Biotech Daily

Tuesday April 11, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NEXT SCIENCE UP 11%; IMUGENE DOWN 13%**

*** CHINA APPROVES TELIX TLX101 GLIOBLASTOMA TRIAL**

*** VOLPARA ADDS $1.9m TO BANNER HEALTH CONTRACT**

*** IMRICOR WINS LAUSANNE HOSPITAL ICMR CONTRACT**

*** MAYNE COMPLETES $135m US GENERICS SALE TO DR REDDY'S**

*** AMPLIA AMP945 PANCREATIC CANCER TRIAL DOSE INCREASE**

*** OSTEOPORE: 'KELYNIAM IMPLANT SUB-DISTRIBUTION PARTNER'**

*** MEDICAL DEVELOPMENTS RENEWS PENTHROX US STRATEGY**

*** CRESO: '$2m RAISE INCLUDES $369k FOR DEBTS'**

*** NYRADA DELAYS PHASE I/II CHOLESTEROL TRIAL, AGAIN**

*** RECCE R327, R529 AUSTRALIAN PATENT '1st OF FOURTH FAMILY'**

*** LEVENSON BELOW 5% IN ANTEO**

*** MERCHANT FUNDS TAKES 10.3% OF AROVELLA**

*** CITIGROUP REDUCES TO 29% OF BIONOMICS**

*** LIS BOYCE REPLACES IMMUTEP DIRECTOR LUCY TURNBULL**

MARKET REPORT

The Australian stock market was up 1.26 percent on Tuesday April 11, 2023, with the ASX200 up 90.9 points to 7,309.9 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 14 fell, three traded unchanged and one was untraded. All three Big Caps rose.

Next Science was the best, up 7.5 cents or 10.7 percent to 77.5 cents, with 129,997 shares traded. Starpharma climbed 8.9 percent; Nova Eye rose 7.7 percent; Medical Developments and Pharmaxis were up more than six percent; Alcidion, Immutep, Impedimed, Mesoblast and Volpara improved more than four percent; Avita and Compumedics were up more than three percent; Atomo, Dimerix, Nanosonics and Orthocell rose more than two percent; Clinuvel and Cyclopharm were up more than one percent; with Cochlear, CSL, Emvision, Paradigm, Pro Medicus, Proteomics and Resmed up by less than one percent.

Imugene led the falls, down two cents or 13.3 percent to 13 cents, with 42.7 million shares traded. Universal Biosensors lost 7.1 percent; Opthea and Patrys were down more than six percent; Cynata fell 4.35 percent; Resonance was down 3.6 percent; Kazia shed 2.8 percent; Actinogen, Antisense, Polynovo and Prescient were down more than one percent; with Genetic Signatures, Neuren and Telix down by less than one percent.

TELIX PHARMACEUTICALS

In an email to investors not released to the ASX, Telix says it has China approval for an up-to 30-patient, phase I trial of TLX101 for glioblastoma.

Telix said that China's National Medical Products Administration Center for Drug Evaluation had approved the phase I study of TLX101 (4-L-[131I] iodo-phenylalanine, or 131I-IPA) in Chinese patients with newly diagnosed glioblastoma.

The company said that the investigational new drug application was submitted by its Greater China partner, Grand Pharmaceutical Group.

Telix said the study was required to establish the safety profile of TLX101 in a Chinese population, enabling Chinese patients to be enrolled in its planned pivotal trial and was "the first of [its] investigational therapies to move into a clinical trial with Grand Pharma".

In 2021, Telix said its 10-patient, phase I/II trial of TLX101 with external beam radiation therapy for glioblastoma met its primary objective of safety and tolerability, and showed overall survival of 15.97 months for nine of 10 evaluable patients (BD: Oct 20, 2021).

Today, the company said the study "delivered encouraging preliminary efficacy data for further evaluation, demonstrating a median overall survival of 13 months from the initiation of treatment in the recurring setting, or 23 months from initial diagnosis".

Telix said it had begun the IPAX-2 study in Australia to confirm the safety of TLX101 as a front-line therapy in combination with standard-of-care, ahead of progressing to a label-indicating phase II/III study in a larger patient population, the IPAX-3 study.

The company said that the IPAX-2 study would run concurrently to the China study.

Grand Pharma chief executive officer Zhou Chao said that China was a rapid adopter of new radio-pharmaceutical diagnostics and therapeutics.

Mr Zhou said that with more than 30,000 patients diagnosed with glioblastoma multiforme in China each year, there was a "very high unmet medical need for new therapeutic options for this disease, which makes studies like this one critical".

Telix Asia-Pacific chief executive officer Dr David Cade said the phase I trial would "enable Chinese patients to be included in the future global registration trial for TLX101 and potentially enable parallel regulatory submissions in Western markets and China".

Telix fell three cents or 0.4 percent to $7.42 with 1.1 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has increased its Banner Health contract by $US1.25 million ($A1.87 million), with annual recurring revenue of up-to $US440,000 ($A660,000).

Volpara said that the Phoenix, Arizona-based Banner Health was one of the largest non-profit hospital systems in the US, with more than 30 hospitals, academic medical centres, and other related health service centres across six states.

The company said the contract expansion included upgrades and installations of its mammography reporting and patient communication software Patient Hub, formerly Aspen Breast acquired with Mammography Reporting Systems (BD: Jun 3, 14, 2019).

Volpara said the expansion also included upgrades and instillations of Analytics, formerly known as Volpara Enterprise; and Risk Pathways, formerly the acquired breast cancer risk assessment company CRA Health LLC (BD: Feb 2, 2021).

Volpara chief executive officer Teri Thomas said the contract would "help deliver more personalized care, find more cancers and identify high risk patients sooner so they can receive recommended interventions".

The company said installation was expected to be completed within the next nine months, with annual payments expected to contribute to revenue in the year to March 31, 2024.

Volpara was up 3.5 cents or 4.9 percent to 75 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it has a purchase order from Switzerland's University Hospital Lausanne, for its interventional cardiac magnetic resonance imaging (ICMR) equipment.
Imricor said University Hospital Lausanne was the first to establish an ICMR laboratory in Switzerland and would allow physicians from other hospitals to be trained in cardiac diagnostic and interventional procedures.
The company said it had a collaboration agreement with the University Hospital Lausanne since 2019, but construction was delayed due to the Covid-19 pandemic.
Imricor did not disclose the value of the agreement.
Imricor chief executive officer Steve Wedan said the site would be "an incubator for new ICMR technologies, and a catalyst for new ICMR adoption across Switzerland and all of Europe".
Imricor was up one cent or 3.45 percent to 30 cents.

MAYNE PHARMA GROUP

Mayne says it has completed the sale of its US generics business to the Hyderabad, India based-Dr Reddy's Laboratories for $US90 million ($A135.0 million) up-front.
In February, Mayne Pharma said it would sell all 85 of its US generic products and four generic pipeline products to Dr Reddy's for an up-front payment of $US90 million and $US15 million in milestones (BD: Feb 27, 2023).
Today, the company said the total cash received at closing was about $US93.8 million, which included the up-front cash consideration and about $US24 million for working capital but was offset by $US21 million in liabilities relating to the sale.
Mayne said the terms of closing included an arm's length, 10-year supply agreement for certain products manufactured at its Salisbury facility in South Australia.
Mayne Pharma said transaction costs and one-time restructuring costs were being finalized, but it expected a total cost of between $US7 million to $US12 million.
Mayne Pharma was up 19 cents or 4.8 percent to $4.17 with 262,469 shares traded.

AMPLIA THERAPEUTICS

Amplia says a safety review committee has approved a dose escalation and third cohort recruitment for its trial of AMP945 for pancreatic cancer.
Last year, Amplia said that it had recruited the first cohort of patients in its phase Ib/IIa 'Accent' trial of focal adhesion kinase inhibitor AMP945 for advanced pancreatic cancer (BD: Nov 29, 2022).
Today, the company said the study explored whether Amplia's AMP945 in addition to chemotherapy in first-line pancreatic cancer patients improved patient outcomes and would continue to escalate the dose until a dose-limiting safety signal was identified or the effect of AMP945 plateaued.
Amplia chief executive officer Dr Chris Burns said "the data collected from the trial to date supports further dose escalation to a third cohort of patients".
"The data is tracking as predicted from our previous phase I healthy volunteer study with preclinical models, and we believe we are closing in on a dose to take forward into stage 2 of the Accent trial," Dr Burns said.
Amplia was untraded at nine cents.

OSTEOPORE

Osteopore says it has signed a sub-distribution partnership with Kelyniam through its US distribution partner Bioplate Inc, to further its cranial implant sales.

Osteopore said the partnership aimed to secure sales for its US Food and Drug Administration approved, bio-resorbable scaffolds for bone regeneration, with the three-year Bioplate and Kelyniam agreement effective from March 30, 2023.

The company said Kelyniam specialized in custom prosthetics production, had more than 60 sales staff in the US eastern region and would focus on 20 hospitals in eight states, including John Hopkins Hospital, Boston Medical Centre and Tampa General Hospital.

Osteopore said the agreement did not contain binding minimum sales thresholds and each party would bear their own costs.

Osteopore was up 1.55 cents or 17.8 percent to 10.25 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it will begin a search for partner organizations for a Penthrox inhaled methoxyflurane analgesic program leading to US approval.

Last year, Medical Developments said that the US Food and Drug Administration had lifted its clinical hold on its Penthrox inhaled analgesic, allowing a 200-patient, phase III trial to begin (BD: Mar 2, 2022).

In 2018, Medical Developments said its US program was on hold pending a series of questions from the US Food and Drug Administration (BD: Jul 25, Aug 29, 2018).

The company's "green whistle" inhaled methoxyflurane analgesic had been used in Australian ambulance for more than 20 years and had been approved in Europe and Canada.

In 2002, the company said the FDA had "unconditionally lifted … [its] clinical hold on Penthrox" and the two-year, phase III trial would be conducted on a targeted trauma and associated pain patient group, with recruitment to begin "in late 2022".

Today, Medical Developments chief executive officer Brent MacGregor said that feedback from a commercial assessment of the US confirmed there was a "substantial opportunity" for its fast-acting trauma and emergency pain relief product.

"It is clear that delivering value from Penthrox in the US will be best achieved through the support of one or more partners," Mr MacGregor said.

Medical Developments was up seven cents or 6.7 percent to $1.12.

CRESO PHARMA

Creso says that its February placement raised $1,632,000, at 1.506 cents a share, with a further $368,862 comprising offsets against company debts.

In February, Creso said it had "firm commitments" to raise $2 million in a placement to institutional, professional and sophisticated investors, which would be used to complete its psilocybin for post-traumatic stress disorder trial (BD: Feb 17, 2023).

The company said the $1,632,000 million included $100,000 from managing-director William Lay, pending shareholder approval to be sought in or around May 2023.

After the market closed for Easter Thursday, Creso said that of the $2 million raised, $368,862 in subscriptions were "offset against invoices owed by the company" including $225,000 to Achievement Nominees Pty Ltd for legal services provided by the Perth-based Steinepreis Paganin, $57,862 to EAS Advisors for advisory services and $86,000 for Sydney's Six Degrees Group Holdings Pty Ltd for investor relations services.

Creso fell 0.1 cents or 10 percent to 0.9 cents with 1.96 million shares traded.

NYRADA

Nyrada says it has delayed its phase I/IIa trial of its drug candidate for lowering cholesterol, with the trial now “expected to start early second half calendar year 2023”.
Last year, Nyrada said that Covid-related China manufacturing had delayed its 56-subject, phase I, oral cholesterol-lowering candidate NYX-PCSK9i trial, expected to begin by July 2023 (BD: Jun 29, 2022).
Today, the company said it had completed pre-clinical dose and toxicology studies, and the necessary safety and pharmacology studies for regulators to approve the trial were expected “to be completed by the end of April”.
Nyrada said that the phase I/IIa study would assess its drug candidate for safety and tolerability, as well as provide an early indication of the drug’s efficacy in the target patient population.
“The inclusion of a small number of high-cholesterol patients in the study positions us well to bring forward the start of a phase IIb study, a potential time saving of up to 12 months,” the company said.
Nyrada said it had appointed former member of Pfizer’s Lipitor marketing team Seth Gordon as principal consultant for the cholesterol-lowering program.
The company said that the phase IIb study would be used to submit an investigational new drug application to the US Food and Drug Administration.
Nyrada fell half a cent or 4.55 percent to 10.5 cents.

RECCE PHARMACEUTICALS

Recce says the Australian Patent Office intends to grant the first of its fourth patent family for its anti-infectives R327 and R529.
Recce said the patent titled ‘Process for Preparation of Biologically Active Copolymer’ would protect its intellectual property until 2041.
The company said the Australian Patent claims related to the process for preparation of its anti-infectives, as well as use for treatment of disease, particularly bacterial infections, viral infections, and more, as well as its administration by oral, inhalation, injection, aerosol, gel, foam or ointment.
Recce said this was the first of its fourth patent family submissions accepted with intention to grant, with Patent Cooperation Treaty country patent submissions in respective stages of review.
Recce was up one cent or 1.7 percent to 58.5 cents.

ANTEOTECH

Levenson Investments Pty Ltd says it has ceased its substantial holding in Anteo by a share disposal as well as being diluted, from 6.65 percent to 4.87 percent.
In 2019, the Caloundra, Queensland-based Levenson said it had become a substantial shareholder in Anteo with 99,126,615 shares or 6.65 percent (BD: Jun 7, 2019).
Levenson said that on April 5, 2023, it and its associated entity Stydon Capital Pty Ltd had ceased to be substantial holders in Anteo.
Anteo fell 0.1 cents or 2.6 percent to 3.7 cents with 1.4 million shares traded.

AROVELLA THERAPEUTICS

The Perth-based Merchant Funds Management says it has increased its substantial holding in Arovella from 69,717,710 shares (9.25%) to 77,604,246 shares (10.27%).
Merchant said that between February 2 and “April 2023” it bought, sold and transferred shares, buying 550,000 shares for $17,050 or 3.1 cents a share in February 2023.
Arovella was up one cent or 17.9 percent to 6.6 cents with 13.95 million shares traded.

BIONOMICS

Citigroup Global Markets Australia Pty Ltd says it has reduced its substantial holding in Bionomics from 441,640,080 shares (30.0694%) to 423,033,300 shares (28.8026%).
Citigroup said on April 6, 2023 its New York, US-based Citibank NA said it held a decreased interest in Bionomics of 18,606,780 shares under an existing American depository receipts program, but did not disclose the price paid for the shares.
Last year, Bionomics said it would offer 600,000 American depository shares (ADS) at $US8.65 ($A12.92) a share on the Nasdaq to raise up to $US5,190,000 ($A7,744,000), with each ADS worth 180 Australian shares, or 7.17 Australian cents a share (BD: Nov 15, 2022).
Bionomics was unchanged at two cents with 1.3 million shares traded.

IMMUTEP

Immutep says it has appointed Lis Boyce as a non-executive director, replacing Lucy Turnbull who re-joined the board following the death of director Grant Chamberlain.
Immutep said Ms Boyce had more than 30 years of experience in the legal sector and was deputy chair of Ausbiotech’s Ausmedtech Advisory Group and a member of Ausbiotech’s New South Wales Leadership Committee.
The company thanked Ms Turnbull for “stepping in under such tragic and unusual circumstances and for her boundless energy and valued insights” (BD: Feb 2, 25, 2023).
Immutep was up one cent or 4.3 percent to 24.5 cents with 1.4 million shares traded.