Biotech Daily

Wednesday February 9, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMUGENE UP 7%; NANOSONICS DOWN 6%**

*** PROTA TO RAISE $20m FOR PEANUT ALLERGY**

*** BIOME: 'TRIAL BACKS PROBIOTICS FOR ACNE'**

*** DORSAVI WINS ISO 27001 DATA SECURITY CERTIFICATION**

*** ACTINOGEN: WORLDWIDE TO MANAGE XANAMEM FRAGILE X TRIAL**

*** VGI ETHICS APPROVAL FOR IBV001 FOR NAFLD, NASH TRIAL**

*** ANTERIS PROPOSES MERGER WITH SIO-RELATED MSAC**

MARKET REPORT

The Australian stock market was up 1.13 percent on Wednesday February 9, 2022, with the ASX200 up 81.4 points to 7,268.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and one was untraded.

Imugene was the best, up two cents or 6.6 percent to 32.5 cents, with 28.75 million shares traded.

Impedimed improved 5.4 percent; Emvision, Opthea and Proteomics climbed more than four percent; Clinuvel, Mesoblast, Neuren, Patrys and Polynovo were up more than three percent; Alcidion, Prescient, Pro Medicus and Starpharma rose more than two percent; Cochlear, Genetic Signatures, Resmed and Universal Biosensors were up more than one percent; with Avita and Telix up by less than one percent.

Nanosonics led the falls for the second day in a row, following a new distribution deal with GE Healthcare, down 29 cents or six percent to $4.51, with 6.4 million shares traded.

Resonance retreated 5.7 percent; Micro-X fell four percent; Dimerix and Next Science lost more than three percent; Amplia, Antisense, Compumedics, Kazia and Medical Developments shed two percent or more; Immutep, Nova Eye and Volpara were down more than one percent; with CSL and Paradigm down by less than one percent.

PROTA THERAPEUTICS

Prota says it hopes to raise $20 million to further develop and commercialize its PRT120 immunotherapy for peanut allergy.

On Monday, the Murdoch Children's Research Institute and Prota said that a 201-patient trial showed that the immunotherapy significantly reduced peanut allergy in children, with about half of the children achieving remission, allowing them to stop treatment and safely eat peanuts freely (BD: Feb 7, 2022).

Today, Prota said that the phase IIb trial results validated its PRT120 investigational oral immunotherapy with a novel high dose, rapid escalation dosing regimen for the treatment of peanut allergy.

The company said that the research was led by the Murdoch Children's Research Institute's Prof Mimi Tang, Prota's chief executive officer

Prota said that "remission of allergy refers to the absence of clinical reactivity that persists after treatment has been stopped for a period of time".

"This allows patients to stop treatment and no longer adhere to strict allergen avoidance," the company said.

Prof Tang contrasted the outcome of "remission" with "desensitization" which was a temporary increase in the amount of allergen that caused a reaction for patients that is only maintained with continuing treatment.

"Desensitization provides protection against accidental exposure to allergen, but patients must remain on daily treatment and also maintain strict allergen avoidance," Prof Tang said.

Prota said that previous studies of peanut oral immunotherapy had shown "limited success at stimulating remission, with only a small subset of patients achieving this endpoint after years of treatment".

The company said that with PRT120, 51 percent of children achieved remission after 18 months, compared to five percent in the placebo arm, recording the highest rate of remission yet reported for a standalone peanut oral immunotherapy treatment in school-aged children.

Prota said the study used its dosing regimen comprising a proprietary rapid escalation, high dose approach believed to contribute to the remission rates being higher than previous oral immunotherapy trials, alongside other factors including the younger age of subjects.

Prof Tang told Biotech Daily that the intellectual property of both the PRT120 probiotic and the dosing regimen to stimulate the immune system were proprietary.

Oneventures founder and Prota lead shareholder Dr Paul Kelly said that peanut allergy was "a growing health concern with an increasing number of patients affected every year".

"This company has the potential to transform the way peanut allergy is treated and we are excited to see it flourish," Dr Kelly said.

Prota said the funds would be used to support further clinical development and commercialization of PRT-120.

The company said that the paediatric peanut allergy market was estimated to be worth $3 billion by 2027, with about 1.1 million patients between the ages of one and 17 years diagnosed in the US alone last year.

Prota said the trial results and the size of the peanut allergy market was "a significant opportunity … to bring PRT-120 to market, providing a highly differentiated long-lasting treatment that offers meaningful improvements to the quality of life of patients and their families".

To apply to the capital raising email Prof Tang: mimi.tang@protatherapeutics.com.

Prota is a private company.

BIOME AUSTRALIA

Biome says a 55-subject trial, as a subset of a 114-patient trial, shows that its probiotic significantly reduces acne better than placebo.

Biome said the trial, titled 'Facial Acne: A Randomized, Double-Blind, Placebo-Controlled Study on the Clinical Efficacy of a Symbiotic Dietary Supplement' was conducted by Milan's Giuliani SpA, published in the journal Dermatology and Therapy and available at: https://link.springer.com/article/10.1007/s13555-021-00664-z.

The journal article said that "the purpose of this study was to test the efficacy of a dietary supplement containing probiotics (Bifidobacterium breve BR03, Lacticaseibacillus casei LC03, and Ligilactobacillus salivarius LS03) and botanical extract (lupeol from Solanum melongena L [eggplant or aubergine] and echinacea extract) in subjects with mild to moderate acne over an 8-week study period".

The journal article said that the 114-subject, four-arm trial showed a significant ($p < 0.05$) effect on the number of superficial inflammatory lesions was reported over the study period in the 30 subjects taking the study agent (group II) (−56.67%), the 29 subjects taking the botanical extracts (group III) (−40.00%), and the 27 subjects in the probiotics group (group IV) (−38.89%) compared with the 28-subject placebo (group I) (−10.00%).

The journal article said that a significant ($p < 0.05$) decrease in mean desquamation score, sebum secretion rate, and porphyrin mean count versus baseline was also reported, and the effect was most evident for group II, taking the study agent.

The article concluded that "the administration of the dietary supplement under study was effective, safe, and well tolerated in subjects with mild to moderate acne and could represent a promising optional complement for the treatment of inflammatory acne as well as for control of acne-prone skin".

A spokesperson for Biome told Biotech Daily that the active probiotic ingredients were licenced from Probiotical SpA in Novara, Italy and the Lund University, Sweden-based Probi AB, but combined and manufactured by Biome.

Biome said that 27 subjects received the probiotic strains, and 28 subjects received a placebo and dosed once a day for eight weeks.

The company said its probiotics showed a 31.1 percent reduction in the number of acne lesions in four weeks, compared to the 10 percent reduction with placebo ($p < 0.05$).

Biome said that at week-4, there was a 31.1 percent decrease in the number of superficial inflammatory acne lesions in probiotics group compared to a 10.0 percent decrease with placebo ($p < 0.05$), measured using the global acne grading system.

The company said the probiotics group and the placebo group "continued to improve after eight weeks with a 38.9 percent reduction in the probiotics group compared to 18.9 percent in the placebo group ($p < 0.05$).

Biome said that the study showed the probiotics group had a greater reduction in erythema, or skin redness ($p < 0.05$), with no reduction reported for placebo.

The company said that there was a significant reduction in the abundance of the main bacteria implicated in the pathogenesis of acne, Cutibacterium acnes ($p < 0.01$), in those who received probiotics at the end of the study, providing evidence for the ability of the oral probiotic to impact the skin microbiome.

Biome said it would launch the over-the-counter Biome Acne Probiotic formulated for the treatment of acne with Probiotical SpA

The company said it expected to launch the product by July 2022, when it would "become one of the world's first clinically proven probiotics for the management of acne".

Biome said that the global acne therapeutic market was estimated to be worth more than $US6 billion in 2019.

Biome was up one cent or 10 percent to 11 cents.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS, ALLIED HEALTH, BIOMD)

Anteris says that it has received a non-binding proposal to merge with the New York-based and Nasdaq listed Medicus Sciences Acquisition Corp (MSAC).
In a separate announcement, MSAC said that it had become a substantial holder in Anteris with 1,274,966 shares or 11.40 percent.
MSAC said the acquisition was “by virtue of [a] co-operation deed”.
According to its March 31, 2021 annual report, Medicus Sciences founding chief executive officer and director Dr Michael Castor was the founder of Sio Capital Management LLC.
In December, Sio and related funds said they increased and were diluted in Anteris from 1,262,680 shares (14.38%) to 1,274,966 shares (12.61%) (BD: Jan 16, 2022).
In 2020, the then Admedus said 77.9 percent of votes at its extraordinary general meeting opposed the issues of 61,969,857 loan shares to SIO (BD: Feb 26, 2020).
In 2019, Admedus said it had a $1 million, 18-month loan from hedge fund Sio Partners at 12 percent compounding monthly, with a $125,000 “facility fee” (BD: May 9, 2019).
Earlier in 2019, Sio Partners said it became a substantial shareholder in Admedus with 131,120,851 shares or 22.2 percent of the company acquiring 131,120,851 shares for $8,617,251 or 6.57 cents a share, in the December rights issue and shortfall placement that raised $18.96 million at eight cents a share (BD: Dec 14, 2018; Jan 21, 2019).
Today, Anteris said that MSAC had “no commercial operations and was established as a blank cheque company for the purpose of, amongst other things, effecting a merger, share exchange or business combination with one or more businesses”.
The company said that the proposed transaction was a “business combination whereby all existing Anteris shareholders will receive shares in MSAC in exchange for their shares in the company by MSAC, to be implemented via a court-approved scheme of arrangement”.
Anteris said that “the proposal contemplates an issuance of new equity by MSAC in exchange for the current shares in the company at an equivalent value and stipulates that post-transaction the merged entity would have a minimum of $US50 million ($A69.8 million) in cash, plus the existing funds held by the company”.
Anteris said there was no certainty that the merger would proceed, that a binding offer from MSAC would be forthcoming or the proposal would result in any transaction.
Anteris was up 20 cents or 1.2 percent to $17.35.

DORSAVI

Dorsavi says it has International Organization for Standardization (ISO) 27001 certification for data security for its range of wearable sensor devices.
Dorsavi said that the certification allowed the company to provide a high “standard of data privacy in the wearable devices industry”.
The company said that it had previous received ISO 13485 certification for the manufacturing of its wearable sensor devices, for “detailed” motion analysis for use in clinical applications, elite sports and occupational health and safety.
Dorsavi said that with the two ISO certifications, US Food and Drug Administration and Conformité Européenne (CE) mark approvals, “cements the company as an industry leader providing the highest standard of data privacy in the wearable devices industry”.
Dorsavi chief executive officer Dr Andrew Ronchi said that there were “many types of wearable sensors available on the market currently, [but] few are able to deliver the high standard of data privacy required to work with leading global institutions such as Medtronic and Stryker”.
Dorsavi was up 0.1 cents or 4.8 percent to 2.2 cents with 1.4 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it will pay Worldwide Clinical Trials $13.6 million to manage its Xanafx, 75-patient, phase II trial of Xanamem for Fragile X syndrome.

In 2021, Actinogen said that it had a letter-of-intent with the Durham, North Carolina-based Worldwide Clinical Trials for the trial and would pay $944,724 “for start-up activities to enable prompt activation of sites” (BD: Nov 9, 2021).

At that time, the company said it had US Food and Drug Administration approval for its investigational new drug application for the patient phase II trial.

Today, Actinogen said the trial would study cognition, anxiety, sleep and behavioral patterns in male adolescents and young adults who had the full genetic features associated with Fragile X syndrome.

The company said the randomized, placebo-controlled, double-blind, 12-week trial of oral 5mg and 10mg Xanamem would be conducted in North America, Great Britain, Australia and New Zealand, with results expected in 2023.

The company said that Worldwide Clinical Trials had a work order, full-service contract worth $13.6 million, in addition to the $944,724 for start-up activities.

Actinogen managing-director, Dr Steven Gourlay said the company was “pleased to finalize a full-service contract with Worldwide Clinical Trials for the management of our phase II, Fragile X syndrome trial, the scope of which has recently been expanded to include a larger number of participants and with investigative sites across the US, UK and NZ, in addition to Australia”.

“There are currently no treatments approved anywhere in the world for [Fragile X] and the commencement of Actinogen’s key Xanafx trial is another important step in our quest to help make a material difference to the quality of life for people and their families living with [Fragile X],” Dr Gourlay said.

Actinogen was unchanged at 11.5 cents with 3.8 million shares traded.

VGI HEALTH TECHNOLOGY

VGI says Adelaide’s Bellberry has granted ethics approval for an 80-patient, phase II trial of IVB001 for non-alcoholic fatty liver disease and non-alcoholic steato-hepatitis.

VGI said that Brisbane’s Gallipoli Medical Research Foundation would conduct the study along with the Royal Melbourne Hospital and the Newcastle, New South Wales-based John Hunter Hospital, with patient recruitment to begin in March 2022.

The company said subsidiary Invictus Ops would conduct a randomized, double-blind, placebo-controlled, phase II clinical study to analyze the efficacy and safety of IVB001 for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steato-hepatitis (NASH).

VGI said that IVB001 was based on the direct delivery of tocotrienols using its transmucosal delivery platform.

VGI chief scientific officer Dr David Kingston said that the approval was “a very exciting milestone for our … phase II clinical study”.

The company said that if left unchecked the diseases could progress to liver cirrhosis and cancer and there were “no approved treatments for NAFLD/NASH and many drug developments have failed, creating a great unmet need”.

On the National (Newcastle) Stock Exchange, VGI fell seven cents or 28.0 percent to 18 cents with 10,010 shares traded.