Biotech Daily

Wednesday September 13, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: STARPHARMA UP 23%; MESOBLAST DOWN 6.5%**

*** IMMURON 'RECORD' $1.2m MONTHLY TRAVELAN SALES**

*** FIREBRICK FALLS 81% ON NASODINE COLD TRIAL MISSING ENDPOINT**

*** STARPHARMA 'POSITIVE DEP-IRINOTECAN DATA'**

*** CLARITY: 'FAVORABLE 64-CU-SAR-BOMBESIN RESULTS'**

*** CHIMERIC PLANS CHM0201 LEUKAEMIA TRIAL**

*** RHYTHM, NUTRIPATH TO 'AUTOMATE' COLOSTAT**

*** MEDLAB RECEIVES INDICATIVE BIDS**

*** EMYRIA BUYS PAX CENTRE**

*** DIMERIX RECEIVES $8.9m FEDERAL R&D TAX INCENTIVE**

*** ISLAND WINS US ISLA-101 PATENT**

*** ALLAN GRAY REDUCES TO 11.7% OF STARPHARMA**

MARKET REPORT

The Australian stock market fell 0.74 percent on Wednesday September 13, 2023 with the ASX200 down 53.0 points to 7,153.9 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and two were untraded. All three Big Caps were down.

Starpharma was the best, up three cents or 23.1 percent to 16 cents, with 12.75 million shares traded. Both Impedimed and Patrys improved 6.25 percent; Medical Developments climbed 4.5 percent; Atomo was up 3.7 percent; Amplia, Pharmaxis and Prescient rose more than two percent; with Dimerix and Next Science up by more than one percent.

Mesoblast led the falls, down three cents or 6.5 percent to 43 cents, with 6.3 million shares traded. Opthea lost 5.8 percent; Actinogen, Avita, Neuren, Telix and Volpara fell four percent or more; Cyclopharm, Emvision and Imugene were down more than three percent; Antisense and Resmed shed more than two percent; Clinuvel, Cochlear, Immutep, Polynovo, Pro Medicus and Resonance were down more than one percent; with 4D Medical, CSL, Nanosonics and Paradigm down by less than one percent.

IMMURON

Immuron says sales of Travelan for traveller's diarrhoea for the month of August 2023 were a record $1.18 million for the month and compared to $14,581 for August 2022.
Immuron said the increased sales partially reflected three months of backorders accruing while waiting for good manufacturing practice clearance from the Australian Therapeutic Goods Administration.
The company said it expected continued demand for Travelan as retail pharmacies sold to consumers, with "short-term resident returns", or people on holidays, in July 2023 up 48 percent on the prior period and approaching pre-pandemic levels.
Immuron said sales through Amazon in August were up compared to sales through its largest business-to-business customer Passport Health.
Immuron was up 0.6 cents or 8.1 percent to eight cents.

FIREBRICK PHARMA

Firebrick says its phase III trial of Nasodine nasal spray for the common cold did not meet its primary endpoint, with sterile water placebo better impacting cold severity.
In May, Firebrick said it hoped to recruit 196 patients with early-stage colds confirmed by polymerase chain reaction (PCR) tests as having viral infections, and in August said it had recruited 500 patients for the trial (BD: May 31; Aug 9, 2023).
Today, the company said the placebo outperformed both the impact on cold severity and quality of life, than the Betadine-based Nasodine.
Firebrick said that in a 52-patient, phase III trial from 2019 using the same protocol and treatment regimen, "the overall cold severity benefit of Nasodine in the viral infected subjects was 22.9 percent ($p = 0.048$)".
Firebrick said results in the current trial were "reversed, with the water placebo outperforming Nasodine by 22.7 percent" in 181 patients with a confirmed viral infection.
The company said the results also "conflict" with its recent phase II Covid-19 trial, in which Nasodine treatment led to 100 percent clearance of Sars-Cov-2 from nasal passages, compared to 48 percent for placebo (BD: Aug 7, 2023).
Firebrick said that result was "significantly better than the placebo ($p = 0.028$), which was the same water placebo as used in the 2022-'23 phase III trial".
The company said that it was concerned that the results were "so confounding, unexpected and at odds with previous data that there may be a systematic error or other issue in the data".
Firebrick said that a detailed analysis was "underway to try to identify any causes of such an error".
The company said that it was working with the contract research organization responsible for trial governance and other service providers to thoroughly investigate the trial results.
Firebrick said that "at this time, there is no evidence that the placebo and Nasodine treatments were switched during production, distribution or treatment".
Firebrick chair Dr Peter Molloy said that "given that sterile water has no antiviral properties and povidone-iodine is a proven potent antiviral agent, the reported results of the current trial are inexplicable."
"[The results] are scientifically confounding and completely at odds with everything we know about povidone-iodine and the results of the first phase III trial," Dr Molloy said.
"We continue to believe in Nasodine and its utility in the treatment of the common cold and will pursue all available avenues to create value for this important asset," Dr Molloy said.
Firebrick fell was up 26.8 cents or 81.2 percent from 33 cents to 6.2 cents, with 42.6 million shares traded.

STARPHARMA HOLDINGS

Starpharma says early data from its phase I/II trial of dendrimer enhance product (DEP)-irinotecan for colorectal and ovarian cancer shows “durable anti-tumor responses”.

In 2020, Starpharma said success in its seven-patient, phase I trial would take DEP-irinotecan to an up-to 30-patient phase II trial for colorectal, pancreatic and breast cancer (BD: May 7, 2020).

At that time, the company said the phase I trial was to evaluate safety, tolerability, pharmacokinetics and preliminary efficacy and had identified a recommended phase II dose of 12.5 milligrams/square metre.

Today, Starpharma told Biotech Daily, that overall, the trial had enrolled more than 100 patients in both the monotherapy and combination cohorts.

The company said that 38 patients with metastatic colorectal cancer were enrolled, with 31 patients evaluable from the group.

Starpharma said the patients received DEP-irinotecan monotherapy with 15 of the 31 patients (48.4%) showed disease control, with stable disease and tumor shrinkage for up-to 72 weeks.

The company said in a separate cohort of DEP-irinotecan substituting for irinotecan with in combination with 5-fluorouracil, leucovorin (Folfiri) five colorectal cancer patients were evaluable and had either stable disease, partial responses or complete responses.

Starpharma said 23 platinum-resistant or refractory ovarian cancer patients were treated with DEP-irinotecan monotherapy with seven treated once every two weeks and 18 dosed once every three weeks.

The company said two of the seven (28.6%) had an “objective response rate” and three of the 18 (16.7%) had an objective response rate, compared to other treatments, which had a nine to 16 percent response rate in patients at the same stage and category of disease.

Starpharma said DEP-irinotecan treated patients experienced no severe diarrhoea, an adverse effect that impacted more than 20 percent of patients treated with conventional irinotecan, or Camptosar, which frequently resulted in hospitalization.

The company said patients also reported no instances of cholinergic syndrome, which impacted about 47 percent of patients treated with conventional irinotecan.

Starpharma said patients reported “significantly improved tolerability and quality of life” with DEP-irinotecan compared to irinotecan, marketed as Camptosar.

The company said recruitment for the monotherapy arm of the study had been completed, with the combination arm expected to complete enrolment by the end of the month, with top-line phase II results to follow.

Starpharma said that the anti-tumor activity of DEP-irinotecan, including prolonged disease control in heavily pre-treated patients was “encouraging as it demonstrates the promising clinical utility of DEP-irinotecan and its potential for application in colorectal and platinum-resistant/refractory ovarian cancers”.

The company said that DEP-irinotecan had shown “encouraging efficacy signals in pancreatic, gastrointestinal and breast cancer patients”.

Starpharma chief executive officer Dr Jackie Fairley said that the company had received “consistent feedback from patients and clinicians indicating that DEP-irinotecan represents a better-tolerated treatment option than conventional irinotecan regimens, which are the mainstay chemo-therapeutics for colorectal cancer”.

“Advanced colorectal and ovarian cancers both represent significant unmet medical needs,” Dr Fairley said.

The company said the results would be presented at the International Conference on Molecular Targets and Cancer Therapeutics in Boston, from October 11 to 15, 2023.

Starpharma rose three cents or 23.1 percent to 16 cents with 12.7 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says early data from its phase II trial shows 64-copper Sar-Bombesin identified eight of 25 (32.0%) of negative or equivocal standard-of-care prostate cancer patients.
Last year, Clarity said the trial would assess safety and diagnostic performance of 64-copper sarcophagine (Sar)-Bombesin for men with negative prostate specific membrane antigen (PSMA) positron emission tomography (PET) or low PSMA, in patients with suspected biochemical recurrence of prostate cancer, and patients with metastatic castrate-resistant prostate cancer not eligible for PSMA therapy (BD: Aug 22, 2022).
Today, the company said patients received a mean dose of 210 mega-becquerels (MBq) and were imaged with positron emission tomography at one, three and 24-hours post-administration.
Clarity said no adverse events were reported and "64-copper Sar-Bombesin PET avid disease was identified in over 30 percent of patients with negative or equivocal standard-of-care PSMA PET".
Clarity chair Dr Alan Taylor said "what is most exciting about this data is the identification of lesions in the most difficult to treat patient group, who are negative on all other standard-of-care imaging".
"This … arms clinicians with accurate diagnostic information and helps them determine the best course of treatment for their patients," Dr Taylor said.
"In essence, for the patients that have had a positive Sar-Bombesin scan, this is the difference between having an incorrect negative cancer diagnosis leading to cancer progression and now having an effective treatment plan that may lead to long term remission," Dr Taylor said.
"This patient-centric approach, reinforced by the flexibility in the timing of the scan, centralized product manufacture and its broad distribution to any imaging centre with a PET camera, would be a true paradigm shift in the management of prostate cancer," Dr Taylor said.
Clarity fell 1.5 cents or 1.2 percent to $1.21.

CHIMERIC THERAPEUTICS

Chimeric says it will run an up-to 20-patient, phase Ib trial of CHM0201 for acute myeloid leukaemia with the Houston's University of MD Texas Anderson Cancer Center.
Chimeric said the study would test its CHM0201 "clinically validated [natural killer] cell platform" in combination with the standard-of-care therapy, Azacitidine with Venetoclax, for patients who were not eligible for intensive chemotherapy or allogeneic stem cell transplant.
The company said it would provide CHM0201 to the MD Anderson Cancer Center as well as partial funding, with the remaining balance supported by grant funding from multiple sources including Chicago's Gateway for Cancer Research.
Chimeric said the study had received US Food and Drug Administration investigative new drug clearance and was expected to begin enrolment by the end of 2023.
Chimeric chief medical officer Dr Jason Litten said the trial "aligns with the emerging evidence that cell therapies provide the best clinical outcomes in the earliest line of treatment".
"By combining CHM0201 with the current standard-of-care for [acute myeloid leukaemia] patients we may be able to significantly enhance the outcomes for these patients," Dr Litten said.
Chimeric was up 0.1 cents or 3.3 percent to 3.1 cents.

RHYTHM BIOSCIENCES

Rhythm says it has a deal with the Melbourne-based Nutripath Pty Ltd to automate its Colostat blood test for the detection of colorectal cancer.

Rhythm said it would work with Nutripath and its diagnostic machine vendor Tecan Australia, a subsidiary of the Switzerland-based Tecan Group, to transfer Colostat's immunoassay procedure and protocol to an automated system using Tecan's Evo laboratory diagnostic machine.

The company said the objective of the agreement was "to reduce manual handling, costs, complexity of processes and improve efficiency to obtaining a result".

Rhythm did not disclose the commercial terms of the deal.

Rhythm chief commercial officer Elena Deak said the company was "excited about the opportunity to collaborate with Nutripath and Tecan to investigate and automate our immunoassay on the Tecan Evo".

"This brings significant synergies between all three parties and is a substantial step to ensure that we can bring Colostat to market and make it easier to operate for our customers," Ms Deak said.

Rhythm was up 2.5 cents or 7.6 percent to 35.5 cents.

MEDLAB CLINICAL

Medlab says it has received "several" indicative bids regarding its proposed restructure and will consider the offers with the assistance of Nova Legal.

In March, Medlab said it had retrenched 78 percent of its staff and Hall Chadwick had been appointed to assist with a "restructure of the company's financial affairs" with four directors resigning and two directors appointed (BD: Mar 7, 16, 2023).

Later that month, the company said it would either sell its intellectual property and pharmaceutical inventory, merge, court a major investor, start a joint venture or sell its corporate shell (BD: Mar 21, 2023).

Today, Medlab said it had closed all bidding and would make an announcement "as soon as the board has finalized the terms of the proposed restructure transaction and an agreement has been entered".

The company said it had paid its ASX annual listing fees would not be removed from the Official List.

Medlab said that it was not the subject of an email broadcast circulated by Hall Chadwick "regarding expressions of interest for a medical company".

The company said that chief executive officer Sean Hall and chief financial officer Kerem Kaya had agreed to reduce their hours to ad-hoc use while maintaining their titles, in an effort to "effectively manage cash".

The company said Mr Hall and Mr Kaya had entered into consulting agreements, with Mr Hall being paid $285 an hour and remaining as a director.

Medlab was in a suspension at a post-150-to-one consolidation $6.60.

EMYRIA

Emyria says it has completed its purchase of Mind Body Consulting Pty Ltd, or the Pax Centre for $1.7 million.

In July, Emyria said it would acquire Perth's Pax Centre, which specializes in psychedelic assisted therapy, for $1.7 million, with $400,000 in cash and through the issue of 10,236,220 shares (BD: Jul 3, 2023).

Emyria was up half a cent or 6.4 percent to 8.3 cents with 1.1 million shares traded.

DIMERIX

Dimerix says it has received $8,934,637 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive Program.
Dimerix said the incentive related to its research and development expenditure for the year to June 30, 2023.
In February, the company said it had a $2,842,500 loan from Radium Capital for “early access” to its Federal Research and Development Tax Incentive, allowing it to access 80 percent of its expected incentive for the six months to December 31, 2022 at a compound interest rate of 1.17 percent per month (BD: Feb 17, 2023).
The company said it would use the rebate to repay its Radium Capital loan.
Dimerix was up 0.1 cents or 1.6 percent to 6.2 cents.

ISLAND PHARMACEUTICALS

Island Pharmaceuticals says the US Patent and Trademark Office has granted it a patent for its ISLA-101 dengue fever treatment.
Island said the patent, titled ‘Method of Viral Inhibition’ would protect its intellectual property until April 16, 2034.
The company said the patent related to “methods of preventing or delaying the onset of one or more symptoms of dengue fever, by administering ISLA-101”.
Island said it had been granted patents for ISLA-101 in Australia, Canada, Brazil and Singapore.
Island chief executive officer Dr David Foster said “with major outbreaks continuing to be reported around the world and the number of dengue fever cases increasing, the need for new approaches and treatments such as the ISLA-101 program is more imperative than ever”.
Island was up 0.3 cents or 3.7 percent to 8.4 cents.

STARPHARMA HOLDINGS

Allan Gray Australia Pty Ltd says it has reduced its substantial shareholding in Starpharma from 51,965,719 shares (12.66%) to 47,820,976 shares (11.65%).
The Sydney-based Allan Gray said that between August 16 and September 8, 2023 it sold 4,144,743 shares for $611,510, or an average of 14.75 cents a share.