Biotech Daily

Thursday April 29, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OSPREY UP 12%; PROTEOMICS DOWN 6%**

*** FEDERAL $2.2m FOR QUEENSLAND UNI mRNA VACCINES, CANCER DRUGS**

*** CELLMID TO SELL LYRAMID FOR $500k PLUS ROYALTIES**

*** CANN RECALLS 250 UNITS OF 50ml MARIJUANA OIL**

*** ATOMO, UNITAID, VIATRIS PARTNER FOR LOWER-COST HIV TESTS**

*** PROTEOMICS FILES FDA 513(g) APPLICATIONS FOR PROMARKERD**

*** REGENEUS $300k DEPARTMENT OF DEFENCE GRANT FOR SYGENUS**

*** BARD1 ASSAYS + CA125: HIGHER ACCURACY FOR OVARIAN CANCER**

*** IQ3: ONCOTEX MANUFACTURING DEAL WITH STERLING PHARMA**

*** CANADA PATENT FOR NEUREN TROFINETIDE FOR RETT, AUTISM**

*** MEMPHASYS: 2 US PATENTS FOR FELIX SPERM SEPARATION DEVICE**

*** BIOTRON RECEIVES $1.4m FEDERAL R&D TAX INCENTIVE**

*** UNIVERSAL BIOSENSORS: GRAPEWORKS SENTIA NZ DISTRIBUTOR**

*** MEDIBIO TO MEET FDA FOR MEBSLEEP 510(K) RE-SUBMISSION**

*** AUSTRALIAN SUPER TAKES 5% OF ALCIDION**

*** OVENTUS HAS LESS THAN 2 QUARTERS CASH; STAFF CUTS**

MARKET REPORT

The Australian stock market was up 0.25 percent on Thursday April 29, 2021, with the ASX200 up 17.6 points to 7,082.3 points. Twenty of the Biotech Daily Top 40 stocks were up, 11 fell and nine traded unchanged.

Osprey was the best, up 0.2 cents or 11.8 percent to 1.9 cents, with 7.8 million shares traded. Cyclopharm climbed 6.1 percent; Polynovo was up 4.45 percent; Amplia, Genetic Signatures and Patrys improved more than three percent; Dimerix, Immutep, Imugene and Starpharma rose two percent or more; Actinogen, Avita, Compumedics, Medical Developments, Pro Medicus and Volpara were up one percent or more; with Cochlear, CSL, Opthea, Orthocell, Paradigm and Telix up by less than one percent.

Proteomics led the falls, down 7.5 cents or six percent to $1.18, with 346,436 shares traded. LBT and Universal Biosensors fell more than four percent; Cynata, Neuren, Next Science, Pharmaxis and Uscom lost more than three percent; Oncosil and Optiscan shed more than one percent; with Mesoblast and Resmed down by less than one percent.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has $2.2 million in matched funding to research messenger ribonucleic acid (mRNA) vaccines and cancer therapies.

Last week, the Victoria Government said it would invest $50 million for mRNA manufacturing technology and research, noting that mRNA vaccines were “a promising alternative to traditional vaccines because of their high efficacy, capacity for rapid development, low-cost manufacture and safe administration” (BD: Apr 21, 2021).

IDT chief executive officer Dr David Sparling told Biotech Daily today that one of its existing buildings, originally funded by Pfizer for antibiotics, “potentially can be redeployed for mRNA vaccine manufacture”.

Today, the University of Queensland said the $2.2 million from the National Collaborative Research Infrastructure Strategy through Therapeutic Innovation Australia would be directed to its Australian Institute for Bioengineering and Nanotechology (AIBN).

The University said the AIBN would conduct mRNA research for cancer and vaccines in partnership with its Base facility, which produced high-quality nucleic-acid, or mRNA and DNA, to support academic, translational and industrial research.

The University of Queensland said the mRNA production would begin “within months after receiving backing from the Australian Government”.

Base researcher Dr Timothy Mercer said that the pandemic response had demonstrated that mRNA vaccines could be quickly designed to protect against new variants and other emerging diseases.

“mRNA vaccines have been key in our fight against Covid-19, while other mRNA vaccines are showing great potential in the fight against cancer,” Dr Mercer said.

CELLMID

Cellmid says it will sell its wholly-owned subsidiary Lyramid and midkine antibody assets for $500,000 plus royalties to the Panama-based Provelmare Holding SA.

In 2016, Cellmid said it established Lyramid to commercialize its midkine antibody assets for therapeutic indications in fibrotic diseases and cancer (BD: Apr 8, 2016).

Last year, the company said that royalty and licence fees from its Lyramid midkine division for the year to June 30, 2020 was $1,110,515 (BD: Aug 27, 2020).

In November, Cellmid said its annual general meeting voted on the divestment of Lyramid and its midkine assets with 80.7 percent in favor (BD: Nov 2, 30, 2020).

Today, the company said that overall, the sale of Lyramid would “save close to one million dollars annually by reducing research personnel and relinquishing the financial responsibility for patent filing and maintenance, amongst other costs”.

Cellmid said it would be reimbursed for costs related to midkine research and development between 1 January and April 28, 2021 and receive a 4.0 percent royalty on the net sale of midkine products and an 8.0 percent royalty on net sub-licencing revenue.

The company said Lyramid would be sold “as a going concern with its operations intact including research and development collaborations, commercial agreements, employees and physical assets critical to the successful development of the midkine program”.

Cellmid said that chief scientific officer Prof Graham Robertson would continue in his role following the sale.

The company said a service agreement between Lyramid and Cellmid would be signed to provide continuity and ongoing support.

Cellmid chief executive officer Maria Halasz told Biotech Daily that she expected the sale to be finalized “in the next few days”.

Cellmid was up 0.3 cents or 4.6 percent to 6.8 cents.

CANN GROUP

Cann Group says one of its customers has begun a class III recall of 250 units of 50ml medicinal marijuana oil products recently released to the Australian market.
Cann said that a class III recall was “not a safety-related recall and is undertaken where a deficient product is not likely to cause adverse health consequences” and followed “the identification of particulate matter” in a batch of the product by Cann’s manufacturer.
The Company said the deficient products were manufactured by an undisclosed third party using ingredients which included a starting material supplied by another party.
The company said that 11 units had been supplied to patients and the balance of the units were being retained by the customer’s distributor.
Cann said that in line with the Australian Therapeutic Goods Administration processes, the distributor was liaising with the TGA to coordinate the recall.
The company said it was working with its customer, manufacturer and supplier to identify the cause of the issues in relation to these products.
Cann was unchanged at 48 cents with 1.4 million shares traded.

ATOMO DIAGNOSTICS

Atomo says Unitaid and Mylan subsidiary Viatris will expand access to self-administered Mylan HIV tests in 135 low-and-middle income countries.
Atomo said it had designed and manufactured the Mylan HIV Self-Test which would be distributed by the Canonsburg, Pennsylvania-based Viatris, with the cost of the test subsidized by the Geneva, Switzerland-based Unitaid health agency.
The company said the agreement between the companies would reduce the cost of the test to improve access and stimulate demand in 135 countries.
Atomo said the handheld test detected the presence or absence of HIV antibodies in a fingertip blood sample.
The company said the test was pre-qualified by the World Health Organisation and reduced common sources of user error.
Atomo said that the World Health Organisation estimated the international “HIV self-testing market to be 11 million tests in 2021, rising to 29 million tests by 2025”.
The company said that its South Africa-based manufacturing facility would support production for HIV test kits orders made through the agreement.
Atomo was unchanged at 20.5 cents with 1.85 million shares traded.

PROTEOMICS INTERNATIONAL

Proteomics says it filed a US Food and Drug Administration 513(g) application for its Promarkerd diabetic kidney disease test, replacing its pre-submission package.
Earlier this year, Proteomics said it filed a pre-submission package to the FDA for Promarkerd to determine the regulatory path as either de-novo classification or the 510(k) pre-market approval route (BD: Feb 8, 2021).
Today, the company said that the FDA had limited the pre-submission route to urgent applications due to the Covid-19 pandemic and advised Proteomics that it was “unable to conduct an in-depth review” of the Promarkerd pre-submission.
Proteomics said the 513(g) application did not require clinical data, but would allow the company to determine the best regulatory path: either de-novo or 510(k).
The company said it expected the FDA to assess the 513(g) application within 60 days and it planned to submit a full application for Promarkerd by October 2021.
Proteomics fell 7.5 cents or six percent to $1.18.

REGENEUS

Regeneus says the Australia Department of Defence will provide $300,000 for the development of its Sygenus stem cell secretion technology for combat causalities.
Last year, Regeneus said that the Canadian Intellectual Property Office had issued a patent for its Sygenus for acne, as it had been shown to improve the appearance of acne, and was safe and tolerated (BD: Feb 6, 2018; Oct 7, 2020).
Today, the company said it would use the funds to optimize the Sygenus formulation as an analgesic gel for damaged tissue and conduct a first in-human study for pain.
Regeneus director of clinical development Dr Sinéad Blaber said that the "Sygenus technology has a number of attributes that make it suitable for battlefield use".
"Sygenus is based on stem cell secretions rather than the cells themselves; these bioactive secretions are far more stable than cells and can be formulated into a gel that can be carried as part of a soldier's standard kit," Dr Blaber said.
"As well as being a replacement for morphine for treating pain, the gel prevents blistering, reduces scarring and can accelerate wound healing," Dr Blaber said.
Regeneus said the research would be conducted in partnership with Prof Mark Hutchinson at Adelaide University.
Regeneus was up half a cent or four percent to 13 cents.

BARD1 LIFE SCIENCES

Bard1 says its auto-antibody assay kit combined with cancer antigen 125 (CA125) can detect ovarian cancer with 91 percent sensitivity and 50 percent specificity.
In February, Bard1 said that data from 69 samples show that its SubB2M protein technology could detect "all stages of ovarian cancer with 100 percent specificity and 100 percent sensitivity" (BD: Feb 11, 2021).
Today, the company said the antibody test was specifically for "early detection of ovarian cancer in high-risk women with hereditary breast and ovarian cancer syndrome (HBOC), given the importance of high sensitivity in this indication", with work continuing on the SubB2M protein technology.
Bard1 said that Brisbane's Griffith University would evaluate its auto-antibody assay kit alone and in combination with cancer antigen-125 (CA125) to detect ovarian cancer in 241 samples, comprising 160 ovarian cancer patient samples and 81 healthy control samples.
The company said CA125 was a protein highly expressed in ovarian cancer cells which has a "less than 50 percent sensitivity for detection of early-stage ovarian cancer".
Bard1 said the CA125 test was a US Food and Drug Administration 510(k) cleared test for monitoring patients diagnosed with ovarian cancer.
The company said that the Bard1 assay kit, which contained 20 peptides, combined with 70 units/ml of CA125 reduced the number of peptides needed for diagnosis to two and increase sensitivity and specificity compared to either test alone.
Bard1 said that the addition of two peptides increase the CA125 sensitivity from 27 percent to 91 percent.
The company said that the high level of sensitivity obtained by combining the tests was "encouraging for the potential use of this assay for early detection of ovarian cancer in high-risk women with hereditary breast and ovarian cancer syndrome".
Bard1 chief scientific officer Dr Peter French said that "the next step in the development of a reliable Bard1 auto-antibody assay for ovarian cancer is to validate the selected peptides and CA125 in the algorithm identified by this combined data set in a larger independent data set to establish the sensitivity and specificity of the test".
Bard1 was up one cent or 0.3 percent to $3.09 with 1.1 million shares traded.

IQ3 CORP

IQ3 says its partly-owned subsidiary Oncotex Inc has an agreement with Sterling Pharma Solutions for the manufacture of platinum-resistant Oxalitex for cancer.
IQ3 says it held 40.5 percent of the New York-based Oncotex, which was developing the Tex Core oncology drug platform.
The company said that Oncotex's manufacturing agreement with the Deeside, Wales-based Sterling Pharma would produce Oxalitex at the standard required by the US Food and Drug Administration for clinical use.
IQ3 said Oxalitex was the first clinical candidate developed from the Tex Core platform, designed to target platinum-resistant ovarian cancer tumor cells by overcoming issues associated with the current platinum-based standard of care.
The company said that Oxalitex was tumor localizing, well-tolerated, and was magnetic resonance imaging-detectable, allowing clinicians and patients to easily monitor tumor regression during treatment.
IQ3 was untraded at 15 cents.

NEUREN PHARMACEUTICALS

Neuren says the Canadian Intellectual Property Office has issued a patent for its trofinetide for Rett syndrome and autism spectrum disorders.
Neuren said the patent, titled 'Treatment of Autism Spectrum Disorders Using Glycyl-L-2-Methylprolyl-L-Glutamic Acid' would provide intellectual property protection until 2032.
The company said it had been granted patents originating from the same international application in the US, Europe, Japan, Australia, Israel and Canada with an application pending in Brazil.
Neuren fell 4.5 cents or 3.4 percent to $1.29.

MEMPHASYS

Memphasys says the US Patent and Trademark Office has granted two patents relating to the bio-separations technology used in its Felix sperm separation device.
Memphasys said the first patent, titled 'Sperm separation by electrophoresis,' covered a method of using at least one physically cross-linked bio-compatible polymeric membrane in the separation of sperm by electrophoresis, protecting the company's intellectual property until November 20, 2037.
The company said the second patent, titled 'Biocompatible polymeric membranes', covered the use of at least one physically cross-linked bio-compatible polymeric membrane in the separation of one or more macro-molecules and/or cells by electrophoresis, protecting its intellectual property until August 15, 2037.
Memphasys said that it had a total of four US patents, with pending patent applications for the methods used in its Felix device in Australia, Europe, the US and parts of Asia.
Memphasys fell 0.1 cents or 1.5 percent to 6.4 cents.

BIOTRON

Biotron says it has received $1,411,944 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Biotron said the rebate related to research and development expenditure for the year to June 30, 2020.
Biotron fell 0.4 cents or 6.25 percent to six cents with 1.8 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed the Grovetown, Marlborough-based Grapeworks NZ as a distributor of its Sentia wine testing device in New Zealand.
Universal Biosensors said the exclusive, five-year, distribution agreement contained undisclosed initial and minimum yearly purchase volumes, as well as standard renewal and termination options for both parties.
The company said that Grapeworks NZ was a subsidiary of Melbourne's Grapeworks Pty Ltd, the Australian distributor of Sentia (BD: Dec 7, 2020).
Universal Biosensors chief executive officer John Sharman said that Grapeworks was the "exclusive distribution partner for Sentia in Australia, so for them to extend our agreement to cover New Zealand's [more than] 500 wineries demonstrates a strong financial commitment and belief in the future success of Sentia".
Universal Biosensors fell three cents or 4.3 percent to 67 cents.

MEDIBIO

Medibio says it will meet with the US Food and Drug Administration to discuss the re-filing of the 510(k) application for its Mebsleep sleep stage identification software.
Last year, Medibio said the FDA had denied breakthrough device designation for its MEB-001 heart rate-based depression diagnostic software, which used Mebsleep algorithms, and suggested that further clinical data would be required for 510(k) application approval of the Mebsleep software (BD: Dec 4, 2020; Jan 17, 2021).
Today, the company said it had commissioned an independent review of Mebsleep and had designed a new prospective, multi-centre clinical trial to address the FDA issues raised and to inform its new 510(k) application.
Medibio said the meeting was scheduled for July 1, 2021 and would discuss aspects of the new trial.
The company said it expected the trial to be completed, and the new application submitted, within six to eight weeks from commencement.
Medibio was up 0.1 cents or 14.3 percent to 0.8 cents with 11.7 million shares traded.

OVENTUS MEDICAL

Oventus says receipts from customers for the three months to March 31, 2021 were up 309 percent to $319,000 and it has less than two quarters of cash.
In its Appendix 4C, Oventus said it had a cash burn of $2,020,000 in the three months to March 31, 2021, with cash and cash equivalents of $2,458,000, which would provide about 1.22 quarters of cash.
The company did not provide an answer in the designated section of the Appendix 4C to explain the steps to be taken to rectify the cash position, as required by the ASX.
In its preamble to the Appendix 4C, Oventus said there would "be some one-off restructuring costs in the June quarter, followed by a lower ongoing operating cost base, quarter on quarter".
The company said that the cost-base reduction would "include a significant reduction in headcount, adjustment of the North American sales strategy, as well as reductions in executive and board compensation," with a targeted cost reduction of 20 percent.
Oventus said it aimed to focus its physical O2Vent Lab-in-Lab program on higher-yielding sites and convert the lower-yielding physical sites to virtual sites to reduce costs.
The company said it expected further revenue growth.
Oventus fell two cents or 10.3 percent to 17.5 cents.

ALCIDION GROUP

Melbourne's Australian Super says it has become a substantial shareholder in Alcidion with 52,491,042 shares or 5.05 percent of the company.

Australian Super said that on April 23, 2021 it acquired 15,000,000 shares through a conversion trade at no cost.

Earlier this month, Alcidion said it had raised $15.4 million in a placement at 32 cents a share and issued the shares on April 23, 2021 (BD: Apr 15, 2021).

Alcidion was unchanged at 39 cents with 2.5 million shares traded.