# Biotech Daily

Monday March 6, 2023

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: PRESCIENT UP 18%; ONCOSIL DOWN 14%**

*** S&P ASX INDICES: 3 BIOTECHS UP; 7 DOWN**

*** RHYTHM WITHDRAWS COLOSTAT TGA APPLICATION; TO RESUBMIT**

*** IMEX, RIMAB $1.1m FAMISANAR MRI CONTRACT**

*** PREMIER TO BUY AROA WOUND REPAIR PRODUCTS**

*** ARGENICA ARG-007 'SAFE, WELL-TOLERATED'**

*** CRESO $2.5m SBC CONVERTIBLE NOTES, PAYS OBSIDIAN**

*** PYC: FDA APPROVES VP-001 RETINITIS PIGMENTOSA TYPE 11 TRIAL**

*** LAZARD TAKES 5.3% OF MAYNE PHARMA**

*** CSL M-D DR PAUL MCKENZIE REPLACES CEO PAUL PERREAULT**

## MARKET REPORT

The Australian stock market was up 0.62 percent on Monday March 6, 2023, with the ASX200 up 45.0 points to 7,328.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and one was untraded. All three Big Caps fell.

Prescient was the best on no news, up 1.6 cents or 18.0 percent to 10.5 cents, with 3.1 million shares traded. Dimerix climbed 13.6 percent; Immutep improved 8.2 percent; Avita was up 4.2 percent; Antisense, Cynata, Emvision, Imugene, Starpharma and Telix were up three percent or more; Atomo and Resmed rose two percent or more; Cochlear, Neuren and Pro Medicus were up more than one percent; with CSL and Mesoblast up by less than one percent.

Oncosil led the falls, down 0.5 cents or 13.5 percent to 3.2 cents, with 8.4 million shares traded. Actinogen lost 8.75 percent; Orthocell was down 7.1 percent; Kazia and Medical Developments were down more than six percent; Nova Eye, Polynovo, Resonance and Volpara shed more than five percent; Genetic Signatures fell 4.7 percent; Alcidion was down 3.85 percent; Amplia, Micro-X, Paradigm and Proteomics shed more than two percent; Universal Biosensors was down 1.7 percent; Clinuvel, Nanosonics, Next Science and Opthea were down by less than one percent.

## STANDARD AND POOR'S DOW JONES INDICES

Polynovo has been promoted into the Standard & Poor's ASX200 index, Anteris and Vitura have been promoted into the All Ordinaries Index, with six demoted.
Effective from March 20, 2023, Standard & Poor's said that 4D Medical, Alcidion, Anteo, Avita, Impedimed, Medical Developments and Volpara would be removed from the ASX All Ordinaries Index.
Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.
The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

## RHYTHM BIOSCIENCES

Rhythm says it has withdrawn its Colostat application to the Australian Therapeutic Goods Administration for an Australian Register of Therapeutic Goods listing
Last year, Rhythm said the final TGA filing for its Colostat blood test for colorectal cancer screening was "a significant regulatory milestone" allowing the commercial sale of Colostat in Australia, with an answer expected within six months (BD: May 12, 2022).
Today, the company said that "after receipt and analysis of a [26-page] thorough application review and its most recent engagement with the Australian Therapeutic Goods Administration … [it] decided to withdraw its current Colostat application".
Rhythm said that the withdrawn submission "was detailed, technical and in excess of 1,300 pages" and expected the new application to be this year.
Rhythm said it expected to be able to answer the majority of questions within the TGA 20 business days required timeframe but "a minority of the questions require new internal analytical testing … which require three different production batches of commercially made Colostat test-kits from our overseas based manufacturer Biotem".
Rhythm said the logistical and supply chain timing would prevent it being able to receive the commercially made test-kits and answer the minority of TGA questions.
The company said that the TGA application withdrawal did not impede its proposed market entry activities into other Conformité Européenne (CE) mark conforming territories and additional international markets, including the US.
Rhythm executive chair Otto Buttula said that "having decided to withdraw [the] current TGA submission for Colostat is clearly disappointing for all stakeholders".
"With a new submission to be completed in line with the questions raised by the TGA, we believe we have a better blueprint to follow in framing our new application," Mr Buttula said. "I remain confident of a TGA registration for Colostat in the future."
Rhythm fell 36.5 cents or 38.0 percent to 59.5 cents with 5.3 million shares traded.

## IMEX HEALTH SERVICES

Imex says subsidiary Rimab has a $1.1 million a year contract for magnetic resonance imaging (MRI) studies for Columbia's fifth largest insurance provider Famisanar.
Imex said the initial four months contract had an automatic four-month renewal and, included a monthly package of 1,500 MRI studies with an option to increase the volume.
The company said it would provide MRI studies using Imex's enterprise software for Famisanar's patients in the Cundinamarca region of Colombia, which included the country's capital Bogota.
Imex said the operations and billing for the contract began in February 2023.
Imex was up two cents or 4.9 percent to 43 cents.

## AROA BIOSURGERY

Aroa says it has the Charlotte, North Carolina-based healthcare provider Premier Inc will buy its Myriad and Symphony sheep-stomach-derived wound repair products.
Aroa said Premier had more than 4,400 US hospitals and health systems as clients, as well as 250,000 other providers and organizations and had supply agreements with "all four of the largest [group purchasing organizations] in the US".
The company did not include the commercial terms of the agreement.
Aroa was unchanged at $1.10.

## ARGENICA THERAPEUTICS

Argenica says interim data from the phase I trial of ARG-007 has shown the drug to be safe and well-tolerated at all doses administered.
Argenica said there were a total of 31 adverse effects, but "only 10 of these were considered related to the administration of ARG-007" and none were dependent on the dosage of ARG-007, with the highest dose not resulting in any adverse events.
The company said the most frequently reported adverse effects were headaches and dermatitis.
Argenica said that ARG-007 did "not induce and immune reaction when administered at any of the four doses tested".
The company said that of all the treatment emergent adverse events 54.2 percent of ARG-007 had at least one mild or moderate event, with the 62.5 percent of the placebo group experiencing at least one mild or moderate event.
Argenica fell one cent or 2.3 percent to 43 cents.

## CRESO PHARMA

Creso says it has commitments for $2.5 million in convertible notes from Melbourne's SBC Global Investment Fund and will pay its debt to New York's Obsidian Global.
Creso said the notes were at an interest rate of eight percent in two tranches, pending shareholder approval, with the first tranche worth $1,700,000 and the second worth $800,000.
In January, the company said it had drawn $500,000 from the convertible note facility it had with New York's Obsidian, taking its previously announced $5 million raised from Obsidian to $5.5 million (BD: Nov 1, 2022; Jan 22, 2023).
Today, Creso said it would pay Obsidian $US1.1 million ($A1.63 million) under the terms and conditions of the previously announced convertible notes plus a cash payment of $US485,000 from the proceeds of the SBC notes and issue it 13,440,924 shares, with Obsidian's convertible notes to be cancelled following these activities.
The company said the convertible notes issue to SBC had a face value of $1.1111 each and a conversion price of the lesser of four cents or 150 percent of the 5-day volume weighted average price.
Creso said in the period between 60 and 90 days after the purchase date, and on every monthly anniversary after, it would redeem $250,000 of the first tranche and $125,000 of the second tranche.
The company said Everblu was lead manager for the raising, and would receive a six percent fee up to $150,000 and, pending shareholder approval, receive 100 million broker options for every $2.5 million raised exercisable at eight cents each by January 31, 2027.
Everblu chair Adam Blumenthal was previously Creso's chair.
Creso fell 0.1 cents or 7.7 percent to 1.2 cents with 11.1 million shares traded.

## PYC THERAPEUTICS

PYC says the US Food and Drug Administration has approved an up-to 15-patient trial of VP-001 for retinitis pigmentosa type 11, with dosing to begin by July 2023.
PYC said retinitis pigmentosa type 11 (RP11) was a blinding eye disease caused by insufficient expression of the PRPF31 gene, and that VP-001 was hoped to restore the expression of the PRPF31 gene.
The company said the first trial would be a single ascending dose study to establish safety and tolerability, with hopes to progress into multi-dose trials in 2024.
PYC was up 0.1 cents or 1.2 percent to 8.7 cents with 6.5 million shares traded.

## MAYNE PHARMA GROUP

Lazard Asset Management says it has again become a substantial shareholder in Mayne Pharma with 4,539,772 shares or 5.3 percent of the company.
The Sydney-based Lazard said that it bought shares between November 11, 2022 and March 1, 2023, with the single largest purchase of 7,035,854 shares on January 17 for $1,586,202 or 22.5 cents a share, prior to the 20-to-one consolidation, equivalent to $4.51 a share.
Mayne was up 16 cents or 4.35 percent to $3.84 with 609,113 shares traded.

## CSL

CSL says Dr Paul McKenzie has formally replaced managing-director and chief executive officer Paul Perreault, effective from today, March 6, 2023.
CSL said Mr Perreault would remain as a strategic advisor to the company until September 6, 2023.
Last year, the company said that its chief operating officer Mr McKenzie would replace 10-year chief executive officer Mr Perreault from today (BD: Dec 13, 2022)
CSL was up $1.48 or 0.5 percent to $294.50 with 490,778 shares traded.