Biotech Daily

Thursday November 12, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: AMPLIA UP 18%; PATRYS DOWN 5%**

*** MEDADVISOR RAISES $35m FOR ADHERIS ACQUISITION**

*** AROA MYRIAD '100% HS SURGERY WOUND HEALING'**

*** RHYTHM: COLOSTAT EARLY DATA 'BEATS MARKET STANDARD'**

*** PARADIGM DOSES 1st PHASE II PPS FOR MPS-I PATIENT**

*** MEDIGARD APPOINTS ADMINISTRATORS**

*** ST VINCENT'S PLANS BARICITINIB TYPE 1 DIABETES TRIAL**

*** PROTEOMICS APPOINTS ZOTAL ISRAEL PROMARKERD DISTRIBUTOR**

*** CLINUVEL 35% REMUNERATION REPORT 1st STRIKE**

*** ACRUX AGM: 18% OPPOSE 10% PLACEMENT FACILITY**

*** MTP CONNECT SKILLS GAP ANALYSIS, INITIATIVES**

MARKET REPORT

The Australian stock market fell 0.49 percent on Thursday November 12, 2020, with the ASX200 down 31.5 points to 6,418.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Amplia was the best on no news, up four cents or 17.8 percent to 26.5 cents, with 643,497 shares traded. Immutep climbed 7.4 percent; Kazia and Next Science were up more than six percent; Imugene improved 5.3 percent; Genetic Signatures was up 4.05 percent; Polynovo, Prescient and Resonance were up more than three percent; Cochlear, Medical Developments and Nanosonics rose two percent or more; Neuren, Nova, Eye, Pharmaxis, Resmed and Volpara were up more than one percent; with Avita, CSL and Opthea up by less than one percent.

Patrys led the falls, down 0.1 cents or five percent to 1.9 cents, with 5.6 million shares traded. Actinogen and Antisense fell more than four percent; Proteomics and Telix were down three percent or more; Clinuvel, Mesoblast, Optiscan, Paradigm and Starpharma shed more than two percent; Cynata, Dimerix and Orthocell were down more than one percent; with Pro Medicus down by less than one percent.

MEDADVISOR

Medadvisor says it has raised $35 million in a placement and institutional rights offer at 38 cents a share and will complete the acquisition of Adheris Health.

Last week, Medadvisor said it aimed to raise $45 million to acquire the Burlington, Massachusetts-based Adheris from Syneos Health US Inc from an up-to $23.5 million placement and an up-to $37.7 million rights offer, with the hoped-for minimum of $35 million to complete the Adheris acquisition (BD: Nov 2, 6, 2020).

Today, the company said the placement raised about $23.5 million, and the institutional rights raised $11.5 million, with the retail right expected to raise a further $20 million.

The company said the retail one-for 2.5 share offer, for investors at the record date of November 12 would open on November 13 and close on December 1, 2020.

Medadvisor said Adheris Health was a direct-to-patient medication adherence program company and it would have access to its network of 180 million patients, 25,000 associated pharmacies and a network of 618,000 prescribers.

Medadvisor managing-director Robert Read said the acquisition of Adheris was “a transformational deal for Medadvisor”.

“Adheris has strong, long term relationships with many of the world’s major pharmaceutical companies-working with them through a suite of products which are powered by data and analytics to help engage patients and health care providers,” Mr Read said. “Their knowhow and market knowledge will help accelerate the development of medication adherence solutions for all our customers.”

Medadvisor fell one cent or 2.5 percent to 39 cents.

AROA BIOSURGERY

Aroa says an eight-patient trial shows its Myriad sheep stomach graft is 100 percent effective for wound healing after surgery in inflammatory hidradenitis suppurativa patient.

Aroa said that hidradenitis suppurativa was an inflammatory skin condition often involving infected lesions particularly in the groin and armpits.

The company said that a study of eight reconstructive surgeries for hidradenitis suppurativa showed a healing rate of 100 percent when Myriad was used, with no major complications reported from three months to up-to 12 months after surgery.

The company said the article, titled: ‘Extracellular matrix graft for the surgical management of Hurley stage III hidradenitis suppurativa: a pilot case series’ was published in the Journal of Wound Care, with an abstract available at: https://www.magonlinelibrary.com/doi/abs/10.12968/jowc.2020.29.11.624.

Aroa said Myriad was a was a highly perforated, thick, multi-layered endoform graft, derived from ovine, or sheep, forestomach, designed for dermal soft tissue reconstruction of complex wounds, tissue resections and injuries from trauma.

Aroa head of research and clinical development Dr Barnaby May said that “all patients who underwent surgical reconstruction for stage III [hidradenitis suppurativa] using Myriad, either as an implant or for regeneration of the dermis, healed well and only one minor complication was reported”.

“Equally important, for such a painful and debilitating condition, all patients reported no complications or recurrences at long-term follow-up,” Dr May said.

Co-author Prof Abigail Chaffin said the study showed “the utility of the Myriad device for both implant procedures and dermal reconstruction, with no significant complications reported and offers a potential solution for people suffering the most serious cases of hidradenitis suppurativa”.

Aroa was up 2.5 cents or 1.9 percent to $1.32 with 2.15 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says its Colostat colorectal cancer test kit prototype outperforms the market standard faecal immunochemical test and data from individual biomarker test kits.
Rhythm said that preliminary test results from 200 blood samples process with its Colostat test kit show high accuracy and successful ongoing differentiation between cancerous and healthy blood samples.
The company said its Colostat showed 77 percent sensitivity and 95 percent specificity in identifying patients with and without cancer, while the faecal immunochemical test showed 63 percent sensitivity and 92 percent specificity.
Rhythm said the results compared to individual biomarker test kit data from the Commonwealth Scientific and Industrial Research Organization which had 73 percent sensitivity and 95 percent specificity.
Rhythm chief executive officer Glenn Gilbert said the preliminary results showed “the high accuracy and specificity of the Colostat prototype test-kit which clearly distinguishes between cancerous and healthy blood samples”.
“This is a significant step forward for the company,” Mr Gilbert said.
Rhythm was up 14 cents or 50 percent to 42 cents with 6.3 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has dosed the first of 10-patients in its 48-week, phase II trial of pentosan poly-sulphate sodium for muco-poly-saccharidosis type-I.
In August, Paradigm said it had received ethics committee approval for an open-label, single-centre, pilot safety and tolerability trial of pentosan poly-sulphate sodium (PPS) for muco-poly-saccharidosis type-I (MPS-I) at the Adelaide’s Women’s and Children’s Hospital (BD: Aug 11, 2020).
Today, the company said MPS-I was a rare metabolic disorder “caused by a genetic defect in the catabolism of two glycosamino-glycans … resulting in abnormal bone development, growth retardation, cardiac and respiratory problems, and sometimes cognitive impairment”.
Paradigm said the trial would enrol up-to 10 patients aged at least five years old, divided into two dosing cohorts of either 0.75mg/kg or 1.5mg/kg.
The company said patients would receive subcutaneous injections of PPS weekly for the first 12 weeks and then every second week until week-48.
Paradigm said the trial would evaluate whether pentosan poly-sulphate sodium could alleviate pain and functional symptoms in MPS-I patients who have received enzyme replacement therapy or haematopoietic stem cell therapy, where these patients continue to have residual joint and muscle pain.
Paradigm chief executive officer Paul Rennie said the trial data would “be vital to support Paradigm’s future regulatory filings and applications for the development of PPS as a potential adjunctive therapy to enzyme replacement therapy”.
Paradigm fell eight cents or 2.6 percent to $3.00 with 1.4 million shares traded.

MEDIGARD

Medigard says it has appointed Mark Pearce and Michael Dullaway from Brisbane’s Pearce & Heers “as joint and several administrators of Medigard”.
In an announcement titled ‘letter to shareholders’ Medigard said it appointed administrators because “the company was insolvent, or would become insolvent”.
Medigard was suspended on accounts and last traded at two cents.

ST VINCENT'S INSTITUTE OF MEDICAL RESEARCH

St Vincent's says it is planning a two-year trial of baricitinib in type 1 diabetes patients aged 12 to 30 years old who have been diagnosed in the last 100 days.

The Institute said the baricitinib in new onset type 1 diabetes (Bandit) trial would provide data to determine if baricitinib, a drug for rheumatoid arthritis, would protect insulin-producing cells from immune attack.

St Vincent's Prof Helen Thomas said that protecting the insulin-producing cells "would allow people who have recently been diagnosed with the disease to continue to produce insulin for a longer period and improve their glucose control".

The Institute said that people with type 1 diabetes were dependent on insulin injections to regulate their blood glucose levels, which carried the risk of long-term complications including heart attack, stroke, vision impairment, kidney disease and nerve damage.

St Vincent Institute director Prof Tom Kay said that "if the trial proves successful, production of insulin will be maintained and people with type 1 diabetes will be significantly less dependent on insulin treatment".

The Institute said that in the trial's first year participants would attend a site once a month and take either baricitinib or placebo once a day and in the second year, they would to visit their trial site on two occasions for follow-up to check blood glucose and other levels.

St Vincent's said by the Juvenile Diabetes Research Foundation funded the trial, at the Royal Melbourne Hospital, the Royal Children's Hospital and St Vincent's Hospital.

PROTEOMICS INTERNATIONAL

Proteomics says it has appointed the Tel Aviv-based Zotal to distribute its Promarkerd immunoassay diabetic kidney disease test in Israel.

Proteomics said Zotal would be responsible for product registration and reimbursement, which were expected to be granted within six months and it would receive payment for each test kit sold, but further details of the two-year agreement were confidential.

Proteomics said diabetes affected one in eight adults in Israel and was the country's fifth leading cause of death.

Proteomics managing-director Dr Richard Lipscombe said that "entering both the European and Middle Eastern markets in recent weeks will drive demand for Promarkerd".

Proteomics fell 1.5 cents or three percent to 48.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says its annual general meeting passed all resolutions, but with 35.35 percent of votes against the remuneration report, earning a first strike.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and, if passed, the directors must stand for re-election.

Last year, Clinuvel said that 40.1 percent of annual general meeting votes opposed the issue of 1,513,750 performance rights worth $43.9 million to chief executive officer Dr Phillipe Wolgen (BD: Nov 20, 2019).

Today, the company said the re-election of chair Willem Blijdorp and Prof Jeffrey Rosenfeld as directors passed more easily.

Clinuvel's annual report said it had 49,410,338 shares meaning the remuneration report opposition was 11.8 percent of the company, sufficient to requisition general meetings.

Clinuvel fell 44 cents or 2.1 percent to $20.30 with 181,314 shares traded.

ACRUX

Acrux says its annual general meeting carried all resolutions, but with 17.9 percent opposition to the 10 percent placement capacity.
Acrux said that there were 34,282,000 votes (82.07%) in favor of the additional placement capacity, with 7,491,960 votes (17.93%) opposed.
The company said the resolution to approve the equity plan and the grant of rights to director Norman Gray faced dissent of 14.29 percent and 13.96 percent, respectively.
Acrux said that the remuneration report had 10.43 percent of votes in opposition, with the re-election of chair Ross Dobinson as a director passed more easily with 94.0 percent of votes in favor.
According to Acrux's most recent Appendix 2A application for quotation of securities, the company had 168,747,403 shares on issue, meaning the 7,491,960 the votes opposed to placement capacity increase amounted to 4.44 percent of the company, not sufficient to requisition extraordinary general meetings.
Acrux was up half a cent or 2.9 percent to 17.5 cents.

MTP CONNECT

MTP Connect says it has identified skill gaps the medical technology, biotechnology and pharmaceutical sectors and will fund training programs to address them.
MTP said the data came from the first of three reports produced by the Researcher Exchange and Development within Industry (REDI) program, a $32 million initiative operated by MTP Connect and funded by the Medical Research Future Fund.
MTP Connect managing-director Dr Dan Grant said that "with nearly 1,300 companies in the [medical technology, biotechnology and pharmaceutical] sector and 68,000 jobs, it is a major contributor to the Australian economy - but we have some work to do to create a future ready workforce".
Mr Grant said the report identified skill gaps including "understanding of quality management systems and protocols, linked to advanced manufacturing; leadership awareness about the importance and best-practice management of cyber security, linked to health data; and strategic clinical trial design to meet regulatory requirements and payer needs, linked to commercialization".
Dr Grant said that "we need to act now to systematically address these gaps in workforce skills".
MTP Connect said that round one of the REDI program to fill emerging skills not addressed in the sector would open on November 13, 2020 and called for proposals for new training courses and programs.
The organization said that an information session will be held via webinar on November 19, 2020 with registration available at:
https://www.mtpconnect.org.au/Story?Action=View&Story_id=321.
MTP said the 'MTP Connect REDI Program Skills Gap Analysis Interim Report' was available at https://www.mtpconnect.org.au/reports/redi-skills-gap.