Biotech Daily

Wednesday May 26, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: IMMUTEP UP 14%; DIMERIX DOWN 12%**

*** HAVAH $53m T+AI DEAL WITH CLARUS FOR MASTITIS, BREAST CANCER**

*** IMAGION ENROLS 1st PATIENT IN MAGSENSE BREAST CANCER TRIAL**

*** MICRO-X: 2nd US FDA APPROVAL FOR ROVER BEDSIDE X-RAY**

*** EPSILON RECEIVES $1m FEDERAL R&D TAX INCENTIVE**

*** MEMPHASYS NOTES RAISE $3m**

*** AVECHO, TGA TO MEET ON O-T-C SOFT-GEL CBD FOR INSOMNIA**

*** ANTISENSE ATL1102 MANUFACTURED FOR DMD TRIAL**

*** IMMUTEP: CHINA PATENT FOR IMP321, CHEMO COMBINATION**

*** CHINESE, HONG KONG PATENTS FOR ORTHOCELL CELGRO**

*** PALLA APPOINTS GW EXECUTIVE GILES MOSS CEO, ON $536k**

MARKET REPORT

The Australian stock market fell 0.32 percent on Wednesday May 26, 2021, with the ASX200 down 22.7 points to 7,092.5 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell and seven traded unchanged. All three Big Caps fell.

Immutep was the best, up eight cents or 13.6 percent to 67 cents, with 10.1 million shares traded. Patrys climbed 8.3 percent; LBT and Orthocell were up more than seven percent; Uscom rose 6.9 percent; both Antisense and Prescient improved five percent; Proteomics was up 4.8 percent; Imugene was up 3.3 percent; Actinogen, Amplia, Cynata, Next Science and Starpharma rose more than two percent; Opthea and Paradigm were up more than one percent; with Clinuvel, Nanosonics, Pro Medicus and Volpara up by less than one percent.

Dimerix led the falls, down three cents or 12 percent to 22 cents, with 3.4 million shares traded. Optiscan lost 5.2 percent; Cyclopharm, Genetic Signatures and Nova Eye were down more than three percent; Avita, Mesoblast, Pharmaxis and Telix shed more than two percent; CSL, Oncosil, Polynovo and Resmed were down more than one percent; with Cochlear, Kazia and Medical Developments down by less than one percent.

HAVAH THERAPEUTICS

Havah says it has a potentially more than $US41,250,000 ($A52,993,125) deal with Clarus Therapeutics for its T+Ai for inflammatory breast disease and breast cancer.

Havah chief executive officer Kathy Harrison told Biotech Daily that the testosterone combination with the aromatase inhibitor anastrozole was “effectively a slow-release pellet version of testosterone, implanted subcutaneously, without the negative impacts of the testosterone being converted to estradiol”.

Ms Harrison said the combination treatment was being developed for inflammatory breast disease, including inflammatory periductal mastitis and oestrogen receptor-positive (ER+) breast cancer.

In a media release, Adelaide’s Havah said the Northbrook, Illinois-based Clarus would pay $US500,000 on signing, with Havah eligible for up-to $US10.75 million in development and regulatory milestone payments, as well as “a modest royalty and up to $US30 million in potential commercial milestones”.

The company said that it would retain the right to promote T+Ai in Australia, and Clarus would be responsible for future global development and regulatory activities for the combination drug, to be renamed CLAR-121, excluding Australia.

Havah founder Dr Stephen Birrell said the company developed the testosterone and aromatase inhibitor combination “to address a significant unmet need in women’s health, and our partnership with Clarus will enable us to advance this therapeutic approach not only for inflammatory breast disease but, more widely we hope, for ER+ breast cancer where data now unambiguously demonstrates that the androgen receptor has an important tumor suppressor role in this form of breast cancer”.

Ms Harrison said that Clarus “understands and appreciates the potentially profound importance of androgen action in the context of inflammatory breast disease, as well as its role as an adjunctive endocrine therapy for certain forms of breast cancer”.

The company said that that, if approved, CLAR-121 would be the first testosterone treatment of its kind for inflammatory breast disease, including inflammatory periductal mastitis, and oestrogen receptor-positive breast cancer.

Havah said that the initial Clarus clinical development target was inflammatory periductal mastitis “a destructive autoimmune inflammatory process of the retro-areolar milk ducts that results in multiple fistulae and inevitably results in disfiguring surgery and a high risk of recurrence”.

The company said there was no known treatment for the condition apart from surgery, which had significant limitations, and due to its low prevalence in the US, could qualify for orphan drug designation by the US Food and Drug Administration.

Havah said it had implanted CLAR-121 in more than 1,000 Australian women with breast disease, and expected that its pharmaco-kinetics, safety and early efficacy data would expedite progress to phase II/III clinical studies in the US.

The company said that periductal mastitis was worth about $US400 million a year and Clarus might also pursue indications in ER+ breast cancer, macromastia, granulomatous mastitis, and autoimmune induced breast pain.

Clarus founder Dr Robert Dudley said that CLAR-121 “allows us to leverage our expertise in androgen biology, as exemplified by Jatenzo, a testosterone replacement therapy for male hypogonadism and Clarus’s first commercial product, and expands our development pipeline with an initial focus on [periductal mastitis] in women”.

Havah said that Reedland Capital Partners, acting through Weild & Co was its financial advisor for the transaction.

Havah is a private company.

IMAGION BIOSYSTEMS

Imagion says it has enrolled the first of about 15-patients in its phase I Magsense human epidermal growth factor receptor-2 (HER2) breast cancer first in-human trial.

Imagion said the study would investigate the use of its Magsense imaging agent as an aid in the staging of HER2 positive breast cancer by detecting if the tumor had spread to the lymph nodes.

The company said the current standard-of-care was biopsy or the surgical removal of lymph nodes to confirm metastases.

Imagion previously said Magsense used nanoparticles coated with tumor-targeting antibodies to tag cancer and sensors to detect the particles by magnetic resonance imaging (BD: Jun 22, 2020).

Today, Imagion said the study's primary endpoint was to determine the safety and tolerability of the Magsense imaging agent and explore effectiveness of the nanoparticles for detection to inform further development and commercial considerations.

Imagion executive chair Bob Proulx said the company was "very pleased to report our first patient has been enrolled in this ground-breaking study".

"Though recruiting newly-diagnosed cancer patients into a research study can be challenging, we and our investigators remain confident we will reach our recruitment target," Mr Proulx said.

Imagion was up 3.6 cents or 38.3 percent to 13 cents with 74.4 million shares traded.

MICRO-X

Micro-X says it has US Food and Drug Administration 510(k) clearance for a Varex flat panel detector and software for its Rover x-ray systems, expanding its potential market.

Last year, the FDA approved its Rover mobile medical x-ray, with a Fuji Film detector, which would be marketed for military medical facilities (BD: Jul 20, 2020).

Today, the company said it had sourced a new digital flat panel detector for its Rover medical bedside imaging x-ray unit from the Salt Lake City, Utah-based Varex Imaging Corp, which could be sold to any US healthcare facility.

Micro-X said its submission for the Rover bedside imaging with the new detector and software was approved within14 days.

The company said that it could sell the system under its own brand and had distribution agreements in the US and Europe, including with a company which specialized in sales to the US Department of Defense-owned Veterans Affairs hospital network.

Micro-X managing director Peter Rowland said the approval was "a huge step forward for Micro-X now to have its own branded, wholly-controlled, entire x-ray imaging system and now FDA approval to sell this in the US."

"Since we ended the exclusivity of our distribution relationship with Carestream Health, we now have the freedom to offer this new version of the Rover product globally and this complete imaging package moves us higher up the value chain," Mr Rowland said.

Micro-X was up two cents or 6.25 percent to 34 cents with 2.1 million shares traded.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS COMPANY)

Epsilon says it has received $1,021,203 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Epsilon said the rebate related to research and development expenditure for the year to June 30, 2020.

Epsilon was up half a cent or 3.3 percent to 15.5 cents.

MEMPHASYS

Memphasys says it has raised $3 million from its two largest shareholders through the issue of convertible notes.
Memphasys said that Peters Investments invested $1.65 million and non-executive director Andrew Goodall invested $1.35 million to the company.
The company said funds would be used to complete verification and validation program of its updated Felix sperm separation device, and progressing a range of products being developed with the University of Newcastle.
Memphasys said Canaccord Genuity was the lead manager and broker, and would receive a gross two percent fee, two percent of the convertible notes subscribed for by Peters Investments when issued and a further two percent fee on the conversion of the convertible notes by Peters Investments.
The company said that subject to shareholder approval, it would issue one unlisted option for every dollar of convertible notes subscriber for Peters Investments and Andrew Goodall exercisable at six cents by December 31, 2023.
Memphasys was up 1.2 cents or 23.1 percent to 6.4 cents with 9.1 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says it has a pre-submission meeting with the Australian Therapeutic Goods Administration for its over-the-counter soft-gel cannabidiol product for insomnia.
Avecho chief executive officer Dr Paul Gavin told Biotech Daily that the company expected to file its submission pack to the TGA in June and “hope to have the meeting shortly after”.
In its media release to the ASX, the company said the meeting was to examine the proposed indication and appropriateness of its clinical program for product registration of its pharmaceutical soft-gel cannabidiol product as a Schedule 3 “pharmacist only” drug in Australia.
Avecho said it would address design aspects of a pivotal phase III trial and safety information related to cannabidiol and its soft gel product.
Avecho said its soft-gel product contained 75mg of cannabidiol per capsule, which was below the 150mg maximal daily dose requirement under the Schedule 3 registration, allowing daily dosing of once or twice.
The company said it had appointed the Melbourne-based Cannvalate to prepare for the pre-submission meeting.
Avecho said its product development strategy would be refined after the meeting and submitted to the market by October, 2021.
Avecho was up 0.1 cents or 6.7 percent to 1.6 cents with 3.4 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says manufacture has been completed of ATL1102 for the planned phase IIb trial in non-ambulant Duchenne muscular dystrophy patients.
Antisense said ATL1102 was being manufactured by the Cincinatti, Ohio-based contract manufacturing organization, Nitto Denko Avecio, and on completion was sent to the Costa Messa, California-based Pyramid Laboratories for formulation into an injectable product.
Antisense chief executive officer Mark Diamond said the company was “very pleased” with the manufacture of clinical supplies “particularly given the challenges that have presented to all [contract manufacturing organizations] during the global covid pandemic”.
Antisense was up one cent or five percent to 21 cents with 2.2 million shares traded.

IMMUTEP

Immutep says the China has granted a patent for a combination therapy of immunotherapy candidate, eftilagimod alpha, or IMP321, and a chemotherapy agent.
Immutep said that the patent, titled 'Combined Preparations for the Treatment of Cancer', would protect its intellectual property until December 19, 2034.
The company said eftilagimod alpha was a soluble lymphocyte-activation gene 3 (LAG-3) fusion protein, the chemotherapy agents used were oxaliplatin, carboplatin, or topotecan and corresponding patents had been granted in Europe, Australia, Japan and the US.
Immutep was up eight cents or 13.6 percent to 67 cents with 10.1 million shares traded.

ORTHOCELL

Orthocell says it has been granted Chinese and Hong Kong patents for its Celgro collagen rope to augment anterior cruciate ligament repair surgeries.
Orthocell said the patents, titled 'Collagen Construct and Method for Producing the Collagen Construct' would provide additional intellectual property protection for the Celgro platform for soft tissue regeneration and repair applications until October 12, 2035.
The company previously said that Celgro was a customizable collagen medical device "with numerous competitive advantages over existing synthetic and biologic tissue repair devices, particularly in the areas of cell compatibility, tensile strength and the promotion of quality tissue in growth and repair" (BD: Nov 2, 2018).
Orthocell said its Celgro Rope made from braided collagen fibres was an alternative to harvesting tendons from patients for repair of anterior cruciate ligament injuries.
The company said that pre-clinical results of Celgro collagen rope indicated that it had "superior bio-mechanical properties and [was] capable of replacing hamstring grafts for [anterior cruciate ligament] reconstruction".
Orthocell was up 3.5 cents or 7.1 percent to 53 cents.

PALLA PHARMA

Palla says it has appointed Giles Moss as its chief executive officer, effective from September 1, 2021, starting on GBP295,000 ($A536,244).
Palla said Mr Moss had more than 30 years of experience in the pharmaceutical industry and was currently GW Pharmaceuticals Europe general-manager and was "central to the rapid successful" launch of its marijuana product for epilepsy.
The company said that Mr Moss was previously an executive with Bristol Myers Squibb, Sandoz and Smithkline Beecham.
Palla said Mr Moss held a Bachelor of Science from Manchester University and a Master of Business Administration from England's Henley Management College.
The company said that Mr Moss would be entitled to up to 75 percent of his pro-rata base salary, pending milestones and would be issued 8,095,669 "share appreciation rights" pending longevity and share price vesting conditions.
Palla was up 6.5 cents or 18.1 percent to 42.5 cents.