Biotech Daily

Tuesday May 17, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: OPTHEA UP 8%; ACTINOGEN DOWN 9.5%**

*** FEDERAL LABOR $1.5b MEDICAL MANUFACTURING FUND**

*** HYDRIX TO DEVELOP REALHEART CONTROL SYSTEM**

*** ZELIRA: HOPE1 MARIJUANA 70% 'MODERATE EFFECTS' FOR AUTISM**

*** INCANNEX, FDA SLEEP APNOEA TRIAL GUIDANCE**

*** PHARMAUST RADIUM $210k RDTI LOAN**

*** MEMPHASYS PLEADS SCHULTZ TO ASX 29% FALL QUERY**

*** NYRADA: EUROPEAN CHOLESTEROL INHIBITOR PATENT**

*** W WHITNEY GEORGE DILUTED TO 39% OF RHINOMED**

*** REGAL FUNDS TAKES 19% OF OPTHEA**

MARKET REPORT

The Australian stock market was up 0.27 percent on Tuesday May 17, 2022, with the ASX200 up 19.5 points to 7,112.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and three were untraded. All three Big Caps fell.

Opthea was the best on no news, up 10 cents or 8.4 percent to $1.29, with 414,249 shares traded. Micro-X, Oncosil and Telix improved more than five percent; Immutep improved 4.1 percent; Dimerix, Kazia and Polynovo were up more than three percent; Orthocell, Proteomics and Resonance rose more than two percent; Neuren and Pharmaxis were up more than one percent; with Volpara up 0.7 percent.

Following two days of rises, Actinogen led the falls, down 0.8 cents or 9.5 percent to 7.6 cents, with 1.05 million shares traded. Impedimed lost 6.2 percent; Atomo fell 5.5 percent; Clinuvel, Pro Medicus and Universal Biosensors were down three percent or more; Antisense, Medical Developments, Nanosonics, Next Science and Resmed shed more than two percent; Avita, CSL, Paradigm and Starpharma were down more than one percent; with Cochlear and Genetic Signatures down by more than one percent.

AUSTRALIAN LABOR PARTY

The Federal Labor Opposition says it will provide a $1.5 billion fund to support Australian medical manufacturing as part of its $15 billion National Reconstruction Fund.
The Federal Opposition said that the Medical Manufacturing Fund would "work with industry to identify ways that government purchasing strategies can help build local medical manufacturing capability to create secure well-paid jobs and strengthen our key sovereign capabilities".
The Australian Labor Party said that the medical technology sector could add $18 billion to the Australian economy and around 28,000 new jobs within the next eight years.
The Party said that the Medical Manufacturing Fund would be managed by an independent board established under the National Reconstruction Fund.
According to its website, Labor said that a proposed $15 billion National Reconstruction Fund would provide loans, guarantees and equity to support projects that "create secure well-paid jobs, drive regional development, and invest in our national sovereign capability, broadening and diversifying Australia's economy".
Labor leader Anthony Albanese said that "a country that takes its pandemic preparedness seriously would have ensured that we made more rapid tests and vaccines here".
"Serious countries should make things," Mr Albanese said. "Serious countries should be led by builders, not bulldozers, which is how I would lead a future Labor Government.".
Labor shadow minister for industry and innovation Ed Husic said Australian firms were ready to manufacture essential medical supplies but need a government to back them
Australia has a Federal election this Saturday, May 21, 2022.

HYDRIX

Hydrix says it will develop the control system for the Västerås, Sweden-based Realheart AB four-chamber total artificial heart (TAH).
Hydrix said the partnership with the Västerås, Sweden-based Realheart was a multi-stage program generating about $2 million in revenue for the year to June 30, 2023.
The company said that the Realheart total artificial heart aimed to "mimic the function and form of the natural heart, gently circulating blood through the atria and ventricles with its unique atrio-ventricular plane" and that its design aimed to "minimize the risk of stroke, bleeding and anaemia, which are common side effects of heart pumps in use today".
Hydrix said that the product development would help "accelerate Realheart's TAH system to in-patient clinical trials in 2024".
Hydrix general manager Michael Trieu said the contract was "a strong endorsement of Hydrix as a best-in-class product development partner for clients building disruptive class III cardio-vascular technologies".
"Hydrix know-how and platform technologies help de-risk and accelerate mechanical circulatory support developers to mature their cardiac technologies with greater confidence and reliability; from bench-top prototype to in-human trials to commercial release," Mr Trieu said.
Realheart chief executive officer Ina Perkins said that the controller for the total artificial heart was "technically very advanced and for those who will live with our artificial heart in the future, its design must be extremely easy to use".
"We are convinced that [Hydrix] experience in safety critical controller systems design is also characterized by a strong focus on human user needs experience which will ensure we can offer our patients and carers, the best controller for
meeting these needs and expectations," Ms Perkins said.
Hydrix fell 0.1 cents or 1.1 percent to 8.9 cents with 1.6 million shares traded.

ZELIRA THERAPEUTICS

Zelira says “almost 70 percent” of 45-patients in its observational trial of its Hope1 marijuana for autism spectrum disorder had at least “moderate” therapeutic effects.

In November 2020, Zelira said it and Emyria had a real-world data agreement for an up to 150-patient observational trial of Zelira’s Hope marijuana for autism spectrum disorder (BD: Nov 9, 2020).

In October of that year, the company said it had launched its marijuana Hope products for autism in Australia through the Australian Therapeutic Goods Administration’s special access scheme (BD: Oct 27, 2020).

According to Zelira’s website, Hope1 is a liquid formulation of equal parts tetrahydrocannabinol (THC) and cannabidiol (CBD), blended with olive oil and taken orally.

Today, Zelira said that Hope1 appeared “effective”, with “close to” 70 percent of patients rated by clinicians as having achieved a “moderate therapeutic effect after five months on Hope1”.

The company said that the average effective daily dose of Hope1 for patients 16 years and under was 2.5mL (equating to 12.5mg THC: 12.5mg CBD a day) and for patients over the age of 18 it was 3.6mL (equating to 17.9mg THC: 17.9mg CBD a day).

Zelira said that Hope1 appeared safe, with no serious adverse events observed and that the mean time of treatment was 4.8 months, with a maximum of 8.9 months.

Zelira managing-director Dr Oludare Odumosu said that “physicians and patients often ask for proof of the safety, efficacy, and dosing guidelines for cannabinoid-based medicines”.

“Zelira is pleased to share the results from this longitudinal real-world trial because it provides prescribers with empirical information and additional confidence to prescribe Hope1,” Dr Odumosu said. “These results provide additional clinical and regulatory validation for our products as we expand into highly regulated global markets.”.

Zelira was up 20.5 cents or 17.45 percent to $1.38.

INCANNEX HEALTHCARE

Incannex says the US Food and Drug Administration has “provided guidance [which] will inform adjustments” to the trial protocols for IHL-42X for obstructive sleep apnoea.

Incannex said that the FDA guidance on the marijuana-based IHL-42X trial included specific parameters to demonstrate safety and efficacy in phase II and III pivotal studies.

The company said that the FDA agreed that it did not need to conduct animal studies and the next stage of development for IHL-42X would be the adjustment of clinical trial designs required for a 505(b)(2) new drug application with the FDA.

Incannex chief scientific officer Dr Mark Bleackley said that “the FDA’s interest in IHL-42X as a potential therapy for [obstructive sleep apnoea] was extremely encouraging … the feedback they provided on the overall proposed development program was positive”.

“The agency’s responses to the specific questions we posed allow us to revise our clinical trial protocols, to ensure that we are running highly efficient studies that generate the type and amount of data the FDA will require in a future marketing application,” Dr Bleackley said. “The results from the [pre-investigational new drug] meeting will shape the IHL-42X development program over the coming months.”

In March, Incannex said that its 11-person, phase II trial of IHL-42X for obstructive sleep apnoea showed IHL-42X reduced patient apnoea-hypopnoea indices and was well-tolerated (BD: Mar 10, 2022).

Incannex was up five cents or 11 percent to 50.5 cents with 9.3 million shares traded.

PHARMAUST

Pharmaust says it has borrowed $210,000 from Radium Capital against its expected Federal Government Research and Development Tax Incentive.
Pharmaust said that the Radium loan would provide it with immediate funds equivalent to 80 percent of its accrued Research and Development Tax Incentive to February 28, 2022 and allowed for a second advance at June 30, 2022.
The company said that loan's compound interest rate was 1.25 percent a month, with repayment timed to coincide with the receipt of its 2022 Research and Development refund, expected by December 31, 2022.
Pharmaust finance director Sam Wright said the Radium facility provided "secure and non-dilutive funds against a backdrop of geo-political uncertainty and broader equity market volatility".
"Bringing forward our future [research and development] refund strengthens Pharmaust's financial position to execute on our upcoming clinical trials," Mr Wright said.
Pharmaust was up 0.1 cents or 1.1 percent to 9.1 cents.

MEMPHASYS

Memphasys has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price fell 1.5 cents or 28.85 percent from a high of 5.2 cents to a low of 3.7 cents, yesterday May 16, 2022, and noted a "significant increase" in trading volume.
Memphasys was up 0.2 cents or 5.3 percent to four cents with 4.1 million shares traded.

NYRADA

Nyrada says the European Patent Office has allowed a patent for its compounds which act as inhibitors of PCSK9 to enable reduction in "bad" cholesterol levels.
Nyrada said that when formally granted, the patent, titled 'Heterocyclic Inhibitors of PCSK9' would protect its intellectual property until March 16, 2038.
The company said that the application covered new compounds it had developed that acted as inhibitors of PCSK9 to enable a reduction in low density lipo-protein (LDL) cholesterol levels.
Nyrada was up 3.5 cents or 21.2 percent to 20 cents.

RHINOMED

W Whitney George says his 112,089,721 shares substantial holding in Rhinomed has been diluted from 40.39 percent to 39.23 percent following a capital raising.
Earlier this month, Rhinomed said it had raised $1,098,000 in a one-for-9.87 retail entitlement offer at 19 cents a share and had placed a $455,000 shortfall from its offer taking the total raised to $4,923,000 (BD: May 4, 6, 2022).
In April, the Darien, Connecticut-based Mr George said he acquired 10,311,841 shares for $1,958,705, or 19 cents a share in the institutional rights offer (BD: Apr 22, 2022).
Rhinomed was up 0.75 cents or 4.5 percent to 17.5 cents.

OPTHEA

Regal Funds Management says it has increased its substantial holding in Opthea from equivalent to 63,815,800 shares (18.13%) to 67,328,864 shares (19.13%).
Sydney's Regal Funds said it held 44,262,448 (12.58%) Australian shares and 2,883,302 American depositary shares, each representing eight Australian shares.
The company said it bought shares between March 7, and April 12, 2022, with the single largest purchase on March 9 of 1,157,333 shares for $946,120 or 81.75 cents a share.
Opthea was up 10 cents or 8.4 percent to $1.29.