



Biotech Daily

Tuesday September 28, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PARADIGM UP 10%; LBT DOWN 18%**
- * **FEDERAL GOVERNMENT: HOME COVID TESTING FROM NOVEMBER**
- * **MACH7: TRINITY ORDERS \$7.4m SOFTWARE, SERVICES**
- * **TGA ISSUES IDT STERILE LICENCE FOR mRNA PRODUCTION**
- * **IMRICOR TO SELL MIRTLE 12-LEAD ECG SYSTEM**
- * **TEPIX: \$12m FEDERAL R&D TAX INCENTIVE; \$139m OFFSHORE OK**
- * **4D MEDICAL 702k CEO OPTIONS, 50% DIRECTORS PAY POOL HIKE AGM**
- * **ADHERIUM 149m CEO RIGHTS AGM**
- * **SG HISCOCK REDUCES TO 6.6% OF RESONANCE**
- * **LBT APPOINTS BRIAN O'DWYER DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.47 percent on Tuesday September 28, 2021, with the ASX200 down 108.6 points to 7,275.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell and eight traded unchanged. All three Big Caps fell.

Paradigm was the best, up 20 cents or 9.9 percent to \$2.22, with 1.7 million shares traded. Immutep climbed 5.6 percent; Cynata and Orthocell improved more than four percent; Alterity was up 3.3 percent; Amplia, Antisense, Cyclopharm and Kazia rose more than two percent; with Opthea and Proteomics up by more than one percent.

LBT led the falls, down 2.5 cents or 17.9 percent to 11.5 cents, with 2.75 million shares traded. Actinogen and Uscom lost more than seven percent; Dimerix, Pro Medicus and Starpharma were down more than six percent; Polynovo fell 4.3 percent; Clinuvel, Cochlear, CSL, Orthocell, Resmed and Universal Biosensors were down three percent or more; Imugene, Nanosonics and Next Science shed more than two percent; Medical Developments, Mesoblast, Neuren, Nova Eye, Osprey, Telix and Volpara were down one percent or more; with Avita down by 0.6 percent.

FEDERAL GOVERNMENT

The Federal Health Minister Greg Hunt says that home tests for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) will be allowed from November.

"I'm delighted that the TGA has now recommended that home testing will be available from November 1, obviously subject to individual tests being approved as being safe and effective," Mr Hunt said.

In a media conference transcript, Mr Hunt said that home testing would supplement polymerase chain reaction (PCR) testing currently performed by testing clinics.

Mr Hunt said that individual test applications would need to be approved to show the diagnostics are safe and effective, with 33 tests already approved for supervised use and more than 70 expressions of interest.

Last week, the Dr Boreham Crucible tabulated a number of tests that could be used as home tests (BD: Sep 24, 2021).

According to the Australian Therapeutic Goods Administration the only Australian manufactured Sars-Cov-2 point-of-care tests of the 59 currently approved and on the Australian Register of Therapeutic Goods are those made by Atomo and the Melbourne private company Innovation Scientific Pty Ltd.

The TGA website said the Administration would "make a new regulation (Specification) by October 1, 2021 that will allow companies to formally apply for TGA regulatory approval after October 1, to legally supply their self-tests for use at home in Australia after November 1, 2021".

"This ... aligns with the timeframe where it is expected that approximately 70 percent of Australians will be double vaccinated," the TGA said.

"Individual tests will require TGA approval and inclusion in the Australian Register of Therapeutic Goods as for all other testing kits [and] the TGA has already commenced the review of data and information for self-tests for those suppliers who have responded to the registration of interest process," the Administration said.

The TGA said that suppliers and manufacturers of self-tests needed to ensure: that instructions were written so that all consumers could understand them; suppliers had appropriate support such as online videos, a free-phone number, website fact sheets for consumers; usability testing was successful with untrained, unsupervised users; and self-tests perform satisfactorily against variants such as Delta, noting that many tests in the international market were developed prior to the Delta variant becoming predominant.

The TGA said that the appropriate systems needed to be in place, including by State and Territories, to ensure the reliable use of these tests at home occurs at the earliest possible time, including enabling any consumer who had a positive rapid antigen test result was supported to immediately have a confirmatory PCR test at a testing centre.

MACH7 TECHNOLOGIES

Mach7 says the Livonia, Michigan-based Trinity Health has signed a \$7.4 million contract for imaging, diagnostic, and worklist software over seven years.

Mach7 said the contract comprised the supply of its Enterprise imaging platform, Eunity diagnostic viewer, Eunity Enterprise viewer and Universal Worklist software, as well as from fees associated with software support.

The company said the contract was additional to the seven-year contract it signed with Trinity Health last year for the Eunity Enterprise viewer and it would supply Trinity Health with its picture archive communication system software (BD: Nov 13, 2020).

Mach7 said the total value of the contracts with Trinity was \$15.6 million.

Mach7 was up 2.5 cents or 2.5 percent to \$1.02.

IDT AUSTRALIA

IDT says the Australian Therapeutic Goods Administration has issued it a manufacturing sterile licence.

IDT said the extension covered the manufacture for sterile injection and solution forms of therapeutic goods and goods for clinical trials.

The company said the existing licence covered the manufacture of active pharmaceutical ingredients, manufacture testing and release for supply of solid tablets and capsules, testing and release for supply of liquids, powders and granules, inhalation, dry herb and oil products for therapeutic goods for trials and export of inhalation, dry herb and oil products. IDT said the manufacture of sterile dosage form, injections and solution was restricted to aseptic primary filling in vials only and the licence was “likely [to] be further extended once IDT has certainty on product content, in alignment with the company achieving other stages in manufacturing capabilities”.

The company said that pending, product content, it was likely to seek extensions for formulation, modifications to the facility and secondary packaging operations, based on an inspection relating to the technical transfer of products into the facility.

IDT said that the TGA Sterile Licence was the completion of the sterile readiness works under its agreement with the Federal Government (BD: Mar 19, Aug 23, Sep 15, 2021).

IDT was up five cents or 7.9 percent to 68.5 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it will be a non-exclusive distributor for Mirtle Medical’s magnetic resonance imaging (MRI)-compatible 12-lead electrocardiogram (ECG) system.

Imricor did not disclose the value of the contract.

The company said it had worked with the North Andover, Massachusetts-based Mirtle, since October 2017, with 12-lead ECGs important for its interventional cardiac magnetic resonance imaging-guided cardiac ablations, especially for complex arrhythmias such as ventricular tachycardia.

Imricor fell 3.5 cents or 2.9 percent to \$1.19.

TELIX PHARMACEUTICALS

Telix says it has received \$12.1 million from the Australian Tax Office and been approved for up to \$139 million in offshore research and development over seven years.

Telix said the \$12.1 million under the Federal Government Research and Development Tax Incentive program related to activities for the year to December 31, 2020.

The company said the Federal Department of Industry, Science, Energy and Resources approved its application for a tax rebate on eligible overseas research and development activities up to a gross value of about \$139 million from this year to December 31, 2027.

In August, Telix said the Federal Department of Industry, Science, Energy and Resources approved its application for a tax rebate on eligible overseas research and development activities up to a gross value of \$55.2 million over five years (BD: Aug 3, 2021).

Telix chief financial officer Doug Cubbin said that “given the growth in the company’s pipeline, Telix sought an expansion to its advance overseas ... tax finding, complementing our significant investment in Australian [research and development]”.

“These funds enable the company to invest in innovative clinical development programs and research partnerships with leading Australian institutions,” Mr Cubbin said.

Telix fell eight cents or 1.4 percent to \$5.82 with 792,406 shares traded.

4D MEDICAL

4D says shareholders will vote to issue 701,719 options to managing-director Dr Andreas Fouras and to raise the directors' fees pool by 50 percent to \$750,000 a year.

4D said the annual general meeting would vote to issue the options as part of Dr Fouras long term incentive and would be exercisable at \$2.60 each by June 30, 2024.

The company said the meeting would vote to lift the cap on the total pool available for non-executive directors' fees from \$500,000 to \$750,000 saying that it would help "attract and retain non-executive directors of a high calibre ... [and] enable the company to increase the number of non-executive directors, if the board considers it appropriate to do so".

4D said shareholders would also vote on the remuneration report, the re-election of director Dr Robert Figlin, the ratification of the prior issues of shares, and the approval of its tax-exempt employee share plan.

The virtual meeting will be held on October 28, 2021 at 2pm (AEDT), and will be available at: <https://agmlive.link/4DXAGM21>.

4D fell 6.5 cents or 4.4 percent to \$1.405.

ADHERIUM

The Adherium annual general meeting will vote on the prior issue of 148,977,337 'stock appreciation rights' to chief executive Rick Legleiter.

Adherium said the rights were part of the 'variable remuneration' in Mr Legleiter's employment contract, with the first tranche of 69,168,049 rights already vested.

The company said that the balance would vest in three instalments of 26,603,096 rights each, at each of three anniversaries of Mr Legleiter's appointment, and contingent on the share price reaching 3.2 cents, 6.4 cents and 9.6 cents respectively.

The company said it would issue of shares in lieu of director fees for the period April 1 to June 30, 2021 with 1,432,199 shares for chair James Ward-Lilley, 716,100 shares each for directors Bruce McHarrie, William Hunter, Jeremy Curnock Cook and Matthew McNamara, and 382,760 shares for George Baran.

Adherium said shareholders would also vote on the adoption of its remuneration report, the election of Mr Baran as a director, the approval of the 10 percent placement facility and the employee share plans.

The virtual meeting will be held on October 27, 2021, at 9.30am (AEDT), and will be at: https://us06web.zoom.us/webinar/register/WN_ukffpWO9Qu-PnlqGYx7sEQ.

Adherium was up 0.1 cents or 6.7 percent to 1.6 cents with 6.7 million shares traded.

RESONANCE HEALTH

SG Hiscock & Co has reduced its substantial holding in Resonance from 30,889,686 shares (7.67%) to 30,174,065 shares (6.55%).

SG Hiscock did not specify the price received for the sale of shares, as required under the Corporations Act 2001.

Resonance was unchanged at 10 cents.

LBT INNOVATIONS

LBT says it has appointed current Q2 Solutions chief executive Brian O'Dwyer as a non-executive director, effective from October 4, 2021.

LBT said that Mr O'Dwyer had more than 20 years' experience in healthcare and laboratory testing and prior to Q2, worked for Iqvia, Eurofins Scientific and Icon.

The company said Mr O'Dwyer held a Bachelor of Business from Dublin City University.

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