Biotech Daily

Monday February 14, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: AMPLIA, ANTISENSE UP 3%**
- IMUGENE DOWN 9.5%

*** CSL SHARE PLAN RAISES $750m; TOTAL $7.05b**

*** OPTHEA: 'PCV SUBSET BENEFITS FROM OPT-302'**

*** CLINUVEL HEALTHY ADULT AFAMELANOTIDE FOR DNA REPAIR TRIAL**

*** CARDIEX: ANDWIN $1.3m ATCOR XCEL TRIAL FOR PHILIP MORRIS**

*** RESAPP: HEALTH TEAMS TO TAKE RESAPPDX TO AGED CARE**

*** BIOME RELEASES FULL RESULTS OF PROBIOTICS ACNE TRIAL**

*** INVICTUS TO RAISE $2.3m TO DEMERGE FROM VGI**

*** AMPLIA UNMARKETABLE PARCEL FACILITY**

*** ADAM LEITZES, KARST PEAK TAKE 12.3% OF PHARMAXIS**

*** FIL BELOW 5% IN TELIX**

*** BCAL RELEASES 21m ASX ESCROW SHARES**

MARKET REPORT

The Australian stock market was up 0.37 percent on Monday February 14, 2022, with the ASX200 up 26.6 points to 7,243.9 points. Just three of the Biotech Daily Top 40 stocks were up, 31 fell, five traded unchanged and one was untraded.

Amplia and Antisense were the best, both up 0.5 cents or three percent to 17 cents, with 31,173 shares and 181,324 shares traded, respectively. Clinuvel and Resmed climbed by less than one percent.

Imugene led the falls, down three cents or 9.5 percent to 28.5 cents, with 41.4 million shares traded. Actinogen lost eight percent; Atomo, Patrys and Prescient retreated more than seven percent; Genetic Signatures lost 6.5 percent; Compumedics, Immutep, Impedimed and Neuren were down more than five percent; Alcidion, Emvision, Opthea, Paradigm, Telix and Volpara fell more than four percent; Pharmaxis was down three percent; Avita, CSL, Cynata, Medical Developments, Micro-X, Oncosil and Polynovo shed two percent or more; Kazia, Mesoblast, Nanosonics and Orthocell were down more than one percent; with Cochlear, Next Science, Pro Medicus, Proteomics and Starpharma down by less than one percent.

CSL

CSL says it had applications for $942,675,000 in shares in its $750 million share purchase plan at $253.57 a share.
Last year, CSL said it raised $6.3 billion at $273.00 a share and hoped a share plan would raise $750 million to acquire Vifor Pharma for $US12.3 billion (BD: Dec 14, 2021).
The company said at that time that the share plan would be priced at two percent discount to the five-day volume weighted average price to the closing date of February 7, 2022.
Today, CSL said that having exceeded the $750 million maximum the share plan applications would be scaled-back.
CSL fell $4.94 or 1.99 percent to $243.56 with 1.1 million shares traded.

OPTHEA

Opthea says a specific subset of patients in its 366-patient, phase IIb, trial of OPT-302 with Lucentis for wet age-related macular degeneration benefitted from the combination.
Opthea said that a 66-patient cohort with polypoidal choroidal vasculopathy had an average 6.7 letter benefit when given the 2mg OPT302 combination therapy over ranibizumab (Lucentis) at week-24 ($p = 0.0253$).
The company said the sub-sector study showed a greater improvement in secondary vision and anatomical outcome measures and the OPT-302 combination therapy had a "safety profile consistent with standard-of-care" anti-vascular endothelial growth factor-A (VEGF-A) monotherapy while demonstrating greater improvements in best-corrected visual acuity and less retinal fluid compared to ranibizumab monotherapy.
In 2019, Opthea said its 366-patient, phase IIb trial of OPT-302 vascular endothelial growth factor receptor 3 (VEGF-3) for wet age-related macular degeneration (AMD) met its primary endpoints with statistical significance ($p = 0.0107$) (BD: Aug 7, 2019).
Today, the company said the data was presented at the University of Miami Bascom Palmer Eye Institute Angiogenesis, Exudation and Degeneration conference by Prof Gemmy Cheung, titled 'OPT-302 Combination Therapy with Ranibizumab for Treatment of polypoidal choroidal vasculopathy' on February 12, 2022.
Opthea said that Prof Cheung was the head of the Medical Retina Department at the Singapore Eye Research Institute.
Opthea chief executive officer Dr Megan Baldwin said that the data built "on our previous work to demonstrate the far-reaching potential of OPT-302".
"Polypoidal choroidal vasculopathy is a subtype of AMD that is particularly prevalent among Asian populations and demonstrates variable response to anti-VEGF-A therapy," Dr Baldwin said.
"As one of the most common forms of wet AMD globally, we are excited by the results in [polypoidal choroidal vasculopathy] patients that further demonstrate the potential of OPT-302 to be a truly differentiated treatment option that, when used in combination, may offer patients improved vision outcomes over standard of care anti-VEGF-A monotherapy," Dr Baldwin said.
"These promising results demonstrate that patients receiving OPT-302 combination therapy showed meaningful improvements in vision over those receiving monotherapy," Prof Cheung said.
"This analysis further supports the potential added value of OPT-302 combination therapy for patients with wet AMD," Prof Cheung said.
Dr Baldwin said the ongoing phase III Shore and Coast trials were expected to enrol a number of treatment naïve patients with polypoidal choroidal vasculopathy.
Opthea fell five cents or 4.5 percent to $1.055 with 974,900 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has dosed the first of up-to 10-healthy adults in a mechanistic study of 16mg afamelanotide for DNA repair.

Clinuvel said the study at an unnamed photo-dermatology unit would expose the adult disease-free subjects to afamelanotide, to quantify whether the treatment can reduce DNA photo-products and increase DNA regeneration.

Clinuvel's head of clinical operations Dr Pilar Bilbao said that 16mg afamelanotide had been "shown to be effective as a systemic photo-protective agent and we are now expanding the use of the molecule in patients at highest risk of skin cancers, the [xeroderma pigmentosum] group".

"This current study is part of our overall DNA repair program to determine the mechanisms of our drug's effects in [ultra-violet]-damage prone subjects, and provides a parallel protocol to the ongoing CUV156 study in [xeroderma pigmentosum C] patients," Dr Bilbao said.

Clinuvel said that the trial, known as the CUV151 study, would evaluate the oxidative damage caused by UV radiation and focus on the potency of the drug in reduction and extent of regeneration of cellular DNA damage.

In 2021, the company said it dosed the first of up-to six xeroderma pigmentosum patients with afamelanotide in its CUV156 DNA repair program pilot study (BD: Oct 22, 2021).

Clinuvel previously said it had Australian Therapeutic Goods Administration, US Food and Drug Administration and EU approvals for sub-cutaneous, slow-release Scenesse, or 16mg afamelanotide, for erythropoietic protoporphyria (BD: Oct 27, 2020).

Today, the company said that the reduction of DNA damage caused by ultraviolet and solar exposure was relevant for both patients and individuals, who were at high risk of contracting skin cancer.

Clinuvel head of scientific affairs Dr Tim Zhou said that data from CUV151 will give us insights into afamelanotide's ability to safely protect skin from light, and restore DNA which has incurred damage from solar exposure".

"The findings of this study assist us to address much broader audiences using our expertise in melano-cortins and other technologies," Dr Zhou said.

"Up to two billion individuals worldwide have deficient DNA repair mechanisms of the skin,' Dr Zhou said.

"Our DNA repair program focuses on understanding and quantifying the role of afamelanotide as an interventional therapy to help those individuals who are at greatest risk," Dr Zhou said.

Clinuvel said that "if left unrepaired, DNA photo-products may cause mutations, leading to skin cancer, and premature ageing, or photo-aging".

The company said the human body had limited capacity, under normal conditions, to eliminate photo-products through processes known as nucleotide excision repair and base excision repair, where the damage was removed and replaced to restore the DNA helix.

Clinuvel said that "due to inherited genetic defects however many individuals have deficient DNA repair mechanisms, increasing their risk of long-term damage, and skin cancer".

"Particularly, [xeroderma pigmentosum] patients belong to a group known to have the highest rate of skin cancer, due to a deficiency in the [nucleotide excision repair] mechanism," the company said.

Clinuvel said that afamelanotide had been shown to reduce photo-products, and research demonstrated the ability of afamelanotide and other melano-cortin molecules to assist skin cells in DNA repair mechanisms as well as protecting skin from ultra-violet light damage.

Clinuvel was up two cents or 0.1 percent to $23.06 with 81,608 shares traded.

CARDIEX

Cardiex says that a trial, sponsored by cigarette and tobacco manufacturer, Philip Morris will pay $1.3 million for its Atcor Xcel devices and data management services.
Cardiex said the Simi Valley, California-based Andwin Scientific and the Morrisville North Carolina-based Syneos Health would conduct the 19-month study across 22 sites.
The company said that the Atcor Xcel devices would be used in multiple endpoints including the "determination of clinically relevant arterial health outcomes based on aortic augmentation index and arterial stiffness, key biomarkers of arterial health that are identified using the Atcor Xcel device".
Cardiex said Andwin would provide the equipment for the trial and had issued its first order for the lease of Atcor Xcel devices and the provision of data management services, and Syneos had been appointed as the clinical research organization for the trial.
Cardiex said that the majority of revenue would be paid in the year to June 30, 2022.
Cardiex was up 0.1 cents or 2.3 percent to 4.5 cents with 1.1 million shares traded.

RESAPP HEALTH

Resapp says that it has a two-year agreement with the Sydney-based Health Teams to distribute its Resappdx respiratory diagnostic to the aged care sector.
Resapp said that Health Teams expected to launch Resappdx on its telehealth platform and for in-room patient consultations by July 2022.
The company said the Resappdx was an "acute respiratory diagnostic test that uses machine-learning technology to analyze signatures in cough sounds to diagnose respiratory disease using a smartphone", and it had Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval.
Health Teams chief executive officer Jonathan Klug said that "as part of our launch of Health Team's new platform, we are bringing the best digital diagnostic tools from around the world to improve the way aged care residents are cared-for".
"We are very excited about Resappdx's high accuracy rates for crucial respiratory diseases such as pneumonia and [chronic obstructive pulmonary disease] exacerbations, which are critical to diagnose early in aged care settings," Mr Klug said.
Resapp managing-director Dr Tony Keating said that the deal "strategically positions us in the growing market of remote patient monitoring in aged care which is recognized as a key driver in improving quality of life for aged care residents".
The company said the quantum of revenue was dependent on market penetration.
Resapp was up half a cent or 7.1 percent to 7.5 cents with 2.9 million shares traded.

BIOME AUSTRALIA

Biome has released a supplementary announcement detailing the complete clinical trial of multiple probiotics for acne.
Last week, Biome said that 55-subject trial, as a subset of a 114-patient trial, showed that its probiotic significantly reduces acne better than placebo (BD: Feb 9, 2022).
At that time, the company provided details for a journal article studying three active arms versus a placebo arm and said its probiotics had a 38.89 percent reduction in acne at eight weeks compared to the placebo group's 10.00 percent reduction ($p < 0.05$).
Today, Biome provided all of the results showing that a different group of probiotics reduced acne by 56.67 percent at eight weeks ($p < 0.05$).
The full information was included in an annexure to today's announcement.
Biome was up 0.1 cents or one percent to 9.8 cents.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE, INVICTUS BIOPHARMA)

VGI says Invictus will raise $2,300,000 to demerge from the National (Newcastle) Stock Exchange-listed entity with VGI retaining 20 percent of the unlisted company.

In June 2020, the then Azure said it had acquired Invictus Biopharma and appointed Lou Panaccio as chair, Dr Glenn Tong chief executive officer and Dr David Kingston chief scientific officer and hoped to raise $10 million to buy Invictus for its tocotrienols food additive, supplements and pharmaceuticals business (BD: Feb 5; Jun 11, 2020).

In April, the company said the $10 million capital raising failed to comply with the ASX Listing Rule 1.1 Condition 8 which stated that a company must have “300 shareholders holding a parcel of shares with a value of at least $2,000”, and would return the funds and withdraw its application for reinstatement (BD: Apr 28, 2020).

In 2021, Azure listed on the National Stock Exchange under the code VTL having raised $2,497,000, with the VGI Group investing $2,250,000 for the company’s tocotrienol-based assets, changed its name “in recognition of the importance of the VGI Group becoming a substantial shareholder” (BD: Apr 20, May 28, Jul 14, 2021).

Today, VGI said it would sell its wholly-owned subsidiary, Invictus Biopharma Pty Ltd Group to Invictus Biopharma Holdings Ltd, a company founded by VGI managing-director Dr Glenn Tong, chief scientific officer Dr David Kingston and head of its US subsidiary Richard Estalella.

VGI said the term sheet included a $2.3 million payment from Invictus to VGI and the issue of 20 percent of Invictus shares to VGI, with VGI having the first right of refusal to participate in any future capital raisings on a pro rata basis.

The company said that Invictus would own the patent rights to the “Transmucosal Delivery of Tocotrienols” patent estates and the licenced patent rights from Monash University for tocotrienol prodrugs.

VGI said that Invictus would grant VGI “an exclusive perpetual global licence to manufacture, market and sell [food additive] products based on the Invictus Group’s intellectual property rights, with a royalty payable of 10 percent of net profit after tax”.

The company said that Invictus would grant VGI “an exclusive perpetual licence to manufacture, market and sell pharmaceutical products based on the Invictus Group’s intellectual property rights in the Peoples Republic of China with a royalty payable of 10 percent of net profit after tax”.

VGI said the completion of the sale was subject to shareholder approval and was expected to be completed on May 10, 2022.

The company said it would manufacture, market and sell the food additive products including NE1-Elite and NE1-Heart.

VGI said that Dr Tong and Dr Kingston would resign from VGI with director Steven Yu appointed managing-director and Mr Estalella appointed an advisor in relation to the commercialization of products, particularly in the Americas, Japan and the EU.

The company said that Dr Tong would return to his role as executive chair of Invicturs and Dr Kingston would be the company’s chief medical officer and chair the scientific advisory board, with Mr Estalella to be an executive director and head of corporate affairs.

VGI said it had “received a clear message from investors that [its] combination of both a human consumer health business and a drug development business is difficult for most investors to understand”.

The company said other investors did support the combination but it was “seldom that both these groups of investors intersect”.

VGI said that drug development was “more suitable for listing on a stock exchange which caters better for capital-intensive, high growth companies in the biotechnology sector”.

On the NSX, VGI was untraded at 18 cents.

AMPLIA THERAPEUTICS

Amplia says it has established a facility for holders of unmarketable parcels of shares worth less than $500 on February 11, 2022.
Amplia said that the facility for holders of 3,030 shares or less was based on 16.5 cents a share at the record date of February 11, 2022.
The company said that the facility would allow shareholders to sell shares without brokerage or handling costs and allow it to reduce administrative costs.
Amplia said that the closing date for the facility would be at 5pm on April 4, 2022.
Amplia was up half a cent or three percent to 17 cents.

PHARMAXIS

Adam Leitzes and Karst Peak Capital, say they have increased their substantial shareholding in Pharmaxis from 50,996,207 (11.27%) to 67,447,130 (12.28%).
The Hong Kong-based Karst Peak Capital said that from June 30, 2021 to February 4, 2022, it bought the shares at a range of prices, with the single largest purchase on November 11, 2021 of 6,302,312 shares for $661,743 or 10.50 cents a share.
Last November, Pharmaxis said its oversubscribed placement raised $7.42 million at 10.5 cents a share and it hoped to raise a further $2 million through a share plan at the same price (BD: Nov 17, 2021).
Pharmaxis fell 0.3 cents or three percent to 9.7 cents.

TELIX PHARMACEUTICALS

FIL (Fidelity) Investment says it has ceased its substantial shareholding in Telix, reducing to 14,136,207 shares or 4.59 percent.
The Hong Kong and Surrey, UK-based FIL said that from November 15, 2021 to February 9, 2022 it sold 2,791,780 shares at prices ranging from $6.2936 a share to $8.6195 a share.
Telix fell 26 cents or 4.1 percent to $6.10 with 1.3 million shares traded.

BCAL DIAGNOSTICS

Bcal says it will release 20,596,692 shares from ASX escrow on February 20, 2022.
According to its most recent filing, the company would have 152,168,754 shares available for trading following the release from ASX escrow, with a further 54,752,379 shares remaining in ASX escrow until July 21, 2023.
Bcal fell 1.5 cents or 10.3 percent to 13 cents.