Biotech Daily

Thursday June 13, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: SYNTARA UP 21%; ACTINOGEN DOWN 9%**

*** FLINDERS UNI OPENS $280m HMRB MEDICAL RESEARCH FACILITY**

*** AROVELLA PAYS TEVA $451k TO 'TERMINATE' ZOLPIMIST LICENCE**

*** BLUECHIIP $300k LOAN; 'POSSIBLE SALE'**

*** FIREBRICK SELLS NASODINE IN SINGAPORE**

*** RACE: 'BISANTRENE SLOWS MYELOMA PROGRESSION, IN MICE'**

*** ANATARA ENROLS 13 PHASE II GARP IBS TRIAL PATIENTS**

*** AVECHO RECEIVES $1.1m FEDERAL R&D TAX INCENTIVE**

*** TELIX REQUESTS 'US IPO' TRADING HALT**

*** MELODIOL COMPLETES 30-TO-1 CONSOLIDATION**

MARKET REPORT

The Australian stock market was up 0.44 percent on Thursday June 13, 2024, with the ASX200 up 34.2 points to 7,749.7 points. Fifteen of the Biotech Daily Top 40 were up, 18 fell, three traded unchanged and four were untraded. All three Big Caps were up.

Syntara was the best, up 0.5 cents or 20.8 percent to 2.9 cents, with 4.3 million shares traded. Percheron rose 7.1 percent; Clarity, Nanosonics and Polynovo climbed four percent or more; Alcidion, Clinuvel, CSL, Immutep, Neuren and Pro Medicus improved two percent or more; Compumedics, Cynata, Imugene, Mesoblast and Orthocell were up more than one percent; with Cochlear and Resmed up by less than one percent.

Actinogen led the falls, down 0.3 cents or 9.1 percent to three cents, with 7.0 million shares traded.

Amplia lost 6.85 percent; Dimerix, Paradigm and Prescient fell more than four percent; Atomo, Impedimed and Proteomics were down three percent or more; 4D Medical, Curvebeam, Emvision, Genetic Signatures and Medical Developments shed more than two percent; Cyclopharm, SDI and Starpharma were down one percent or more; with Avita and Next Science down by less than one percent.

FLINDERS UNIVERSITY

Flinders University says it has opened a $280 million Health and Medical Research Building (HMRB) at its Bedford Park, Adelaide campus.

A media release from the University said the 10-floor facility would employ more than 600 medical researchers, clinicians and support staff and was “poised to tackle the most pressing health challenges of our time, from chronic diseases and Indigenous health disparities to pioneering treatments”.

A Flinders University spokesperson told Biotech Daily the University financed the $280 million project, independent of government funding, with partners including the National Australia Bank, Tetris Capital and building industry companies.

The University said the building was opened by vice-chancellor Prof Colin Stirling, joined by Prime Minister Anthony Albanese and South Australian Premier Peter Malinauskas.

Flinders University said the facility was “purpose-built to foster collaboration among researchers, healthcare professionals and industry partners to drive advances in medical science”.

The University said the building was located next to the Flinders Medical Centre and Flinders Private Hospital and was part of Adelaide’s bio-medical research precinct “that brings together research, education and accommodation, driving $1.5 billion in economic activity and sustaining over 20,000 jobs, both directly and indirectly”.

Flinders University said the building included cell-imaging equipment and “one of South Australia’s largest banks of … physical containment laboratories across five floors, together with … bio-security containment zones”.

The University said it was the “first university integrated into a public hospital” in Australia and the building was “one of Australia’s most sustainable research institutions and is the first medical research facility in the world to achieve a coveted platinum rating for best-in-class digital connectivity”.

Flinders University said it was “Australia’s fastest-growing research institution, with a 140 percent surge in research income in just five years” and ranked eighth nationally for National Health and Medical Research Council grants.

Flinders University vice-chancellor Prof Stirling said the building was “a game-changer in medical research, turning breakthrough research and clinical trials into real benefits for Australians in disease prevention and treatment”.

“This state-of-the-art facility will drive collaboration and empower our researchers and students to push the boundaries of medical innovation,” Prof Stirling said. "HMRB is a major leap forward, building on Flinders’ 50-year legacy of health innovation”.

“It supports our rapid research growth and paves the way for discoveries that solve challenges and improve lives,” Prof Stirling said.

Prime Minister Mr Albanese said the building would “be making breakthroughs and changing lives for the better for many generations to come”.

“I’m incredibly excited to see history being made at the HMRB, whether it’s better understanding neural pathways to control chronic pain, unravelling the secrets in our DNA to address debilitating genetic conditions, [or] supporting the health of mothers and babies, there are endless possibilities to what the 600 researchers here will be able to achieve,” Mr Albanese said. “When I speak about a future made in Australia this is what it looks like”.

South Australian Premier Peter Malinauskas said “boosting the quality and volume of research undertaken in our state is fundamental to increasing the complexity of our economy”.

“The research undertaken at this incredible new facility will help save lives,” Mr Malinauskas said.

AROVELLA THERAPEUTICS (FORMERLY SUDA PHARMACEUTICALS)

Arovella says that it will pay Tel Aviv, Israel's Teva Pharmaceuticals $US300,000 ($A451,000) to terminate its Zolpimist oral spray for insomnia licence agreement.

In 2017, the-then Suda said Teva would pay an up-front $US300,000 and milestones of up-to $US1,750,000 to licence Zolpimist in Brazil, Mexico and Chile (BD: Jul 5, 2017).

Today, the company said the deal had been terminated with immediate effect and by mutual consent, with Teva assigning a Chilean Zolpimist marketing authorization to Arovella and it would pay the $US300,000 to Teva within 90 days, with both companies providing mutual releases from any liability and continuing obligations.

Arovella chief executive officer Michael Baker said Zolpimist was "a legacy product which Suda, as the company was then known, sought to commercialize in 2017".

Mr Baker said Arovella had moved away from Zolpimist activities, to focus on the invariant natural killer T-cell (iNKT) therapy platform, with ALA-101 in a phase I clinical trial.

Last year, Arovella said it had shut its Perth Oromist research and development facility to focus on its iNKT program after a strategic review found that closing the site would cost up-to $US300,000 and save about $1.5 million a year (BD: Oct 26, 2022; May 1, 2023).

Arovella fell half a cent or 3.6 percent to 13.5 cents with 1.4 million shares traded.

BLUECHIIP

Bluechiip says it has taken a $300,000 loan from an unnamed shareholder and is conducting a strategic review to explore the "possible sale of the business".

Yesterday, Bluechiip said it had raised $367,600 at 0.44 cents a share in a placement "for working capital purposes while undertaking a strategic review" (BD: Jun 12, 2024).

Today, the company said that the $300,000 shareholder loan was payable within six months at an interest rate of 14 percent and might be exchanged into convertible notes, subject to shareholder approval, with "a general security agreement in favor of the lender".

Bluechiip said its review would explore "strategic partnerships, investments or possible sale of the business targeting interested parties across North American and Europe".

Bluechiip fell 0.2 cents or 40 percent to 0.3 cents with 7.5 million shares traded.

FIREBRICK PHARMA

Firebrick says it has Singapore's Health Sciences Authority approval to market its antiseptic Nasodine nasal spray, which will sell for about $28 per 25ml bottle.

Firebrick said Nasodine was "classified as a topical antiseptic and does not require approval or licencing by Singapore's Health Sciences Authority before sale" but it did need prior approval to advertise the product to Singapore consumers.

In April, the company said it began marketing Nasodine online in the US for $US24.99 ($A38.94) a unit, for "'nasal hygiene' without any therapeutic claims" (BD: Apr 17, 2024).

Firebrick said Nasodine would be promoted in Singapore as "the nasal spray that kills germs … [and] can help defend against the daily threat of germs in situations such as commuting, socializing, working and travelling … the first [povidone-iodine] nasal spray available in the region, and therefore represented a "first-in-class product".

The company said it would exclusively sell Nasodine to Singapore customers online through its Singapore-dedicated website but that "in the future, the product may also be sold through pharmacies and may attract pharmaceutical marketing partners".

Firebrick said it had engaged a Singapore-based marketing agency to "manage the online social media promotional campaign" for Nasodine.

Firebrick was up one cent or 16.95 percent to 6.9 cents.

RACE ONCOLOGY

Race says studies show bisantrene “significantly delayed progression of multiple myeloma disease” compared to carfilzomib alone or vehicle, in mice ($p < 0.0001$).

Race said the study dosed three groups of eight mice twice daily with either 5.0mg/kg of bisantrene, 5.0mg/kg of bisantrene with 1.25mg/kg of carfilzomib or 1.25mg/kg of carfilzomib alone.

The company said carfilzomib was an intravenous drug for treating multiple myeloma in patients with relapsed or refractory disease after previous therapy and was used in combination with dexamethasone alone, or dexamethasone with lenalidomide.

Race said carfilzomib had been shown in previous studies to cause cardiac side-effects and had led to arrhythmia in 13.3 percent of patients, heart failure in 7.2 percent, cardio-myopathy in two percent and ischaemic stroke in three percent.

In 2021, the company said pre-clinical heart safety research on bisantrene found it was able to protect heart muscle cells while improving the carfilzomib’s ability to kill cancer cells, in-vitro (BD: Dec 8, 2021).

Today, the company said bisantrene was found to “significantly slow multiple myeloma disease progression, whereas carfilzomib at the maximum tolerated dosage showed no single-agent activity”.

Race said carfilzomib alone produced “no reductions in multiple myeloma tumor burden” compared to control, all mice dosed with bisantrene alone showed “significantly delayed progression” with the bisantrene and carfilzomib combination slowing “disease progression more than bisantrene treatment alone” ($p < 0.05$).

The company said bisantrene at 5mg/kg and carfilzomib at 1.25mg/kg were “well-tolerated both alone and in combination across all mice, with no weight loss observed for any animal”.

Race said carfilzomib doses that were more than 1.25mg/kg “were poorly tolerated in the mice, causing significant weight loss and deaths”.

The company said carfilzomib was toxic to mice and displayed much lower efficacy in animals compared to in-vitro conditions “due to its relatively short half-life in blood … [which was] an excellent example of how sometimes results from cell culture experiments do not translate to animal models, or the clinic”.

Race said it would conduct additional studies in mice to investigate what caused the delay in multiple myeloma disease progression as well as the cardio-protective properties of bisantrene.

The company said it did “not currently have plans to undertake new trials of bisantrene in multiple myeloma patients, but is open to supporting investigator-sponsored trials, subject to resourcing”.

Race said carfilzomib was owned by Amgen and that Amgen’s patent protection for generic competition expired in 2027.

The company said the combination of carfilzomib with bisantrene “may offer a way of extending the commercial value of carfilzomib beyond 2027” and it had applied for patent protection for the use of the combination treatment in multiple myeloma.

Race chief executive officer Dr Daniel Tillett said it was “always exciting to see the potential clinical utility of bisantrene grow”.

“Carfilzomib is a highly active treatment for multiple myeloma, but it comes with very serious cardiotoxicity risks,” Dr Tillett said.

“The potential for using bisantrene to not only better treat multiple myeloma, but also protect patients from the heart damage caused by carfilzomib, is worthy of further investigation,” Dr Tillett said.

Race fell 2.5 cents or 1.3 percent to $1.865 with 653,480 shares traded.

ANATARA LIFESCIENCES

Anatara says it has enrolled 13 patients of up-to 100 patients in stage two of its phase II trial of gastrointestinal reprogramming, or Garp, for irritable bowel syndrome (IBS).
Last year, Anatara said it had dosed all 70 patients in the first stage of its phase I/II trial of Garp, and that the treatment was a "multi-component, coated complementary medicine" that included its pineapple stem-based bromelain (BD: Aug 31, 2023).
In April, the company said it had opened five sites for the 60-to-100-patient, second stage of its up-to 140-patient phase II trial of Garp (BD: Apr 9, 2024).
Today, Anatara said there "had been high levels of interest shown at all five sites situated in Melbourne, Sydney and Brisbane with a total of over 500 expressions of interest".
The company said it expected to meet its enrolment target for stage two of the trial by October 2024, with results anticipated before 2025, "in line with previous guidance".
Anatara was unchanged at four cents.

AVECHO BIOTECHNOLOGY

Avecho says it has received $1.07 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Avecho said the incentive related to research and development expenditure for the year to December 31, 2023, and that the funds would be used to support its phase III marijuana for insomnia trial as well as commercialization.
Avecho was up 0.1 cents or 33.3 percent to 0.4 cents.

TELIX PHARMACEUTICALS

Telix has requested a trading halt pending an announcement in relation to its "proposed US initial public offering of new American depositary shares (ADSs)".
Trading will resume on June 17, 2024, or on an earlier announcement.
Telix last traded at $16.46.

MELODIOL GLOBAL HEALTH

Melodiol says it has completed its 30-to-one stock consolidation and has 36,449,783 post-consolidation shares on issue.
In February, Melodiol said it had completed a 20-to-one stock consolidation which had been opposed at an extraordinary general meeting by 33.65 percent of the vote, and that it had 245,825,445 post-consolidation shares on issue (BD: Jan 23, 2024).
In May, the company said shareholders approved a 30-to-one consolidation after an annual general meeting opposed the resolution by 32.85 percent (BD: May 31, 2024).
Melodiol fell 0.1 cents or 4.8 percent to a post-consolidation two cents with 1.0 million shares traded.