Biotech Daily

Tuesday February 20, 2024

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: CYNATA UP 9%; ACTINOGEN DOWN 14%**

*** FEDERAL $50m FOR 3 MONASH UNI HEART DEVICES**

*** BIOMEBANK: FEDERAL $2.15m FOR MICROBIOME MANUFACTURING**

*** CERTA WINS US FT011 FDA FAST-TRACK STATUS FOR SCLEROSIS**

*** ACTINOGEN TELLS ASX AWARE QUERY: '2 HOURS NOTICE'**

*** ORTHOCELL REQUESTS 'PLACEMENT' TRADING HALT**

*** RHYTHM APPOINTS PAC PARTNERS RIGHTS ISSUE LEAD MANAGER**

*** HARBOUR TAKES 6% OF AROA**

*** OPTHEA APPOINTS DR ARSHAD KHANANI CHIEF MEDICAL ADVISOR**

MARKET REPORT

The Australian stock market slipped 0.08 percent on Tuesday February 20, 2024, with the ASX200 down 6.1 points to 7,659.0 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and two were untraded.

Cynata was the best, up 1.5 cents or 9.1 percent to 18 cents, with 191,313 shares traded. Pro Medicus improved 8.3 percent; Medical Developments was up 7.1 percent; Compumedics climbed 3.2 percent; Avita, Clarity and Curvebeam rose two percent or more; 4D Medical, Emvision, Immutep, Mesoblast, Polynovo and Proteomics were up one percent or more; with Cochlear and CSL up by less than one percent.

Actinogen led the falls for the second day in a row, down 0.6 cents or 13.95 percent to 3.7 cents, with 7.9 million shares traded.

Alcidion lost 9.1 percent; Opthea was down 5.6 percent; both Imugene and Syntara (Pharmaxis) fell 4.35 percent; Starpharma was down 3.7 percent; Nova Eye, Paradigm and Prescient shed more than two percent; Clinuvel, Impedimed, Neuren, Next Science and Percheron (Antisense) were down one percent or more; with Resmed and Telix down by less than one percent.

FEDERAL GOVERNMENT, MONASH UNIVERSITY

The Federal Government says its Medical Research Future Fund will provide $50 million for the development of three cardiac devices.

A media release from the Federal Minister for Health and Aged Care Mark Butler said the funds would be used to open the Artificial Heart Frontiers program, bringing together five universities, three clinical partners and an Australian company to develop three, "next-generation cardiac technologies collectively known as the total artificial heart".

The Government said the parties included Monash University, the University of Sydney, the University of New South Wales, Brisbane's Griffith University and the University of Queensland, Melbourne's Alfred Hospital, the Baker Heart and Diabetes Institute, Sydney's St Vincent's Health Australia and the Huntington Beach, California Bivacor Inc.

The Federal Government said unlike previous devices, Bivacor's total artificial heart would use magnetic levitation technology that "promises to be durable for more than 10 years, is small enough to implant in a child, and powerful enough for an adult".

The media release said the technology would "allow patients to maintain an active lifestyle and improve their quality of life, and if successful could "save millions of lives globally, halving the deaths from heart failure".

The Government said in the next 15 years the three projects were expected to contribute $1.8 billion to the Australian economy including savings to the healthcare system, an industry expansion in research and manufacturing, the creation of more than 2,000 jobs and giving Australian patients early access to clinical trials and emerging technologies.

A separate media release from Melbourne's Monash University said it had been appointed to lead the development and commercialization of the three implantable cardiac devices.

Monash University said the devices included an implantable mini-pump for patients with heart failure symptoms who had no other options, a left ventricle assist device implanted next to a natural heart and Bivacor's total artificial heart fully replacing the natural heart.

The University said current devices operated with a relatively fixed blood flow rate, or pump speed, that "significantly curtails activity by leaving patients out of breath".

Monash University said all three devices used technologies that would allow them to mimic a natural heart by automatically responding to the body's physical demands and "for the first-time offering heart failure patients a treatment that helps to keep them active".

The University said the Medical Research Future Fund grant would be used to support future clinical trials at Melbourne's Alfred Hospital and Sydney's St Vincent's Hospital.

Monash University said the development and manufacture of the devices would be the basis for a medical device industry in Australia, comprising advanced engineering and pre-clinical evaluation and building local capacity to support ongoing translational research in Australia's health and medical sector.

Mr Butler said the funds were "the third-largest grant in the nearly 10-year history of the Medical Research Future Fund".

"As well as the obvious health benefits, this is an incredible story of Australian ingenuity and sovereign manufacturing, with collaboration across universities, clinical hospitals and industry to develop the world's most advanced artificial heart," Mr Butler said. "This will give hope to the half a million Australians who suffer from heart failure."

Monash University vice-chancellor and president Prof Sharon Pickering said "the Artificial Heart Frontiers program underlines Monash's commitment to purpose-driven research and innovation to deliver tangible and significant outcomes".

"An [Medical Research Future Fund] grant of this scale recognises the strength of Monash's world-leading cardiac and engineering research, and our commitment to working with partners in research, industry, government and the community to address global challenges," Prof Pickering said.

BIOMEBANK

Biomebank says it has received $2,147,887 from the Federal Co-operative Research Centres projects for its cultured microbial therapeutics manufacturing facility.

The Adelaide-based Biomebank said the project was in collaboration with the Marlborough, Massachusetts' Cytiva Pty Ltd (formerly General Electric Life Sciences) and Melbourne's Hudson Institute of Medical Research.

The company said the three-year project had a budget of $5.7 million, including the Federal Government grant, and aimed to develope the infrastructure and capabilities to scale its microbial therapies to commercially viable volumes.

Biomebank said its cultured microbial biotherapeutic products were being developed to "target chronic debilitating diseases that current medicine does not satisfactorily treat".

The company said the grant followed its "world first" regulatory approval of a donor-derived microbiome drug product and the opening of its expanded manufacturing facility in Adelaide's biomedical precinct last year.

Biomebank chief executive officer Dr Sam Costello said "the loss of gut microbes is a significant contributor to many common diseases".

"We have developed a technology to produce cultured human gut microbes as therapies to treat these diseases," Dr Costello said.

"This grant will accelerate our efforts to scale our breakthrough microbiome therapies and meet the needs of patients globally," Dr Costello said.

Biomebank is a private company.

CERTA THERAPEUTICS

Certa says it has US Food and Drug Administration fast-track designation for its FT011 for systemic sclerosis, following orphan drug designation.

Certa said that the designation was granted based on results from its 30-patient, phase II study of 400mg of oral FT011, which showed a "clinically meaningful improvement" in 60 percent of systemic scleroderma patients ($p = 0.019$) (BD: Nov 16, 2023).

The company said the designation was designed to facilitate an expedited development and review of drugs that were intended to treat serious or life-threatening conditions and showed the potential to address unmet medical needs.

Certa said FT011 was a therapy for the treatment of chronic fibrosis in multiple organs by targeting a membrane proton-sensing G-protein-coupled receptor (GPCR), called GPR68, which had an "extensive body of data demonstrating promising efficacy".

The company said orphan status meant it could be eligible for more frequent FDA interactions, a rolling review of its application, accelerated approval and priority review.

Certa said it had begun preparing a pivotal clinical trial of FT011, the trial design and development plans would be discussed with the FDA as soon as possible in 2024, with complementary scientific advice sought from the European Medicines Agency mid-2024, with the aim of starting the pivotal study in late-2024.

Certa chief executive officer Prof Darren Kelly said the company was "thrilled to have received fast-track designation".

"It also provides validation of FT011's potential to offer patients with scleroderma the first anti-fibrotic and disease modifying treatment of this type," Prof Kelly said.

"We know that this debilitating and life-threatening disease can severely impact the lives of patients and to date existing treatments only focus on the relief and management of symptoms, whereas FT011 precisely targets the root cause of fibrosis and has the potential to offer treatment across multiple organs within these patients," Prof Kelly said.

Certa is a private company.

ACTINOGEN MEDICAL

Actinogen has told an ASX aware query that it announced the information of its UK innovation passport for Xanamem to the ASX “less than two hours after receipt”.
In an ASX query, the ASX said that on February 15, 2024, Actinogen announced it had been granted an innovation passport from the UK regulatory authorities for its Xanamem.
The ASX said Actinogen’s share price increased 38.7 percent from 3.1 cents at the close of trading on Friday, February 9, 2024 to 4.3 cents on Wednesday February 14, 2024.
Last week, the company said the UK Medicines and Healthcare products Regulatory Agency had approved an ‘innovation passport’ for Xanamem as a treatment for Alzheimer’s disease (BD: Feb 15, 2024).
The ASX asked Actinogen when it became aware of the Xanamem innovation passport, whether the information was kept confidential prior to its release and if it had any explanation for the increase in the price of its securities.
Actinogen told the ASX it first became aware of the information by email from the UK regulatory agency at 11.54am (AEDT) on February 15, 2024.
The company said “only the need-to-know group of the chief executive officer, head of communications, company secretary, regulatory associate and a small number of others knew of the award in the two hours prior to the ASX announcement”.
Actinogen said that the increase in its share price on the day of the announcement “only occurred after the announcement at approximately 2pm, increasing from 2.25pm”.
The company said that it had previously “made a series of announcements over the period [from] January 24 to February 15, 2024”.
“Notably, the non-price sensitive ASX announcement of January 24 advising that a peer reviewed manuscript of a [positron emission tomography brain scan study had been published in a medical journal led to an increase in share price and volume from a base of approximately 2.7 cents,” Actinogen said.
The company said these announcements could have explained the price increase, as well as the issue of 18 million restricted long-term incentive shares to its chief financial officer William Souter, which appeared “to have triggered gradual price and volume increases from three cents to 4.3 cents on February 14”.
Actinogen fell 0.6 cents or 13.95 percent to 3.7 cents with 7.9 million shares traded.

ORTHOCELL

Orthocell has requested a trading halt “pending an announcement by the company in relation to a proposed strategic placement”.
Trading will resume on February 22, 2024, or on an earlier announcement.
Orthocell last traded at 38 cents.

RHYTHM BIOSCIENCES

Rhythm says it has appointed Melbourne’s Pac Partners as lead manager and sole bookrunner for any shortfall from its rights issue.
Earlier this month, Rhythm said it hoped to raise up-to $6.6 million in a three-for-10 rights offer at 10.0 cents a share, with one attaching option for every two shares purchased (Feb 9, 2024).
Today, the company said parties wanting to participate in the take-up of shortfall shares, if any, from its rights issue should contact Pac Partners principal Sean Kennedy at: corporate@pacpartners.com.au.
Rhythm fell half a cent or 4.35 percent to 11 cents with 1.1 million shares traded.

AROA BIOSURGERY

The Wellington, New Zealand-based Harbour Asset Management says it has increased its substantial holding in Aroa from 18,000,512 shares (5.252%) to 21,481,136 shares (6.252%).

Harbour said that between November 9, 2022 and February 19, 2024, it bought and sold shares acquiring 4,952,654 shares for $4,330,458 or an average of 87.4 cents a share; and sold 1,546,530 shares for $1,388,427 or an average of 89.8 cents a share.

Aroa fell half a cent or 0.8 percent to 59 cents.

OPTHEA

Opthea says it has appointed Dr Arshad Khanani as its chief medical advisor.

Opthea said Dr Khanani was a managing partner and director of clinical research at the University of Nevada's Reno School of Medicine, had been the lead principal investigator for multiple clinical trials and held elected memberships at the Macula Society and Retina Society.

According to his Linkedin profile, Dr Khanani holds a Bachelor of Arts and Master of Arts from St Louis' Washington University and a Doctor of Medicine from the Texas Tech University Health Sciences Centre.

Opthea fell 3.5 cents or 5.6 percent to 59.5 cents.