



Biotech Daily

Tuesday April 16, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: IMPEDIMED UP 6%; AMPLIA DOWN 18%**
- * **AMPLIA UNDERWRITTEN RETAIL RIGHTS FOR \$4.3m**
- * **IMUGENE TO SELL US PLANT TO KINCELL FOR \$9.4m**
- * **CORRECTION: MONASH UNIVERSITY, SEAPORT**
- * **IDT 'UP-TO \$3.5m TO MANUFACTURE SANOFI mRNA'**
- * **TELIX: FDA FAST-TRACKS TLX101-CDX FOR GLIOMA IMAGING**
- * **NEXT SCIENCE XPERIENCE 'REDUCES KNEE ARTHROPLASTY INFECTION'**
- * **ISLAND: 'SINGLE ISLA-101 DOSE MEETS REQUIRED BLOOD CONCENTRATION'**
- * **DORSAVI 'NATURAL MOVEMENT ALGORITHM' FOR AGED CARE**
- * **ONCOSIL TREATS 1st TÜRKIYE PANCREATIC CANCER PATIENT**
- * **RECCE MANUFACTURES 5k R327 DOSES FOR TRIALS**
- * **TM VENTURES DILUTED TO 6% OF CLARITY**
- * **PLATINUM REDUCES TO 18% OF SYNTARA**
- * **MICROBA OPENS INVESTOR HUB**

MARKET REPORT

The Australian stock market was down 1.81 percent on Tuesday April 16, 2024, with the ASX200 down 140.0 points to 7,612.5 points. Just six of the Biotech Daily Top 40 stocks were up, 24 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Impedimed was the best, up 0.5 cents or 5.6 percent to 9.4 cents, with 3.5 million shares traded. Cynata climbed five percent; Starpharma was up 3.85 percent; Clarity rose 2.3 percent; Paradigm was up 1.8 percent; with Genetic Signatures up by 0.7 percent.

Amplia led the falls, down 1.5 cents or 17.65 percent to seven cents, with one million shares traded. Actinogen lost 12.1 percent; Imugene shed 8.8 percent; Mesoblast was down 7.2 percent; Polynovo lost 6.5 percent; Avita and Universal Biosensors were down more than five percent; Emvision, Medical Developments, Neuren, Opthea and Pro Medicus fell more than four percent; Atomo, Dimerix, Nanosonics, Nova Eye, Percheron and Prescient were down more than three percent; Orthocell and Proteomics shed more than two percent; 4D Medical, Cochlear, CSL and Telix were down more than one percent; with Clinuvel, Resmed and SDI down by less than one percent.

AMPLIA THERAPEUTICS

Amplia says it expects to raise \$4.27 million at 5.5 cents a share in a two-for-five, fully-underwritten, non-accelerated, non-renounceable retail entitlement offer.

Amplia said the issue price was a 29.6 percent discount to the 15-day volume weighted average price up-to April 11, 2024, or a 35.3 percent discount to the last closing price.

The company said the funds would be used for an interim analysis of its phase IIa trial of narmafotinib, or AMP945, for pancreatic cancer, manufacture of an additional 25,000 capsules of narmafotinib and to support an investigator-led ovarian cancer trial.

Amplia said the offer was fully-underwritten by lead manager Taylor Collison, with director Dr Robert Peach committing \$150,000 as a sub-underwriter.

The company said managing-director Dr Chris Burns intended to take-up about \$33,400 of the offer, with director Jane Bell expected to take-up about \$44,600.

Amplia said the offer had a record date of April 19, would open on April 24 and close on May 8, 2024.

Amplia fell 1.5 cents or 17.65 percent to seven cents with one million shares traded.

IMUGENE

Imugene says it will sell its Durham, North Carolina manufacturing facility to the Gainesville, Florida-based Kincell Bio LLC for up-to \$US6 million (\$A9.35 million).

Imugene said under a manufacturing and process development partnership agreement, Kincell would acquire its cell therapy manufacturing plant and continue to manufacture the company's 'azer-cel' to support its clinical trials.

The company said it would transfer the process and analytical development of the technology to Kincell to "support progress and method optimization for commercial readiness".

Imugene said it would receive the payment through up-front and milestone-driven payments and that the sale of the 32,800 square-foot (3,048.2 square metre) facility would reduce its staff costs by 50 percent, or about \$US32 million over the next three years.

The company said Kincell intended "to evolve the site capabilities ... to manufacture a broad portfolio of autologous and allogeneic products".

Imugene managing-director Leslie Chong said the company was "delighted to have found a strong partner for the development and manufacturing of our [chimeric antigen receptor T-cell] 'azer-cel' program".

"We are confident that this strategic partnership with Kincell will enable Imugene to reach key upcoming data inflection points and extend the company's cash runway to 2026," Ms Chong said.

"Moreover, this partnership allows us to focus on our key capabilities, namely the development of novel cancer treatments," Ms Chong said.

"With the transaction, we look forward to continuing to work with many of our former manufacturing colleagues in a new relationship as our contract development and manufacturing organization partner," Ms Chong said.

Imugene fell 0.8 cents or 8.8 percent to 8.3 cents with 79.0 million shares traded.

MONASH UNIVERSITY, SEAPORT THERAPEUTICS

Last night's edition incorrectly said Seaport Therapeutics was a Monash University spin-out, when in fact it is a spin-out from Boston's Puretech Health using Monash technology.

The mistake was made by a confused Monday sub-editor, who has been dismissed.

We apologise unreservedly for the error.

IDT AUSTRALIA

IDT says it has an up-to \$3.5 million master service agreement with the Paris-based Sanofi to manufacture messenger (m)RNA-based vaccines for Sanofi's clinical trials. IDT said it would advance the formulation and manufacture mRNA-based vaccines for Sanofi's clinical trials targeting a range of indications to support unmet medical needs. The company said the value of the services to be provided under the initial order was expected to be between about \$3 million to \$3.5 million, excluding costs relating to storage, shipping and any equipment purchase.

IDT said the revenue from the contract would fall under its advanced therapies vertical and that it supported its goal of pursuing "higher-value contracts that require more complex formulation".

The company said it had "one of the few aseptic sterile fill facilities to complete mRNA downstream processing in Asia Pacific".

IDT chief executive officer Paul McDonald said the company was "thrilled to secure an agreement with Sanofi, progressing their groundbreaking science into ... manufacture to deliver mRNA product solutions to unmet medical needs".

IDT was up 1.1 cents or 12.4 percent to 10 cents with 1.7 million shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has granted fast-track designation for Pixclara, or TLX101-CDx, positron emission tomography (PET) for glioma imaging.

Telix said the designation was for the characterization of progressive or recurrent glioma, or brain cancer, using positron emission tomography and would give it an expedited review and closer consultation with the FDA during the review process.

The company said it was in the final stages of preparing its new drug application to the FDA for TLX101-CDx, or 18-fluorine-floretyrosine, for glioma imaging.

Telix said it had an exclusive research collaboration and data licence agreement with the University of California San Francisco, allowing it to offer TLX101-CDX as a commercial product in the US, subject to regulatory approval.

The company said the Los Angeles, California-based Pharmalogic Holdings Corp would manufacture and supply finished doses of TLX101-CDX to the US market.

Telix chief commercial officer Richard Valeix said the "milestones represent significant progress as we bring this investigational product closer to market in the US and commercial launch".

Telix fell 18 cents or 1.4 percent to \$12.73 with 1.4 million shares traded.

NEXT SCIENCE

Next Science says a study of 524 total knee arthroplasty patients shows its Xperience surgical irrigation treatment decreases peri-prosthetic joint infection (PJI) post-surgery.

Next Science said the retrospective study's primary objective was to evaluate the effect of Xperience on surgical site infections in primary total knee arthroplasty.

The company said study had one peri-prosthetic joint infection within 90 days of surgery and the 0.19 percent infection incidence rate showed Xperience efficacy.

Next Science said the study, titled 'Real World Evidence of the Impact of a Novel Surgical Irrigant on Surgical Site Infections in Primary Total Knee Arthroplasty Performed at an Ambulatory Surgery Center' was conducted by Charlotte, North Carolina's Orthocolina and published in the Journal of Surgical Infections, at: <https://bit.ly/3W3Y7pF>.

Next Science was unchanged at 38 cents.

ISLAND PHARMACEUTICALS

Island says its 24-subject, single-ascending dose study of ISLA-101 shows a single dose of the drug achieves the required levels of blood concentration.

Last year, Island said it had dosed the first of 24 volunteers in its single-ascending dose study of its ISLA-101 for mosquito-borne diseases (BD: Nov 24, 2023).

In February, the company said it had completed dosing all three cohorts in the single ascending dose study and the drug was "safe and well tolerated" (BD: Feb 6, 2024).

Today, Island said the data showed that following a single dose, ISLA-101 achieved blood concentrations "demonstrated to be effective against dengue infections".

The company said the concentration of ISLA-101 was expected to increase with multiple days of dosing, which was being examined in the pharmaco-kinetic modelling work.

Island said the data reinforced the drug's safety and tolerability at levels equivalent to up to 10 times the dose given in successful preclinical animal models.

The company said the data would be used to establish an appropriate dosing regimen for its planned phase IIa clinical trial.

Island chief executive officer Dr David Foster said the "pharmacokinetic data reinforces our strong confidence in ISLA-101".

"The data has shown us that even following a single dose, we are achieving blood concentrations that have previously been shown to be effective against dengue fever infections," Dr Foster said. "This is exactly the outcome we hoped for, it provides a critical data-point to underpin our dosing regimen as we prepare for the phase II clinical study, which will include dosing for multiple days."

Island was unchanged at six cents.

DORSAVI

Dorsavi says it has released its artificial intelligence-based "natural movement algorithm" for sensing movements outside normal levels in aged-care facilities.

Dorsavi said the algorithm had been implemented into its wearable sensor portfolio, and used a single sensor to capture and monitor patient movement data.

The company said the algorithm would provide general practitioners and other clinical user with predictive bio-mechanics monitoring suitable for aged-care facilities and potentially post-spinal surgery patient analysis.

Dorsavi said the inclusion of the algorithm was "a significant milestone for the company and builds upon the initial beta testing undergone from October 2022".

In 2022, the company said it had developed "the first beta version of a new sensor application for the assessment of movement quality in patients with various spinal conditions" with Dublin, Ireland's Medtronic, and that testing was underway at a clinical site in the US (BD: Oct 4, 2022).

Today, Dorsavi said it was in early discussions with US healthcare providers to begin implementing the natural movement algorithm into their existing product portfolios.

The company said it aimed to generate greater recurring revenues from the algorithm and increase sales in the aged care market.

Dorsavi chief executive officer Dr Andrew Ronchi said the release of the natural movement algorithm would "drive new commercial applications within the aged care sector domestically and internationally".

"This upgrade is the result of extensive clinical research, and we are proud of our technical team for creating such a unique solution with significant benefits," Dr Ronchi said.

Dorsavi was unchanged at 1.4 cents with 1.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has treated the first patient in Türkiye's Istanbul Memorial Hospital with its radiation device for pancreatic cancer.

Oncosil said the treatment was less than three months after it appointed EDH Nuclear Medicine & Health Services as its distributor in Türkiye.

Oncosil managing-director Nigel Lange said the company was "delighted to see the delivery of another milestone in our strategy to penetrate the large and potentially lucrative European market".

Oncosil was unchanged at 0.7 cents.

RECCE PHARMACEUTICALS

Recce says it has produced 5,000 R327 antibiotic doses for use in its ongoing phase I and phase II trials as well as its expected phase III trial.

Recce said due to the "increased demand of R327 required for the clinical studies" it had transferred its manufacturing clinic to a third-party cleanroom facility and manufactured the doses there, rather than at its Macquarie Park, Sydney facility.

The company said manufacturing 5,000 doses a week was "a significant achievement that provides surplus sample material" for its planned trials.

Recce was up 5.5 cents or 11.1 percent to 55 cents.

CLARITY PHARMACEUTICALS

Sydney's TM Ventures Pty Ltd says its 18,788,460 share-holding in Clarity has been diluted from 7.34 percent to 6.13 percent due to a capital raise.

In March, Clarity said it had raised \$110 million at \$2.55 a share, with an \$11 million retail offer closing on April 19, 2024, to follow (BD: Mar 28, 2024).

Clarity was up six cents or 2.3 percent to \$2.71 with 390,580 shares traded.

SYNTARA

Platinum Investment Management Ltd says it has decreased its substantial holding in Syntara from 229,216,122 shares (19.24%) to 215,860,418 shares (18.08%).

The Sydney-based Platinum said that between April 2 and April 12, 2024 it sold 13,355,704 shares for \$239,504, or 1.8 cents a share.

Syntara was unchanged at 1.7 cents with 3.6 million shares traded.

MICROBA LIFE SCIENCES

Microba says it has opened an "interactive investor hub" to allow shareholders, stakeholders and prospective investors to learn more about its activities.

Microba said the program would allow investors to communicate directly with its leadership team, and invited shareholders and interested parties to join at:

<https://ir.microba.com/welcome>.

Microba was unchanged at 17 cents.