports and has allowed them to play harder for longer and recover quicker," Mr Estalella said.

"These real-life results are totally consistent with the clinical data that we have gathered to date," Mr Estalella said.

Azure said that both products were ready for sale in the US and were listed on the Australian Register of Therapeutic Goods as complementary medicines.

Azure managing-director Dr Glenn Tong said that "having the first finished products ready for sale in a major market like the US is a huge milestone".

"We started with simply a concept nine years ago which we have now taken through the various stages of intellectual property protection, product development, and clinical development," Dr Tong said.

"We are extremely excited to see the products coming off the manufacturing line and ready to sell to consumers," Dr Tong said.

Azure is a public unlisted company.

RHYTHM BIOSCIENCES

Rhythm says its sixth study of Colostat blood test shows “very high accuracy for the detection of colorectal cancer” with 84 percent sensitivity and 95 percent specificity.
Rhythm said the third-party commercially-manufactured Colostat prototype test-kit was tested against 300 cancerous and healthy blood samples and the results were confirmed on an independent set of 100 cancerous and healthy blood samples, with the 84 percent sensitivity and 95 percent specificity “surpassing all prior test results”.
Rhythm chief executive officer Glenn Gilbert told Biotech Daily that the samples were approximately 50 percent cancerous and 50 percent healthy.
The company said that the test was reproducible, robust, scalable, consistent and could meet the performance expectations of patients, clinicians and testing laboratories.
Rhythm said that its current clinical trial, effectively its seventh study, would “demonstrate the clinical utility of Colostat to the relevant regulatory bodies, such as the Conformitè Europëenne (CE) mark and in Australia to the Therapeutic Goods Administration”.
The company said that its development program was designed to establish its own sources of antibodies and target antigen materials that were scalable, with Colostat test-kits that could be commercially produced by a third-party manufacturer.
Mr Gilbert said the Colostat was intended to “a disruptive cancer detection technology for the global mass screening market to address the growing burden of colorectal cancer”.
“The completion, increase in performance and generally positive outcome of Study 6, is a critical milestone for the company as we progress our clinical trial, and importantly, how we now consider our entry plans for the global markets, including the US,” Mr Gilbert said.
Rhythm said that a US Centers for Medicare and Medicaid Services draft criteria for the reimbursement required minimum sensitivity of 74 percent and minimum specificity of 90 percent.
Rhythm was unchanged at $1.50 with 2.5 million shares traded.

INCANNEX

Incannex says its IHL-675A combined cannabidiol (CBD) and hydroxychloroquine improved rheumatoid arthritis in rats better than (CBD) or hydroxychloroquine alone.
The company said the low dose of IHL-675A was found to be more effective than higher doses at reducing arthritis and results demonstrated a potential for 10-fold reduction in hydroxychloroquine (HCQ) dose without sacrificing efficacy in the arthritis treatment.
Incannex managing-director Joel Latham said the company was “delighted with the results from this study.”
“Hydroxychloroquine was an established medication for rheumatoid arthritis and IHL-675A has been demonstrated to outperform it at reducing disease severity in an animal model,” Mr Latham said.
“The benefit of the CBD and hydroxychloroquine combination in IHL-675A is potent,” Mr Latham said.
“The observation that IHL-675A was as effective or better than a standard dose of hydroxychloroquine, even though it contained 90.0 percent less drug, was an exciting result for the company,” Mr Latham said.
“It indicates that IHL-675A has the potential to be a breakthrough in the treatment of rheumatoid arthritis in humans,” Mr Latham said.
“The company is rigorously working with its scientific team and advisors to arrange the next steps to advance IHL-675A for use in patients with rheumatoid arthritis,” Mr Latham said.
Incannex was up one cent or 4.9 percent to 21.5 cents with 11.3 million shares traded.

IMEX HEALTH SERVICES

Imex says since launching its Aquila in the [internet] Cloud radiology analysis system in May last year, it has signed 54 deals worth $1.2 million in annual recurring revenue.
Imex said Aquila in the Cloud offered affordable medical imaging technology to small and mid-size customers and the company recently added three new distributors.
Imex chief executive officer Dr Germán Arango said “we are encouraged by the ongoing strong demand for Aquila in the Cloud which, in less than 12 months, has generated $1.2 million in [annual recurring revenue]”.
“We are getting significant traction across a number of regions including the US, where we recently received two new orders in South Florida,” Dr Arango said.
“Aquila in the Cloud solves a long-standing problem that has affected small to medium-size clinics which could not afford customized medical imaging [products],” Dr Arango said.
“Aquila in the Cloud … provides these operators with a user-friendly and low-cost alternative, increasing physician productivity and leading to better healthcare outcomes for patients,” Dr Arango said.
Imex was up four cents or two percent to $2.00.

IMAGION BIOSYSTEMS

Imagion says it has received a Federal Government $50,000 grant from the Entrepreneurs’ Programme of Department of Industry, Science, Energy and Resources.
Imagion said the grant was part of the Innovations Connections program delivered by the Commonwealth Scientific and Industrial Research Organisation “to facilitate connecting industry with researchers to help fast-track [research and development] projects”.
The company said the grant would be used to support its pre-clinical research project with Melbourne’s Monash University to achieve early concept validation for its Magsense prostate cancer imaging product.
Imagion executive chair Bob Proulx said the collaboration with Monash, assisted by funding from the CSIRO, “helps jump-start our prostate cancer project by leveraging the expertise at Monash University and provides a key opportunity to advance our Magsense technology for another important cancer indication”.
“We’re grateful for the support from the … Government through the Entrepreneurs’ Programme and their recognition of the medical need for improved methods of prostate cancer detection,” Mr Proulx said.
Imagion fell half a cent or 2.9 percent to 17 cents with 8.2 million shares traded.

BLUECHIIP

Bluechiip says it has received $1,622,685 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Bluechiip said the rebate related to expenditure for the year to June 30, 2020.
Bluechiip was up 0.1 cents or 2.4 percent to 4.2 cents.

ADHERIUM

Adherium has requested a trading halt in relation “to a proposed placement to sophisticated and professional investors”.
Trading will resume on March 18, 2021 or on an earlier announcement.
Adherium last traded at 2.1 cents.

REGENEUS

Regeneus says the European Patent Office has granted a patent for its stem cell technology platform Progenza for pain.
Regeneus said the patent, titled 'Therapeutics using adipose cells and cell secretions' would protect its intellectual property until 2032.
In 2018, the company said the European Patent Office intended to grant a patent for its Progenza fat-derived mesenchymal stem cells (BD: Oct 18, 2018).
Today, Regeneus said the patent would expand Progenza's protection beyond treatment of inflammatory conditions.
Regeneus chief executive officer Karolis Rosickas said it was "positive to see our patents being allowed and granted across the major European, US and Japanese markets."
"This patent will help facilitate our discussions with commercial partners for licensing Progenza for the $85.5 billion global pain market," Mr Rosickas said.
Regeneus was up 1.5 cents or 14.3 percent to 12 cents.

OSPREY MEDICAL

Brandon Capital says it has increased its holding in Osprey from 236,891,133 Chess depository instruments (CDIs) (9.23%) to 702,144,984 CDIs (27.37%).
The substantial shareholder notice said the shares were acquired in the 2020 $15.5 million placement through a partly-underwritten, three-for-one entitlement offer at 1.2 cents per CDI and through the exercise of options (BD: Apr 3, 2020).
Brandon said the shares were held directly as well as through the Medical Research Commercialisation Fund 3 (MRCF3) Services and the Health Employees Superannuation Trust Australia (Hesta).
Osprey was unchanged at 2.1 cents with 14.4 million shares traded.

BTC HEALTH

NAOS Asset Management says it has increased its substantial holding in BTC Health from 67,507,793 shares (27.43%) to 72,564,683 shares (29.48%).
The Sydney-based NAOS said that on March 12, 2021 it bought 5,048,880 shares for $392,211 or 7.77 cents a share.
BTC fell 0.3 cents or 3.9 percent to 7.4 cents.

RESAPP HEALTH

FIL Limited says it has decreased its substantial holding in Resapp from 69,720,439 shares (9.48%) to 63,999,559 shares (8.44%).
The Hong Kong-based FIL said between July 29, 2020 and March 11, 2021 it bought, sold and transitioned-out shares at prices ranging from 5.61 cents a share to 14.16 cents a share.
FIL said the shares were held by HSBC Bank, Brown Brothers, Clearstream Banking, State Street Bank and Tr Co, and JP Morgan (Bournemouth).
Resapp was up 0.6 cents or 8.3 percent to 7.8 cents with 9.1 million shares traded.

ALTERITY THERAPEUTICS

Regal Funds Management says it has decreased its substantial holding in Alterity from 158,030,555 shares (7.58%) to 136,945,316 shares (6.57%).
The Sydney-based Regal Funds said between March 1 and 11, 2021 it sold 21,085,239 shares for $684,745 or an average of 3.25 cents a share.
Alterity was unchanged at 3.4 cents with 2.3 million shares traded.

ELIXINOL GLOBAL

Elixinol says it has appointed Ms Kim Bradley-Ware as joint company secretary supporting Teresa Cleary.
Elixinol said that Ms Bradley-Ware had been “supporting the company since [its initial public offering]”.
Elixinol was unchanged at 21 cents with 1.7 million shares traded.