Biotech Daily

Wednesday July 29, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 20%; ACTINOGEN DOWN 11.5%**

*** DIMERIX: DMX-200 SAFE, REDUCES FSGS PROTEINURIA 29%**

*** CLARITY STARTS CU-64 SAR-BOMBESIN BREAST CANCER TRIAL**

*** ECOFIBRE REVENUE UP 42% TO $51m, PROFIT UP 119% TO $13m**

*** TOTAL BRAIN RECEIPTS UP 81.5% TO $5m**

*** PROTEOMICS RECEIPTS UP 1.3% TO $1.8m**

*** INCANNEX RECEIPTS UP 18% TO $1.4m**

*** IMAGION 'OVERSUBSCRIBED' PLACEMENT RAISES $5m**

*** NOVA EYE (ELLEX) PAYS INVESTORS $61m FROM LUMIBIRD SALE**

*** NYRADA RECEIVES $1.1m R&D TAX INCENTIVE**

*** ECOFIBRE PAYS $59m FOR TEXINNOVATE**

*** CANN GLOBAL RIGHTS RAISE $2.2m OF HOPED-FOR $4.7m**

*** TBG EXPROBE SARS-COV-2 TEST WINS TAIWAN EMERGENCY USE**

*** SUDA: TGA APPROVES ZOLPIMIST FOR INSOMNIA**

*** INVION INVESTIGATES ANTI-CANCER COMPOUNDS**

*** BARD1 COMPLETES SIENNA ACQUISITION**

*** CANN GROUP NOTES CONVERT TO 17m SHARES**

*** INVION LOSES CEO CRAIG NEWTON, CO-SEC MELANIE FARRIS**

MARKET REPORT

The Australian stock market fell 0.23 percent on Wednesday July 29, 2020, with the ASX200 down 14.1 points to 6,006.4 points. Six of the Biotech Daily Top 40 stocks were up, 25 fell and nine traded unchanged. All three Big Caps fell.

Dimerix was the best, up 7.5 cents or 19.7 percent to 45.5 cents, with 15.3 million shares traded. Amplia climbed 6.45 percent; Proteomics was up 5.4 percent; Polynovo rose 3.2 percent; Pharmaxis was up 2.4 percent; with Compumedics up 1.15 percent.

Actinogen led the falls, down 0.3 cents or 11.5 percent to 2.3 cents, with 10.2 million shares traded. Osprey and Resonance lost more than six percent; Orthocell and Paradigm fell more than four percent; Cynata, Imugene, Kazia, LBT and Prescient were down more than three percent; Avita, Clinuvel, Impedimed, Opthea, Starpharma and Uscom shed two percent or more; Cyclopharm, Genetic Signatures, Medical Developments, Nanosonics, Neuren, Pro Medicus, Telix and Volpara were down one percent or more; with Cochlear, CSL, Mesoblast and Resmed down by less than one percent.

DIMERIX

Dimerix says its 10-patient, phase IIa trial of DMX-200 for focal segmental glomerulosclerosis met its primary and secondary endpoints, reducing proteinuria.

Dimerix said that the double-blind, randomized, placebo-controlled, cross-over design trial showed was an average 29 percent reduction in proteinuria in seven patients treated with DMX-200 compared to placebo.

Dimerix chief executive officer Dr Nina Webster told Biotech Daily that focal segmental glomerulosclerosis (FSGS) patients entered the trial with a minimum of 150mg/mmol proteinuria with an average baseline for the seven patients completing the trial of 354mg/mmol proteinuria.

Dr Webster said that all patients continued a stable 300mg dose of the angiotensin receptor blocker irbesartan and received either a 120mg DMX-200 capsule twice daily or placebo, prior to a washout period and joining the other arm of the trial.

She said patients receiving placebo had an average 1mg/mmol reduction in proteinuria, compared to 119mg/mmol on DMX-200, a 29 percent reduction compared to placebo.

Dr Webster said that six of the seven patients demonstrated reduced proteinuria on DMX-200 compared to placebo, with two of the seven showing a greater than 40 percent reduction in proteinuria.

In its announcement to the ASX, the company said that DMX-200 was “generally safe and well-tolerated” with multiple patients from both this trial and the diabetic kidney disease studies continuing on DMX-200 through an Australian Therapeutic Goods Administration special access scheme.

Dimerix said that the primary endpoint was safety, as measured by the number and severity of adverse events and clinically significant changes in the patient safety profile with the use of DMX-200 compared to placebo.

The company said the preliminary safety findings showed “no variation in the incidence or severity of adverse events between treatment with DMX-200 or placebo”, with no patient withdrawals from the study and no serious adverse events related to the drug.

Dimerix said that the secondary endpoints were the proportion of patients who achieved a response during treatment with DMX-200 compared to placebo as well as the percent change from baseline in 24-hour proteinuria after 16 weeks of treatment with DMX-200 as compared to placebo.

The company said that unlike other investigational drugs in development for focal segmental glomerulosclerosis, patients stayed on the standard-of-care angiotensin receptor blockade and “as a result, the reduction in proteinuria observed from DMX-200 is in addition to any reduction in proteinuria expected from background therapy that would have occurred prior to starting on DMX-200.

Dimerix said that study was short and “not powered for statistical significance, [but] it was designed to derive maximum insight from a small number of patients, while retaining the ability for a flexible number of patients to complete the study.

Dimerix medical advisory board chair Dr Hiddo Heerspink said the results “together with the positive outcomes of the company’s prior phase IIa study in chronic kidney disease, further validates Dimerix’ lead candidate, DMX-200, in sclerotic kidney diseases”.

“The positive signals suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS,” Dr Heerspink said. “To have 86 percent of patients see a benefit on DMX-200 versus placebo in a disease is very impressive.”

Dimerix said DMX-200 had both US and European orphan drug designation for FSGS and was planning a phase III pivotal program in focal segmental glomerulosclerosis.

Dimerix was up 7.5 cents or 19.7 percent to 45.5 cents with 15.3 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says the first of 10 patients has been treated in its initial imaging trial of copper-64 bombesin for metastatic breast cancer.

Clarity said that the C-Bobcat trial was a first-in-human, investigator-led clinical trial of 64Cu-sarcophagine-bombesin in hormone receptor positive (HR+) and negative human epidermal growth factor receptor 2 negative (HER2-) patients.

The company said the trial was a collaboration with Sydney's St Vincent's Hospital's led by nuclear medicine head Prof Louise Emmett.

Clarity said that bombesin was "a natural homolog to the mammalian gastrin-releasing peptide, able to specifically bind to the gastrin-releasing peptide receptor (GRPr).

The company said that the gastrin-releasing peptide receptor was present on the membrane of most prostate, breast, ovarian and small cell lung cancers, gastro-intestinal stromal tumors, and in tumoral vessels of urinary cancers.

Clarity said that HR+/HER2- breast cancers comprised about 67 percent of new breast cancer cases diagnosed each year, affecting about 181,000 women in 2019 in the US, and about 13,000 women in Australia.

Clarity executive chairman Dr Alan Taylor said that sarcophagine-bombesin (SAR-BBN) was the company's second product after Sartate to enter clinical development.

Dr Taylor said that St Vincent's Hospital had been involved in "pioneering radio-pharmaceutical studies".

"We hope that SAR-BBN will allow for positron emission tomography imaging and localization of metastatic breast cancer lesions that express GRPr, and we look forward to utilizing that data to progress SAR-BBN into other diagnostic and therapeutic trials in a range of cancers that express GRPr with our ultimate goal of better treating children and adults with cancer," Dr Taylor said.

Clarity is a public unlisted company.

ECOFIBRE

Ecofibre says revenue for the year to June 30, 2020 was up 42.4 percent to $50,717,000 with net profit after tax up 119.3 percent to $13,156,000.

Earlier this month, Ecofibre said it would conduct US trials of its cannabidiol for Alzheimer's disease and chemotherapy-induced neuropathy (BD: Jul 17, 2020).

Today, the company said revenue included $46,819,000 from its Ananda Health hemp-based food additives, $1,469,000 from its Ananda Food hemp-based food products and $2,429,000 from its Hemp Black hemp-based fibre products.

Ecofibre said diluted earnings per share were up 100 percent to 4.34 cents, net tangible assets per share were up 41.9 percent to 19.6 cents and it had cash and cash equivalents of $18,252,000 at June 30, 2020 compared to $25,740,000 at June 30, 2019.

Ecofibre fell one cent or 0.4 percent to $2.49.

TOTAL BRAIN

Total Brain said receipts from customers for the year to June 30, 2020 were up 81.5 percent to $4,997,000 compared to the previous corresponding period.

Total Brain said receipts from customers for its mental health platform for the three months to June 30, 2020 rose 187.4 percent to $1,713,000.

The company said it had cash and cash equivalents of $11,104,000 at June 30, 2020 compared to $5,215,000 at June 30, 2019 and an estimated 4.4 quarters of funding.

Total Brain was unchanged at 32 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says receipts from customers for the year to June 30, 2020 were up 1.3 percent to $1,752,000 compared to the previous corresponding period.
Proteomics said the revenue was from sales of its Promarkerd platform for diabetic kidney disease.
The company said it had cash and cash equivalents of $2,365,000 at June 30, 2020 compared to $1,511,000 at June 30, 2019 and an estimated three quarters of funding.
Proteomics was up three cents or 5.4 percent to 59 cents.

INCANNEX HEALTHCARE

Incannex says receipts from customers for the year to June 30, 2020 were up 17.8 percent to $1,389,000 compared to the previous corresponding period.
Incannex said receipts were from sales of its cannabinoid products, including four marijuana oils and a cannabidiol (CBD) inhaler.
The company said it had cash and cash equivalents of $3,603,000 at June 30, 2020 compared to $93,000 at June 30, 2019 and an estimated 2.78 quarters of funding.
Incannex was up 0.3 cents or 4.6 percent to 6.8 cents with 3.7 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it has raised $5 million through an oversubscribed placement at 4.5 cents a share.
Imagion said the share price was at a 33.9 percent premium to the 60-day volume weighted average price (VWAP) and equal to the 30-day VWAP.
The company said the funds would provide capital past completion of its first-in-human phase I study of Magsense for breast cancer, allow it to begin work on additional indications and accelerate preparation for a pivotal study for regulatory clearances.
Imagion said Evolution Capital Advisors was the lead manager to the placement.
Imagion fell 0.4 cents or 6.7 percent to 5.6 cents with 23.3 million shares traded.

NOVA EYE MEDICAL (FORMERLY ELLEX MEDICAL LASERS)

Nova Eye says it has paid $61 million to shareholders, following the Lumibird acquisition of its laser and ultrasound business.
Last month, the company said it had completed the $97.4 million sale of its laser and ultrasound business to Lumibird and would change its name to Nova Eye (BD: Jun 30, 2020).
Today, Nova Eye said it had returned $41.6 million to shareholders at 29 cents a share and paid $19.4 million in a fully franked 13.5 cents dividend per share.
Nova Eye was unchanged at 33 cents.

NYRADA

Nyrada says it has received $1,050,041 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Nyrada said the rebate related to research and development expenditure for the year to June 30, 2019.
Nyrada fell half a cent or 2.6 percent to 18.5 cents.

ECOFIBRE

Ecofibre says it has a conditional agreement to pay $US42,000,000 ($A58,605,540) for the businesses and assets of its North Carolina manufacturer Texinnovate.
Ecofibre said the assets included five businesses with “deep technical expertise” in textiles, including Triad Polymers, Trident Fibers, Fibex, Knitmasters and Texinnovate.
The company said the agreement included $US10,500,000 in cash and the equivalent in shares by September 1, 2020 and a $US21,000,000 earnout, payable in three tranches.
Ecofibre said it would also pay $US7,000,000 in consideration for real estate, which would be determined by independent market appraisal.

CANN GLOBAL

Cann Global says its one-for-four renounceable entitlement offer at 0.5 cents a share has raised $2,200,748 of a hoped-for $4,661,235.
Earlier this month Cann Global said it had repriced the offer prospectus from 0.55 cents to 0.5 cents a share, to comply with ASX requirements (BD: Jul 3, 2020).
Today, the company said that for every two new shares acquired, shareholders would receive one attaching option, exercisable at 1.2 cents a share by January 31, 2022.
The company said applications included $241,997 from chair Pnina Feldman and managing-director Sholom Feldman and $649,254 from largest shareholder, LBT Corp.
Cann Global said it had the option to place the remaining $2,036,744 shortfall within three months or by October 23, 2020.
Cann Global was unchanged at half a cent with 5.9 million shares traded.

TBG DIAGNOSTICS

TBG says its subsidiary TBG Biotechnology Corp has Taiwan approval for its Exprobe severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) testing kit.
TBG said the Exprobe was a ribonucleic acid (RNA)-based diagnostic kit that used real time polymerase chain reaction (PCR) technology, with a multiplex design, to detect distinctive segments within RNA-dependent RNA polymerase (RdRP), nucleoprotein (N) and envelope small membrane protein (E) genes of the Sars-Cov-2 virus.
The company said the test was commonly used to confirm active infection of the virus from a specified range of upper and lower respiratory samples.
TBG said the Exprobe would be available under emergency use authorization for in-vitro diagnostics, but it had not undergone the same type of review with the US Food and Drug Administration as an in-vitro diagnostic.
The company said emergency use would be effective until December 31, 2021 and Exprobe was one of 10 in-vitro diagnostics with Taiwan emergency use authorization.
TBG was in an ASX suspension and last traded at 27 cents.

SUDA PHARMACEUTICALS

Suda says the Australian Therapeutic Goods Administration has approved its Zolpimist for adults with short-term insomnia.
Suda said the approval included as a supplemental active pharmaceutical ingredient (API) supplier and final product manufacturer, which allowed the company to supply Zolpimist at a more competitive price and was submitted subsequent to the initial marketing authorization application.
Suda was up 3.7 cents or 137.0 percent to 6.4 cents with 276.3 million shares traded.

INVION

Invion says it has identified several photo-sensitizer active pharmaceutical ingredients with greater anti-cancer activity than its existing IVX-P02 and IVX-P03.
Invion said the new compounds appeared to be more effective at targeting specific cancers and were taken up more actively by certain cancer cells than both IVX-P02 and IVX-P03.
The company said it would shift its focus to progress these new compounds, beginning with cancer localization and killing studies with Melbourne's Hudson Institute of Medical Research later this year.
The company said Covid-19 had imposed many challenges and had an ongoing potential to directly impact the conduct of its planned studies, particularly in Victoria where most of its research partners were located.
Invion was unchanged at 0.9 cents with 1.5 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says it has completed its acquisition of Sienna Cancer Diagnostics, appointing Dr Geoff Cumming as chairman and Helen Fisher as a non-executive director.
Last week, Bard1 and Sienna said the Federal Court of Australia had approved their scheme of arrangement for Sienna to be acquired by Bard1 (BD: Jul 20, 2020).
Today, Bard1 said it had appointed Carl Stubbings as chief operations officer and Tony Di Pietro as chief financial officer and company secretary.
Bard1 fell 0.3 cents or 8.8 percent to 3.1 cents with 5.7 million shares traded.

CANN GROUP

Cann Group says it has issued 17,185,723 shares at 34 cents a share, following the conversion of 5,600,000 convertible notes at $1.00 a share.
In February, Cann Group said it would issue convertible notes to raise $8 million, at a base rate of 7.5 percent, for working capital requirements (BD: Feb 7, 2020).
Today, the company's Appendix 2A announcement said it had 193,031,985 shares on offer, following the issue.
Cann Group was up three cents or 6.45 percent to 49.5 cents with 2.6 million shares traded.

INVION

Invion says chief executive officer Craig Newton and company secretary Melanie Farris will retire, effective from October 31 and July 31, respectively.
Invion said Mr Newton, who was appointed as chief executive officer in November 2019, would retire "for personal reasons", replaced by chair Thian Chew on an interim basis (BD: Oct 24, 2019).
The company said Ms Farris would be replaced by chief financial officer Melanie Leydin but would continue as a non-executive director until August 30, 2020.