Biotech Daily

Wednesday March 27, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 5%; CYNATA DOWN 8%**

*** CSL US BONDS RAISE $1.9b**

*** AMPLIA: 'NARMAFOTINIB COMBO BEATS CHEMO FOR PANCREATIC CA'**

*** PHARMACHAL NOPAYNE, 16AC IMPROVE WOUND HEALING, IN MICE**

*** OSTEOPORE JUMPS 1,062% ON SINGAPORE, VIETNAM APPROVAL**

*** EMVISION ENROLS 180-PATIENT STAGE 2 'EMU' A.I. STROKE STUDY**

*** FEDERAL COURT ORDERS PYRIDAM, PROBIOTEC ACQUISITION MEETING**

*** ANTEOTECH RECEIVES $1.4m QUEENSLAND GRANT**

*** SOMNOMED REQUESTS 'UPDATE, GUIDANCE' TRADING HALT**

*** BIOTRON PLEADS 'SCHULTZ' TO ASX 35% PRICE QUERY**

*** MERCHANT FUNDS REDUCES TO 5.2% OF BCAL**

MARKET REPORT

The Australian stock market was up 0.51 percent on Wednesday March 27, 2024, with the ASX200 up 39.4 points to 7,819.6 points. Nineteen of the Biotech Daily Top 40 were up, nine fell, nine traded unchanged and three were untraded. All three Big Caps rose.

Actinogen was the best, up 0.15 cents or 5.3 percent to three cents, with 2.8 million shares traded. Emvision and Opthea climbed four percent or more; Avita, Clinuvel, Dimerix, Mesoblast and Proteomics were up more than three percent; Amplia, Neuren, Resmed and SDI rose two percent or more; CSL, Cyclopharm, Impedimed, Nanosonics, Orthocell, Paradigm, Polynovo and Pro Medicus were up more than one percent; with Cochlear and Telix up by less than one percent.

Cynata led the falls, down 1.5 cents or 7.9 percent to 17.5 cents, with 118,289 shares traded. Next Science and Percheron (Antisense) lost more than six percent; Medical Developments, Micro-X and Syntara (Pharmaxis) fell more than four percent; Immutep and Prescient were down more than three percent; with Genetic Signatures down by 1.5 percent.

CSL

CSL says it has raised $US1.25 billion ($A1.91 billion) through the issue of US corporate bonds to four banks.
CSL said that it would raise $US500 million in notes at a fixed rate of 5.106 percent per annum for 10-years, with $US750 million in notes to be issued at 5.417 percent a year for 30-years.
The company said it would use the funds to “refinance existing bank debt and the remainder for general corporate purposes”.
CSL told Biotech Daily that the notes would be issued to JP Morgan, Bank of America, Citibank and Hongkong and Shanghai Banking Corporation (HSBC) which would raise the funds from their clients.
The company said settlement of the notes was expected on April 3, 2024, subject to closing conditions.
CSL was up $3.88 or 1.4 percent to $286.35 with 509,185 shares traded.

AMPLIA THERAPEUTICS

Amplia says further data from its 14-patient, phase Ib pancreatic cancer trial shows narmafotinib had “substantially better” response rates compared to chemotherapy alone.
Last year, Amplia said initial data from the phase Ib trial of narmafotinib, then AMP945, for pancreatic cancer with standard-of-care gemcitabine and Abraxane showed it was safe and well-tolerated (BD: Oct 30, 2023).
At that time, the company said no patients had a complete response, five patients (35.7%) had a partial response and eight patients (57.1%) had stable disease, with one patient unevaluable.
Today, Amplia said six patients (42.9%) had a partial response with the remaining eight patients (57.1%) recording “stable disease”.
The company said that seven patients were on the trial for more than six months with two patients on trial for more than 10 months, “substantially higher than predicted from historical studies of gemcitabine and Abraxane treatment alone” which was 5.5 months.
Earlier this year, Amplia said that it had dosed the first of up-to 50 patients in its phase IIa trial of narmafotinib, formerly AMP945, with the standard-of-care for pancreatic cancer (BD: Jan 21, 2024).
Today, the company said the phase IIa portion of the study had enrolled 11 of up-to 26 patients at six trial sites in Australia and five sites in South Korea.
Amplia said the phase IIa study’s primary endpoints were objective response rate and duration on trial, with progression free survival, overall survival and safety and tolerability to be assessed as secondary endpoints.
Amplia said it would conduct a phase IIa interim analysis of efficacy by October, and if the assessment showed six or more partial or complete responses of the 26 patients, it would enrol an additional 24 patients to reach the total 50-patient population.
Amplia managing-director Dr Chris Burns said “the clinical responses we are seeing in patients from the phase Ib stage is very promising”.
“The duration on trial, given the aggressiveness of the disease in these patients, is also extremely encouraging,” Dr Burns said.
“As reported at the end of our phase Ib trial, the drug safety and tolerability also appear to be very acceptable for this patient group,” Dr Burns said.
“We look forward to reporting on further data from the trial as the phase IIa patients are assessed,” Dr Burns said.
Amplia was up 0.2 cents or 2.7 percent to 7.7 cents.

PHARMACHAL HEALTH GROUP

Melbourne's Pharmachal says a trial of 24 mice shows its Nopayne anaesthetic spray with Peptide 16AC coagulant improved wound healing compared to control.

Pharmachal said the trial, with Haifa, Israel's Rambam Medtech compared its Nopayne mini-emulsion local anaesthetic spray alone, Nopayne with Rambam's Peptide 16AC, Peptide 16AC with soft paraffin, and soft paraffin alone, with six mice in each group.

The company said the results showed that after eight days a 10mm wound was reduced to 1.8mm in the Nopayne alone group, 0.6mm in the Nopayne with Peptide 16AC group and 0.4mm in the Peptide 16AC with soft paraffin group, compared with 7.4mm in the soft paraffin alone control group.

Pharmachal said that at five days of treatment both Nopayne with Peptide 16AC and Peptide 16AC with control both reduced wound size by 8.6mm from baseline or 7.0mm smaller wound size compared to control.

The company said the results were a step to producing "a three-in-one spray to rapidly stop bleeding and alleviate pain, whilst also significantly accelerating wound healing".

Pharmachal said it had completed human clinical trials for Nopayne and Rambam had previously conducted animal trials for Peptide 16AC, with clinical trials for the combination treatment expected this year, and the Nopayne and Peptide 16AC combination aimed to "reduce the complications associated with extensive bleeding in cases of trauma and, or haemophilic patients".

The company said the treatment formulation was "significantly more economical than current clotting factor therapies" which could cost a severe haemophilia patient up to $US300,000 ($A460,000).

Pharmachal chief executive officer Charles Fridlender said "the rate of cuts, burns and wounds sky-rocketed in the last few years with 2023 having the most documented conflicts in three decades … [and] we will prepare for human trials mid-year as the next step towards fast-tracking new products for trauma, haemophilia, and diabetic ulcers".

Pharmachal told Biotech Daily the company was hoping to raise up to $C5 million ($A5.6 million) to list on the Toronto Stock Exchange (TSX) Venture Exchange by July 2024.

Pharmachal is a public unlisted company.

OSTEOPORE

Osteopore says Singapore and Vietnam have approved its off-the-shelf orthopaedic products for complex bone reconstruction and bone grafting procedures.

Osteopore said the approvals from Singapore's Health Sciences Authority and Vietnam's Department of Medical Equipment and Construction included its Axopore product for high tibial osteotomy, bone grafting and customizable implants for complex bone loss.

The company said Singapore and Vietnam were two of its three highest performing countries in the past four years and focusing on these territories allowed it to leverage its existing sales and distribution channels to accelerate market access, while managing the costs associated with market expansion.

Osteopore chief executive officer Dr Yujing Lim said the company was "delighted to share another positive step in the ongoing transformation of the company".

"The orthopaedic market is a high-value and high-volume segment with the [high tibial osteotomy] market expected to grow at a [compound annual growth rate of 9.2 percent," Dr Lim said. "These approvals enable Osteopore to supply off-the-shelf and customizable implants, positioning us to capture the potential of these high growth market segments."

Osteopore climbed as much as 69 cents or 1,061.5 percent to 75.5 cents, before closing up 23.5 cents or 361.5 percent at 30 cents with 4.8 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has enrolled all 180 patients in its stage two study of its artificial intelligence-based 'Emu' diagnostic for acute stroke hemorrhage.

Last year, Emvision said it began an up-to 150-patient, stage two, multi-site trial of its Emu portable brain scanner for stroke and stroke mimic patients in emergency departments at three Australian clinical sites (BD: May 29, Jun 29, 2023).

Today, the company said the study enrolled 75 ischaemic stroke, 18 hemorrhagic stroke, 20 transient ischaemic attacks and 67 stroke mimics and showed the Emu device's "suitability … within the streamlined code-stroke hospital protocol along with promising interim analysis of stroke diagnostic performance".

Emvision said in the study its device had a mean scan time of 5.5 minutes and encouraging usability feedback from clinics.

The company said it was preparing a US Food and Drug Administration pre-submission meeting which would help its validation trial meet regulatory requirements.

Emvision managing-director Scott Kirkland said the performance of the company's artificial intelligence models "to help answer the big question 'blood or not' in acute stroke care is particularly encouraging".

"We will be using what we have achieved to help inform our upcoming consultation with the [US Food and Drug Administration]," Mr Kirkland said. "Additionally, we have been pleased with the Emu device's ease-of-use and suitability to the clinical environment given the time sensitive nature of acute stroke care."

"The feedback from the clinical community is clear, the use of non-ionizing and portable neuroimaging devices, that can be easily deployed and provide insights in minutes, has game changing implications for prehospital and bedside stroke management," he said.

Emvision was up 10 cents or four percent to $2.62.

PROBIOTEC

Probiotec says the Federal Court of Australia has ordered it to hold a scheme meeting of shareholders to approve its acquisition by Jakarta's PT Pyridam Farma Tdk.

Last year, Probiotec said it had a binding scheme implementation deed to be acquired by PT Pyridam Farma Tdk at $3.00 a share, a 26 percent premium to the one-month volume weighted average price, valuing it at $251.3 million (BD: Dec 22, 2023).

Today, the company said it had registered the scheme booklet with the Australian Securities and Investments Commission.

The meeting will be held online and in person at Arnold Bloch Leibler, Level 21/333 Collins St, Melbourne on May 29, 2024 at 10am (AEST).

Probiotec was up seven cents or 2.5 percent to $2.86.

ANTEOTECH, QUEENSLAND GOVERNMENT

Anteotech says the Queensland Government has awarded a $1.39 million grant to develop its ultra-high silicon anode for electrical devices including electrical vehicles.

Anteotech said the product was based on its Anteox battery binder additive, that aimed to increase the amount of silicon in battery anodes for cost and weight savings in battery construction as well as decreased charge time and increased battery life.

The company said the grant would be used to purchase equipment and upgrade its facilities, which would help confirm the performance of the anode in commercially accepted pouch-cell formats.

Anteotech fell 0.1 cents or 2.6 percent to 3.8 cents with 5.4 million shares traded.

SOMNOMED

Somnomed has requested a trading halt pending an announcement “regarding a trading update and earnings guidance”.
Trading will resume on April 2, 2024, or on an earlier announcement.
Somnomed last traded at 38.5 cents.

BIOTRON

Biotron has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said the company’s share price increased 34.8 percent from a low of 6.9 cents to a high of 9.3 cents on March 26, 2024, and noted a “significant increase” in the volume of shares traded.
Biotron was up 0.2 cents or 2.6 percent to 7.9 cents with 1.55 million shares traded.

BCAL DIAGNOSTICS

Merchant Funds Management Pty Ltd says it has decreased its shareholding and been diluted in Bcal from 15,686,999 shares (6.23%) to 13,012,000 shares (5.16%).
Perth’s Merchant Funds said it sold 2,674,999 shares in March 2024 for $256,321, or 9.6 cents a share, and was diluted on February 27, 2024 in a share issue.
Last year, Bcal said its over-subscribed share plan at 10 cents a share raised $615,500 of a hoped-for $500,000, taking the total raised with the $2.4 million placement to $3,015,500 (BD: Sep 18, 2023).
Bcal fell half a cent or 4.55 percent to 10.5 cents.