Biotech Daily

Tuesday October 22, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AROA UP 11.5%; IMPEDIMED, OPTHEA DOWN 11%**

*** CSL 'R&D INVESTMENT UP DESPITE TRIAL SET-BACKS'**

*** AROA H1 RECEIPTS UP 26% TO $37m**

*** LBT SELLS 1st APAS SYSTEM TO BRISTOL MYERS SQUIBB**

*** PYC: 'VP-001 SAFE FOR RP11 AT HIGHEST DOSE'**

*** IMMUTEP 6.3m M-D, CSO RIGHTS AGM**

*** ARTRYA PLEADS 'SCHULTZ' TO ASX 38% PRICE QUERY**

*** EBR: HOST PLUS TAKES 12%, HESTA 9%, BRANDON 6%**

*** PLATINUM REDUCES TO 14.9% OF SYNTARA**

MARKET REPORT

The Australian stock market fell 1.66 percent on Tuesday October 22, 2024, with the ASX200 down 138.7 points to 8,205.7 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 23 were down and three traded unchanged. All three Big Caps were down.

Aroa was the best, up six cents or 11.5 percent to 58 cents, with 915,374 shares traded. Orthocell improved 7.4 percent; Amplia and Prescient climbed more than six percent; Alcidion and Medical Developments were up more than five percent; Cynata and Micro-X improved more than four percent; Actinogen, Clarity and Curvebeam rose more than three percent; Imugene and Nova Eye climbed more than two percent; with SDI up 1.6 percent.

Opthea led the falls, down 10 cents or 11.0 percent to 81 cents, with 6.5 million shares traded, followed by Impedimed down 10.9 percent to 5.7 cents, with 6.3 million shares traded.

Polynovo lost 8.4 percent; Paradigm and Pro Medicus fell four percent or more; Compumedics, Genetic Signatures, Nanosonics and Starpharma were down more than three percent; CSL, Medadvisor, Mesoblast, Neuren, Percheron and Telix shed more than two percent; 4D Medical, Avita, Cochlear, Dimerix, Proteomics, Resonance and Syntara were down one percent or more; with Clinuvel, Cyclopharm, Emvision and Resmed down by less than one percent.

CSL

By JAMIE MILLER, DEPUTY EDITOR

CSL says that despite "a few late-stage [trial] setbacks" it is continuing to invest in its "core [immunoglobulin], plasma and vaccine platforms to support future growth".

CSL said it had the late-stage setbacks included Kcentra for trauma, Hizentra for dermatomyositis and clazakizumab chronic active antibody-mediated rejection; but “each of these products have promising follow-on indications which we are actively pursuing”.

The company said that “enrolling and dosing [Kcentra trauma] patients, with [the] highest risk of mortality in hospitals according to clinical trial standards is challenging, impacting both feasibility and sample size”.

CSL said that the 134-patient, phase III trial of Hizentra for dermatomyositis “did not meet [the] primary efficacy endpoint”.

The company said that a “futility analysis enabled [a] clear decision to terminate [the] study” of clazakizumab for chronic active antibody-mediated rejection; with the “results disappointing and unexpected given phase II … data”.

In its 2024 research and development briefing, CSL said it was continuing to invest in its “core [immunoglobulin], plasma and vaccine platforms to support future growth”.

In August, the company said that research and development spending for the year to June 30, 2024 was up 12.8 percent to $US1,428 million ($A2,147 million), compared to the prior period; or 9.6 percent of revenue, compared to $US1,269 million or 9.5 percent of revenue in 2023 (BD: Aug 13, 2024).

Last year, CSL said that it had replaced its annual research and development briefing with its first “capital markets day” (BD: Oct 16, 2023).

Today, the company said that its cardiovascular and metabolic segment had released top line results from its18,200-patient, phase III trial of CSL112 for acute myocardial infarction and dosed the first phase III patient with clazakizumab for end stage kidney disease.

In February, CSL said the CSL112 trial to reduce the risk of major adverse cardiovascular events following a heart attack did not meet its primary endpoint (BD: Feb 12, 2024).

Today, the company said it had advanced research in its immunology business completing its phase III trial of Hizentra for dermatomyositis, enrolling the first patient in its phase II study of anumigilimab for the skin disease hidradenitis suppurativa and filed US, EU and Japan regulatory submissions for garadacimab for hereditary angioedema.

CSL said it was advancing a phase III study of Idelvion in China and CSL889 for sickle cell disease as well as completing a phase III trial of CSL964 for acute graft-versus-host disease.

The company said that 35 percent of its research and development expenditure was used for its recombinants, genetic medicines and Vifor products, with 35 percent for plasma, 20 percent for vaccines and the remaining 10 percent for regulatory approvals.

CSL said its Hemgenix for haemophilia B showed a “consistently favorable safety profile, with no treatment-related adverse events reported and no safety events reported three years post-treatment”, with registration, launch and post-registration studies ongoing and the final phase III patient enrolled this month.

The company said it had advanced regulatory submissions for Hemgenix in the US, EU, UK, Australia, Japan, France, Canada and South Korea, as well as Kostaive in Japan and the US and garadacimab in the EU, Japan and the US.

CSL said its vaccine business continued to research self-amplifying messenger RNA which it believed had “potential advantages” compared to conventional messenger RNA.

The company said it had 21 programs in clinical development with six phase I trials, six phase II trials and nine phase III trials currently running.

CSL fell $8.90 or 2.9 percent to $294.13 with 696,832 shares traded.

AROA BIOSURGERY

Aroa says receipts from customers for the six months to September 30, 2024 were up 25.9 percent to $NZ37,709,000 ($A34,152,000).

Aroa said the increase was “primarily due to an increase in the sales of its sheep forestomach-based Myriad, Ovitex and Ovitex PRS” (plastic and reconstructive surgery) for complex wound and soft tissue reconstruction products.

The company said it continued “to see productivity gains across the whole sales organization, as well as five percent quarter-on-quarter growth in active Myriad accounts to 265”.

Aroa said during the six months it had received regulatory approval to sell its Myriad Matrix and Endoform products in Argentina and Endoform in Egypt.

The company said it had a cash burn of $NZ1,224,000 for the three months to September 30, 2024, with cash and cash equivalents of $NZ21,600,000, compared to $NZ33,955,000 at September 30, 2023.

Aroa was up six cents or 11.5 percent to 58 cents.

LBT INNOVATIONS

LBT says it has sold its first automated plate assessment system (Apas) for microbiology culture analysis to Princeton, New Jersey’s Bristol Myers Squibb.

LBT said that in July 2024, it had completed the installation and training of the Apas system at Bristol Myers Squibb to commence an evaluation of the technology’s ability to read microbiology culture plates collected during environmental monitoring.

The company said the initial phase of the evaluation would focus on the performance of Apas Independence to read the 90mm culture plates.

LBT said that it expected to complete the installation by July 2025.

The company said that it was performing tests at Bristol Myers Squibb’s manufacturing facilities in the US as part of its development of an Apas application for 55mm contact culture plates that would “further increase the opportunity of placements across their network”.

Earlier this year, the company said it was developing a module for its Apas to read 55mm contact plates for pharmaceutical environmental monitoring (BD: Aug 26, 2024).

Today, LBT said that to date, eight Apas instruments had been sold to pharmaceutical customers since the product was launched in March 2024 (BD: Mar 13, 2024).

The company said the sale price was consistent with pricing previously disclosed to the market.

Previously, LBT managing-director Brent Barnes told Biotech Daily that the standard retail price per unit was $US300,000 ($A436,566) with a further $US20,000 ($A29,103) per year licence fee, but that varied with each deal (BD: May 18, 2021).

Today, Mr Barnes said the company was “focused on delivering against our strategy to engage with large multinational pharmaceutical manufacturers for the sale and placement of Apas instruments”.

“We remain highly engaged in supporting Bristol Myers Squibb with their evaluation of Apas Independence at their Microbiology Centre of Excellence in the US,” Mr Barnes said.

“The evaluation is an important process that determines the potential benefits our Apas technology may bring to enhance environmental monitoring operations across their global manufacturing facilities,” Mr Barnes said.

LBT was up 0.1 cents or 6.7 percent to 1.6 cents with 1.5 million shares traded.

PYC THERAPEUTICS

PYC says the safety and tolerability of VP-001 for retinitis pigmentosa type 11 (RP11) is consistent in the three patients receiving three highest doses of 75 micrograms (µg).
Earlier this year, PYC said its nine-patient, single-ascending dose study of VP-001 for the blinding eye disease RP11 showed the drug was safe and well-tolerated at the highest intravitreal dose of 75µg (BD: Jul 1, 2024).
Later, the company said it had approval for the nine patients in the single ascending dose study to receive multiple doses (BD: Jul 23, 2024).
Today, PYC said no treatment-emergent severe adverse events were reported in the three patients administered three times with the maximum dose of VP-001.
The company said that the improvements in RP11 patients who received a single dose of VP-001 had been repeated in patients who had received multiple doses of the drug.
PYC said two of three patients in the highest multiple-dose cohort showed that the "treated eye outperformed the untreated eye and showed improvement across all three endpoints" including mean retinal sensitivity, number of scotomas and visual acuity.
The company said in the third patient, the treated eye "outperformed the untreated eye and showed improvement from baseline across two endpoints and was equal to the untreated eye in the third endpoint, [with] no change in number of scotomas in both eyes".
According to Moseby's medical dictionary a scotoma is a visual defect in a defined area.
PYC said it would provide an update on the two multiple dose studies by July 2025.
PYC was unchanged at 20 cents with 7.4 million shares traded.

IMMUTEP

Immutep says its annual general meeting will vote to issue managing-director Marc Voigt and chief scientific officer Prof Frederic Triebel 6,300,000 performance rights.
Immutep said shareholders would vote to issue Mr Voigt 3,600,000 performance rights valued at 40 cents each, the five-day volume weighted average price up to September 9, 2024, and vesting in three equal tranches subject to performance milestones.
The company said shareholders would vote to issue chief scientific officer and director Prof Triebel 2,700,000 rights, under the same conditions as Mr Voigt's rights.
Immutep said the securities were in addition to Mr Voigt's EUR306,316 ($A496,111) yearly salary and Prof Triebel's EUR277,800 ($A449,898) annual pay.
The company said investors would vote on the remuneration report, elect Prof Triebel as a director, ratify the prior issue of shares, approve termination benefits, the issue of performance rights and/or options under the incentive plan and the takeover provisions.
The meeting will be held at Piper Alderman, Level 23, Governor Macquarie Tower, 1 Farrer Place, Sydney, on November 22, 2024 at 10.30am (AEDT).
Immutep was unchanged at 30 cents with 2.1 million shares traded.

ARTRYA

Artrya has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 37.7 percent from 34.5 cents on Thursday October 17, 2024 to a high of 47.5 cents yesterday, and noted a "significant increase" in the volume of shares traded.
Artrya noted that "an investor roadshow was undertaken last week on the east coast of Australia" and referenced its presentation announced to the ASX on October 15, 2024.
Artrya was unchanged at 45 cents.

EBR SYSTEMS

EBR says Health Employees Superannuation Trust, Host Plus Superannuation Trust and Brandon Capital Partners are substantial shareholders following its capital raise.

Last month, EBR said that it had raised $45.8 million in a fully-underwritten placement and one-for-20, institutional rights offer at 82 cents per Chess depository instrument (CDI), with a retail offer to raise a further $4.2 million (BD: Sep 18, 20, 2024).

Today, the company said it had completed the capital raising.

EBR said the Health Employees Superannuation Trust Australia Ltd, or HESTA, held 27,194,074 CDIs, or 8.87 percent, Host Plus Pty Ltd held 34,927,768 CDIs, or 11.39 percent, and Brandon Capital Partners held 20,923,126 CDIs, or 6.82 percent.

The company said the Brandon Capital-managed Medical Research Commercialisation Fund and three of its “services” were the registered holders of the CDIs.

EBR was up two cents or 1.9 percent to $1.06.

SYNTARA

Platinum Investment Management Ltd says it has reduced its substantial shareholding in Syntara from 205,406,102 shares (15.92%) to 204,352,115 shares (14.88%).

The Sydney-based Platinum said that on October 18, 2024 it sold 1,053,987 shares for $54,725, or 5.2 cents a share.

Syntara fell 0.1 cents or 1.85 percent to 5.3 cents with 4.3 million shares traded.