Biotech Daily

Monday April 4, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: TELIX UP 10%; DIMERIX DOWN 6%**

*** TELIX: ILLUCIX PROSTATE CANCER IMAGING US COMMERCIAL LAUNCH**

*** TELIX: FEDERAL $23m FOR COLLABORATIVE MANUFACTURING**

*** BIOTECH DAILY WEBSITE UPGRADE**

*** ALCIDION $2.8m SILVERLINK UK HOSPITAL RENEWALS**

*** MEDADVISOR FINAL SYNEOS PAYMENT FOR ADHERIS; TOTAL $46m**

*** MICRO-X, DMS TO INCLUDE ROVER COMPONENTS**

*** RHYTHM COLOSTAT TRIAL 'MEETS ENDPOINTS'**

*** USCOM, FOXCONN CHINA MANUFACTURING AGREEMENT**

*** RADIOPHARM: UCLA DUNP19 FOR CANCER LICENCE**

*** IQ3 ADMINISTRATORS SEEK EXTENSION DUE TO 'COMPLEXITIES'**

*** ARGENICA: DR LIZ DALLIMORE M-D; DR MEGHAN THOMAS APPOINTED**

*** CLINUVEL APPOINTS PROF ANDREW LIKIERMAN DIRECTOR**

*** INVEX RENEWS DR TOM DUTHY ON $180k**

MARKET REPORT

The Australian stock market was up 0.27 percent on Monday April 4, 2022, with the ASX200 up 19.9 points to 7,513.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 17 fell and seven traded unchanged. All three Big Caps were up.

Telix was best, up 43 cents or 10 percent to $4.70, with 2.3 million shares traded. Neuren climbed 6.6 percent; Alcidion was up five percent; Pharmaxis improved 4.6 percent; Volpara was up 3.45 percent; Avita, Cyclopharm, Immutep, Next Science and Proteomics rose more than two percent; Cochlear, Genetic Signatures, Kazia, Pro Medicus, Starpharma and Uscom were up more than one percent; with CSL, Nanosonics and Resmed up by less than one percent.

Dimerix led the falls, down one cent or 5.7 percent to 16.5 cents, with 1.15 million shares traded. Actinogen, Antisense, Imugene and Oncosil fell four percent or more; Impedimed, Nova Eye, Patrys, Prescient and Resonance were down more than three percent; Micro-X and Paradigm shed more than two percent; Cynata, Opthea and Polynovo were down one percent or more; with Clinuvel and Medical Developments down by less than one percent.

TELIX PHARMACEUTICALS

Telix says its prostate cancer imaging product Illuccix is commercially available in the US from Cardinal Health, Pharmalogic and United Pharmacy Partners pharmacies.

Telix said its prostate imaging product, Illuccix kit for the preparation of 68-gallium, prostate specific membrane antigen-11 injection (68Ga-PSMA-11) had US Food and Drug Administration and Australian Therapeutic Goods Administration approval.

The company said that first doses for positron emission tomography (PET) imaging were being scheduled for April in “key academic centres across the US”.

Telix managing-director Dr Christian Behrenbruch said that “physicians across the United States are now able to order doses and schedule patients for Illuccix scans”.

“This important milestone significantly improves access to PSMA-PET imaging across the US and allows physicians to confidently schedule dose delivery any time of the day, optimizing flexibility and control for patients,” Dr Behrenbruch said.

“With the recent approval in the US of PSMA therapy - and the importance of 68Ga-PSMA-11 for patient selection - it is an exciting time for molecular imaging in [genito-urinary] oncology,” Dr Behrenbruch said.

Telix said that eligible customers could claim reimbursement for Illuccix under the Centres for Medicare and Medicaid Services (CMS), Not Otherwise Classified code with further reimbursement code assignment expected “in the near term”.

Telix was up 43 cents or 10 percent to $4.70 with 2.3 million shares traded.

TELIX PHARMACEUTICALS

Telix says the Federal Government has granted $23 million to it, Global Medical Solutions Australia and Monash University for a manufacturing collaboration.

Telix said the $23 million was part of the $71.2 million Australian Precision Medicine Enterprise (APME) project with partners the Sydney-based Global Medical Solutions Australia and Melbourne’s Monash University to “address the good manufacturing practice manufacturing gap in the Australian radiopharmaceuticals manufacturing sector”.

The company said the funds were intended to help Australian manufacturers scale-up, compete internationally and create jobs and that the finds were for “a small number of large transformational projects”.

Telix said the project would support development and manufacturing of precision medicines, diagnostics and therapeutics for Australia and the Asia Pacific, with business-to-business and business-to-research collaboration at its core.

Telix said APME’s vision was “the fit-out and build of a high energy cyclotron which will be the source of critical radio-isotopes, many of which are currently imported into Australia”.

The company said that as a project partner it would benefit from the increased capacity to develop and manufacture radio-pharmaceuticals in Australia, strengthening its supply chain for both clinical and commercial products.

Telix said that the project partners would contribute $41.2 million over the three-year project period, with $25 million from Global Medical Solutions, $11.2 million from Monash University and $5 million from Telix, subject to the establishment of a formal agreement and receipt of grant funding.

Telix Asia Pacific chief executive officer Dr David Cade said Australia was “a leading innovator in terms of clinical development and isotope supply for nuclear medicine, which was recently included in the Australian Government’s list of critical technologies in the national interest … but there remains a significant need to achieve sovereign isotope and drug product manufacturing capabilities suitable for the future of the industry, both commercially and academically”.

BIOTECH DAILY WEBSITE UPGRADE

The Biotech Daily website has been upgraded and all pages should be fully functional.
For readers using the Back Copies library, this has been renamed The Archive and everything is there – back to May 14, 2008.
If you have book-marked any pages they might need to be refreshed and/or cookies removed.
Any small glitches will be ironed out in the next few days.
If there are any issues, please let us know.
We are deeply grateful to Cristian Rojas at Red Box Communications Design for the changeover – and Dr Glenn Tong for the recommendation – as well as the team at our hosting service Carringbush.net for their excellent work, enabling a smooth transition.
If users of the website don't notice any changes, we have been successful.

David Langsam
Editor

ALCIDION GROUP

Alcidion says it has $2.8 million in renewal agreements with Moorfields Eye Hospital and the Liverpool Heart and Chest Hospital for its Silverlink patient care system.
In December, Alcidion said that Silverlink was "one of the largest and few remaining specialist patient administration system providers servicing the UK [National Health System]" and its Patient Case System was recognized as flexible and cost-effective to full electronic patient records without a single supplier locked-in (BD: Dec 16, 2021)
Today, the company said that the renewal of agreements with London's, Moorfields Eye Hospital and the Liverpool Heart and Chest Hospital had a combined value of $2.8 million over three years and triggered a payment of $2.6 million, 50 percent of the earnout figure agreed during the Silverlink acquisition.
Alcidion managing-director Kate Quirke said that the patient care system "forms a core part of our modular electronic patient record strategy and we value the knowledge and experience that the [patient care system] customers and staff bring to Alcidion in this critical area of patient administration".
"Customers renewing contracts is a sign of commitment and satisfaction with what Alcidion is providing and we are very much looking forward to working with all the Silverlink customers," Ms Quirke said.
Alcidion was up one cent or five percent to 21 cents with 4.8 million shares traded.

MEDADVISOR

Medadvisor says it will pay its final earn-out payment to Syneos Health for the Adheris acquisition, taking the total price of Adheris to $US34.5 million ($A46.0 million).
In November 2020, Medadvisor said it had raised $35 million in a placement and institutional rights offer at 38 cents a share and would complete the acquisition of Adheris Health (BD: Nov 12, 2020).
Today, the company said that it had paid the first earn-out payment in May 2021 and that the top revenue earn-out level of $US32.5 million ($A43.3 million) for the Adheris acquisition was exceeded for the 12 months to December 31, 2021.
Medadvisor said that the Morrisville, North Carolina-based Syneos Health had agreed to defer the second earn-out payment date until September 15, 2022.
Medadvisor was unchanged at 25.5 cents.

MICRO-X

Micro-X says it has a collaboration and supply agreement with DMS Imaging SA to include Rover components in its x-ray products.

Micro-X said the Gallargues-le-Montueux, Southern France-based DMS would produce an "innovative x-ray" product manufactured in DMS Imaging facilities in France, with partial funding from the French government, planned to be released by the end of 2023.

The company said that DMS Imaging would use its Rover lightweight mobile medical x-ray machine's x-ray tube and generator as part of its product development.

Micro-X said that it would have the capability to extend its Rover sales by integrating DMS Imaging's Adam imaging software which used artificial intelligence based post-processing image capabilities and workflow management for image management in x-ray.

Micro-X managing-director Peter Rowland said the company was "very pleased to be collaborating with DMS Imaging as this represents another validation of Micro-X's core, cold cathode x-ray technology by a highly regarded player in the imaging sector".

"We are very confident that DMS Imaging's new products with our x-ray technology will be both competitive and innovative and further advance the market awareness of the benefits [nanotube electronic x-ray] technology can bring," Mr Rowland said.

"We are very confident that DMS Imaging's new products with our x-ray technology will be both competitive and innovative and further advance the market awareness of the benefits NEX technology can bring," Mr Rowland said.

"This collaboration greatly helps Rover's commercialisation as it will create further awareness and broader adoption of the Micro-X technology across the imaging market," Mr Rowland said.

Micro-X did not disclose the financial terms of the agreement.

Micro-X fell half a cent or 2.3 percent to 21.5 cents.

RHYTHM BIOSCIENCES

Rhythm says its 737-patient sample trial for its simple blood test Colostat, for the detection of colorectal cancer has met its primary and secondary endpoints.

Rhythm said that the primary endpoint of the prospective, cross-sectional study was an evaluation of Colostat relative to colonoscopy and resulted in "very high accuracy for the detection of colorectal cancer, recording a sensitivity of 81 percent and a specificity of 91 percent".

The company said that the secondary endpoints were the Colostat performance in detecting advanced adenomas and a comparison against the faecal immunochemical test.

Rhythm said that the trial showed that Colostat was "35 percent more accurate" than the faecal immunochemical test for detecting colorectal cancer and that Colostat was "more accurate … for detecting advanced adenomas".

Rhythm said that Colostat was "not directly related to any adverse events recorded, all of which were classified as minor".

Rhythm managing-director Glenn Gilbert said the company was "extremely pleased with the significant positive outcomes from this study …[which] supports our conviction that Colostat has the potential to transform the way colorectal cancer is detected".

"To achieve such a strong overall performance result and further, the meaningful clinical significance versus the current market standard [faecal immunochemical test] further strengthens Rhythm's position for significant positive outcomes moving forward, both economically and socially," Mr Gilbert said.

The company said it expected to apply for Australian approval by mid-2022.

Rhythm was up 29 cents or 19.7 percent to $1.76 with 1.2 million shares traded.

USCOM

Uscom says the Taipei, Taiwan-based Foxconn will manufacture its Uscom 1A ultra-sonic cardiac output monitor and three new devices in Beijing, China.

Uscom said that Foxconn, through its Beijing subsidiary Futaijing Precision Electronics, would provide a production site, manufacturing facilities, access to a new research and development facility and a manufacturing system that included assembly and regulatory staff to accelerate manufacturing accreditation and China's National Medical Products Administration (NMPA) regulatory approvals.

The company said that the facility was expected to deliver domestically approved and manufactured devices to market in six months.

Uscom said the partnership would "provide scale and capacity for expanded device manufacturing to meet the expected demand from the rapidly growing China market and for export through Uscom's new regional [headquarters] in Singapore".

The company said the manufacturing agreement leveraged invested capital from a previous rights issue in December where its non-renounceable rights issue at 11 cents a share raised $4,359,073 (BD: Dec 15, 2021).

Today, Uscom chair Prof Rob Phillips said that the partnership "solves Uscom's domestic manufacturing challenges while expanding Foxconn's commitment to precision medical technology manufacturing in China".

"Local manufacture is now essential for medical device sales in China and this partnership re-opens the door for Uscom's Chinese sales, particularly as the first task for Foxconn will be for the manufacture of three new specialized products currently undergoing NMPA regulatory assessment for the Chinese market," Prof Phillips said.

"Under the 'Made in China 2025' … national strategic plan giving locally manufactured goods preferentially market support … Uscom is a Chinese Government-designated national high technology enterprise and Foxconn will provide experienced manufacturing staff and facilities as well as [research and development] laboratories for development of new [intellectual property] and new devices in Foxconn's Beijing Technology Industry Zone, nearby to our current Beijing regional headquarters," Prof Phillips said.

Uscom was up 0.1 cents or one percent to 9.9 cents.

IQ3 GROUP

The DVT (de Vries Tayeh) Group says it will seek court orders to extend by three months the time required to sort out the financial affairs of the IQ Group.

DVT said that the administration related to Farmaforce Limited, IQ3Corp Ltd, IQX Limited and The IQ Group Global Ltd

DVT said that "due to the complexities of the financial affairs of the companies, managing the expressions of interest, and the resulting volume of work required, the administrators are of the view that it would be in the best interests of creditors to extend the convening period of all four companies".

The administrators said that the convening period would end on April 7, 2022.

"Accordingly, the administrators intend to apply to the court on Wednesday, April 6, 2022 seeking orders … for an extension of the convening period for all four companies for a period of three months," DVT said.

The administrators said that if any creditor had an objection to the proposed extension, they needed to make contact by 4pm on Tuesday April 5, 2022.

Biotech Daily attempted to contact the administrators, but had no response at the time of publication.

IQ3 was in a suspension and last traded at 12 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has licenced the LRRC15-targeting DUNP19 antibody from the University of California Los Angeles for solid tumors starting with osteo-sarcoma.
Radiopharm said that the DUNP19 monoclonal antibody targeted both the tumor cells and the tumor micro-environment, or stroma and had a “unique ability to effectively find, internalize and destroy both cancer and the [tumor micro-environment] cells.
The company said that current antibodies for cancer treatment omit the tumor micro-environment cells which comprised more than 50 percent of tumor masses”.
Radiopharm said that LRRC15 protein expression was produced by cancer cells and the surrounding tumor micro-environment but not by healthy normal tissue and was highly produced in aggressive and treatment-resistant tumors.
The company said the licence gave it the rights to develop DUNP19 as an antibody-drug conjugate within radiotherapy as part of its clinical development pipeline, it was applicable to a broad range of currently untreatable cancers and it would begin its study with osteo-sarcoma, a of bone cancer that primarily affected children, adolescents and the young adult population with only surgery and chemotherapy as available treatments.
Radiopharm managing-director Riccardo Canevari said that DUNP19 had “demonstrated promise for several indications, but its potential as first-in-class therapy or osteo-sarcoma is particularly exciting, considering the high unmet need in the children and adolescents who typically suffer this disease”.
Radiopharm said that the cost of the agreement was “not material to the company and is allowed for in its existing research budget” but that there were unspecified milestone payments due under the agreement, such as the enrolment of the first patient in a phase II trial of the product as well as a nominal percentage royalty for future sales of products development under the agreement.
The company said that while the agreement allowed it to develop products using DUNP19, UCLA retained ownership of the antibody.
Radiopharm was unchanged at 25 cents.

ARGENICA THERAPEUTICS

Argenica says it has promoted chief executive officer Dr Liz Dallimore to managing director and appointed Dr Meghan Thomas as its head of clinical developments.
Argenica said that Dr Dallimore’s salary excluding superannuation would increase from $220,000 to $250,000 a year.
Argenica was up three cents or 4.55 percent to 69 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it had appointed Prof Andrew Likierman as a non-executive director, effective from today.
Clinuvel said that Prof Likierman was currently a professor of management practice at the London Business School and had previously worked in the UK Cabinet Office, as head of the UK Government Financial Management Service as well as the chief financial officer of the UK Treasury.
The company said that Prof Likierman was previously a director of the Bank of England, the UK National Audit Office, the Tavistock and Portman National Health Services Trust, Times Newspaper Holdings, Monument Bank, Barclays Bank PLC, Beazley PLC, Applied Intellectual Capital PLC and Mori Ltd.
Clinuvel fell five cents or 0.3 percent to $17.89 with 169,312 shares traded.

INVEX THERAPEUTICS

Invex says it has renewed its executive director contract with Dr Tom Duthy, effective from April 1, 2022 and valued at $180,000 a year, excluding GST.

Invex said that Dr Duthy would receive an executive director fee of $50,000 a year as well as consulting fees of $130,000 excluding GST.

The company said that Dr Duthy was not entitled to any short-term incentives, except as incurred in normal operations of the business, but was eligible for long term incentives through participation in the Invex Employee Securities Incentive Plan, subject to shareholder approval as required.

Invex said that Dr Duthy was “primarily responsible for Invex’s corporate activities within Australia, including corporate governance, ASX requirements and investor relations while also providing advice relating to strategy, structuring and corporate development”.

Invex was unchanged at 62 cents.