Biotech Daily

Monday September 30, 2024

Daily news on ASX-listed biotechnology companies

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*** RHYTHM TO LOSE DR TREVOR LOCKETT, LOU PANACCIO; M-D**

*** POLYNOVO LOSES 14-YEAR DIRECTOR BRUCE RATHIE**

*** ABBY MACNISH NIVEN REPLACES ALTERITY CFO PHILLIP HAINS**

*** ONCOSIL: PETER HALL WON'T JOIN BOARD**

MARKET REPORT

The Australian stock market was up 0.7 percent on Monday September 30, 2024, with the ASX200 up 57.6 points to 8,269.8 points. Twenty of the Biotech Daily Top 40 companies were up, 16 fell and four traded unchanged.

Atomo was the best, up 0.2 cents or 10.5 percent to 2.1 cents, with 622,400 shares traded; followed by Syntara, up 0.4 cents or 10.3 percent to 4.3 cents, with 4.25 million shares traded. 4D Medical and Universal Biosensors both climbed 7.1 percent; Percheron and Prescient improved five percent or more; Mesoblast was up four percent; Amplia, Cyclopharm and Medadvisor were up more than three percent; Aroa, Cynata, Imugene, Medical Developments, Nova Eye, Paradigm and Pro Medicus rose two percent or more; Compumedics, Starpharma and Telix were up one percent or more; with Cochlear and CSL up by less than one percent.

Immutep led the falls, down 1.5 cents or 4.4 percent to 32.5 cents, with 2.8 million shares traded. Micro-X fell 4.3 percent; Clarity, Curvebeam and Impedimed lost more than three percent; Clinuvel, Dimerix and Proteomics shed two percent or more; Alcidion, Emvision, Genetic Signatures, Nanosonics and Polynovo were down one percent or more; with Avita, Neuren, Opthea and Resmed down by less than one percent.

MESOBLAST

Mesoblast says it has an up-to $US50 million ($A72.2 million) convertible note agreement at five percent yearly interest with largest shareholder Gregory George.

In July, the Tampa, Florida-based Gregory George and G to the Fourth Investments, including James George and Grant George, said that they held 179,847,742 Mesoblast shares, or 15.81 percent of the company (BD: Jul 12, 2024.

Mesoblast said it would issue “at its sole discretion” up-to $US50 million of convertible notes in $US10 million tranches within 90-days of receiving US Food and Drug Administration approval of its Ryoncil (remestemcel-L) treatment for children with steroid-refractory acute graft-versus-host disease.

The company said the conversion price of the notes would be $US9.06 per American depositary receipt (ADR), equal to $1.32 per Australian share, or a 25 percent premium to its five-day volume weighted average price on the Nasdaq to September 27, 2024.

Mesoblast said the notes had a maturity date of four years from the first issue and a commitment fee of 2,000,000 options, or warrants, to subscribe for-up to 2,000,000 shares was payable on signing the convertible note agreement, with a further 3,000,000 options for up-to 3,000,000 shares payable on the first issue of notes.

The company said the options were exercisable at $US9.06 within four years from the date of the first issue of warrants.

Mesoblast said that the funding would be used “to seamlessly implement its go-to-market commercial strategy”.

The company said it expected a response from the FDA prior to or on the FDA’s prescription drug user fee act (PDUFA) goal date of January 7, 2025.

Mesoblast chief executive officer Silviu Itescu said the company appreciated “the ongoing support from our major shareholder in ensuring that the company is well capitalized for commercial product launch and can hit the ground running immediately following approval of Ryoncil by FDA”.

Mesoblast was up 4.5 cents or four percent to $1.17 with 5.1 million shares traded.

EBR SYSTEMS

EBR says the US Food and Drug Administration has begun the substantive review of its pre-market approval application for its Wise inside-the-heart pacing system.

Last year, EBR said its 183-patient pivotal trial of its Wise wireless stimulation endo-cardially device met both the primary efficacy and safety endpoints with statistically significant improvement against pre-set benchmarks (BD: May 22, 2023).

In January, EBR chief executive officer John McCutcheon told Biotech Daily the company would file the final Wise application module to the FDA, including technical specifications and testing data involving the device’s ability to withstand shocks, heat, cold and other potentially damaging conditions (BD: Jan 29, 2024).

Today, the company said the FDA would begin a substantive review of its application, with approval expected by April 2025 and commercial product launch later in 2025.

Mr McCutcheon said the company was “delighted that our [pre-market approval] application has progressed to substantive review by the FDA, effectively moving into the final stages of our regulatory timeline”.

“The FDA moved quickly through this step, which could have taken up-to 45 days,” Mr McCutcheon said. “This significant milestone brings us even closer to US commercialization and to making available our life-changing Wise technology to heart failure patients in need.”

EBR fell one cent or 1.1 percent to 87 cents with 1.1 million shares traded.

CORRECTION: CYNATA THERAPEUTICS

Friday's edition incorrectly said that Cynata acquired Adelaide's Tekcyte but in fact it acquired Tekcyte's Cytopatch intellectual property, for shares worth $230,000.
The Friday sub-editor was in a hurry to go to the Australian Rules Football Grand Final and has been turned from a Lion into a Swan.
Cynata was up half a cent or 2.4 percent to 21.5 cents.

ARTRYA

Artrya says it has submitted a 510(k) application to the US Food and Drug Administration for approval of its Salix coronary anatomy product.
In 2023, Artrya said it had lodged a "Q-submission" to the FDA for its Salix coronary anatomy software system for coronary plaque identification, a "key enabling step" in the US regulatory process; and this year, said it had lodged a second "Q-submission" and expected to file a 510(k) application (BD: May 3, 2023, June 7, Aug 21, 2024).
Today, the company said it had received feedback from the FDA at its two Q-Submission meetings which "validated and confirmed" the approach it had taken to meet requirements for a compliant 510(k) application.
Artrya chief executive officer Mathew Regan said he was pleased to report the company had "submitted its FDA application for regulatory approval of our Salix coronary anatomy product, after completing key stages of preparation".
"We look forward to hearing from the FDA in due course," Mr Regan said.
"Over the last 10 months we have also worked with US hospital groups and healthcare systems in strategic agreements to do final testing and validation on the Artrya system, which will allow us to reduce the sales cycle post-FDA approval," Mr Regan said.
Artrya was unchanged at 26 cents.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says it has completed a nine-month toxicology study of avicursen, or ATL1102 in non-human primates, a regulatory requirement to conduct US clinical trials.
In 2021, the then Antisense said the US Food and Drug Administration required updated clinical and toxicology protocols to be resubmitted to lift a partial clinical hold on ATL1102; and later, said it planned a nine-month chronic monkey toxicology study to support ATL1102 dosing beyond six months (BD: Aug 12, Dec 9, 2021).
In 2022, the company said it expected the toxicology study of ATL1102 to allow the FDA to lift the partial clinical hold on ATL1102 which limited dosing to 25mg weekly for six months; and last year, said it had begun the study (BD: Nov 22, 2022, Mar 14, 2023).
Today, Percheron said that no animals died in the study, no additional or unexpected toxicities were observed.
The company said that "expected low-grade [toxicity] findings were fully reversible during the recovery period".
Percheron said dosing concluded in December 2023 and that "the majority of the animals then underwent pathological examination, while the remaining animals continued into a recovery phase during which avicursen was not administered".
The company said the recovery phase was designed "to establish that any observations seen in the dosing phase of the study reversed on cessation of treatment".
Percheron said it expected to discuss the study's outcomes with the FDA "in early 2025" with the hope of conducting US trials to support potential US product approval.
Percheron was up half a cent or five percent to 10.5 cents with 2.5 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says it has delayed its planned re-domicile to the US, its Nasdaq listing, scheme meetings and its extraordinary general meeting.

Anteris said that it could “not guarantee that the US [initial public offer] will be successfully completed, including that there is no guarantee that an achievable issue price of [Anteris Technologies Global Corp] shares under the US IPO will be acceptable to the ATGC board of directors”.

In August, the company said it intended to redomicile to the US, list on the Nasdaq this year, through the Delaware-based ATGC, and remain on the ASX (BD: Aug 13, 2024).

Earlier this month, the company said it would hold scheme meetings on October 4, 2024.

Today, Anteris said the original timetable had been extended and it still intended to implement the schemes “during this calendar year”, saying the change in timing was “not unexpected when undertaking a complex cross border transaction and capital raising”.

The company said it believed the delay did “not reflect any negative sentiment or impediments to the proposed scheme or the US [initial public offering]”.

Anteris fell 29 cents or 2.3 percent to $12.20.

CANN GROUP

Cann 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 Cann’s share price rose 62.2 percent from 4.5 cents on September 26 to a high of 7.3 cents today and noted a “significant increase” in the volume of shares traded.

Cann said it had released an investor presentation by managing-director Jenni Pilcher on September 19, 2024, which received media attention, had launched a public advertising campaign for the sale and lease-back of its Mildura facility and it was the subject of an article published in the Weekly Times.

The company said that an article in Mergermarkets discussed “acquisition opportunities” and it was “contemplating raising further capital via a rights issue, which has been mentioned in previous ASX announcements” but it did not consider this a reason to explain the increase in its share price.

Cann Group was up 3.5 cents or 58.3 percent to 9.5 cents with 12.7 million shares traded.

NYRADA

Nyrada says its annual general meeting will vote to issue 9,000,000 options to chair John Moore and directors Christopher Cox, Marcus Frampton and Dr Rüdiger Weseloh.

Nyrada said shareholders would vote to issue 3,600,000 unlisted incentive options to Mr Moore as well as 1,800,000 options to Mr Cox, Mr Frampton and Dr Weseloh, each, vesting in three equal, annual tranches.

The company said that all the options were exercisable at the higher of the fair market value of its shares on the grant date or 120 percent of the 10-day volume weighted average price of its Chess depositary interests prior to the options’ vesting date within three years from their vesting date.

Nyrada said investors would vote to re-elect Mr Moore, Mr Cox, Mr Frampton, Dr Weseloh, Dr Ian Dixon and Dr Gisela Mautner as directors as well as approve its additional 10 percent placement capacity.

The meeting will be held at Automic Group, Level 5, 126 Phillip Street, Sydney on November 12, 2024 at 9:30am (AEDT).

Nyrada fell 0.4 cents or 5.8 percent to 6.5 cents.

RHYTHM BIOSCIENCES

Rhythm says it has promoted Dr David Atkins to managing-director, with directors Dr Trevor Lockett and Lou Panaccio to retire at the 2024 annual general meeting.
Earlier this year, Rhythm said it had appointed Dr Atkins as its chief executive officer, effective from May 13, 2024 (BD: Apr 24, 2024).
The company said founding director Mr Panaccio and founder Dr Lockett had been directors since before its ASX listing, had served more than seven years on the board, and were retiring “in the interests of renewal”, effective from its annual meeting on November 20, 2024.
Rhythm said Mr Buttula would step down as non-executive chair after more than five years in the position, effective on the appointment of a replacement board member and chair, which was expected before 2025.
The company said Dr Atkins’ remuneration would remain unchanged.
Mr Buttula said “having observed Dr Atkins in the role of chief executive officer since May, the board has admired his leadership and team building skills, his strong and tireless commitment and tenacious approach to building out Rhythm’s protected intellectual property portfolio”.
“Despite retiring, Dr Lockett has offered to continue to provide support on an as required, consultancy basis,” Mr Buttula said.
Rhythm fell 0.6 cents or 8.6 percent to 6.4 cents.

POLYNOVO

Polynovo says 14-year non-executive director Bruce Rathie has retired, effective from September 30, 2024.
Polynovo said Mr Rathie was appointed a director in February 2010, and had since supported the company through initial research and development to product commercialization, its initial public offering and its subsequent expansion.
Polynovo chair David Williams said Mr Rathie had been “the one constant on the Polynovo board”.
“After 14 years Mr Rathie has selflessly decided to stand aside to make way for new blood and concentrate on his other board roles,” Mr Williams said.
“He will be missed but I am confident he will still be available for his sage advice,” Mr Williams said.
Polynovo fell three cents or 1.1 percent to $2.61 with 1.2 million shares traded.

ALTERITY THERAPEUTICS

Alterity says Abby Macnish Niven will replace chief financial officer Phillip Hains, effective immediately, with Mr Hains to remain as its company secretary.
Last year, Alterity said its company secretary Mr Hains would replace chief financial officer Kathryn Andrews, effective from January 31, 2024 (BD: Dec 22, 2023).
Today, the company said Ms Macnish Niven had “extensive experience in private wealth management: including having worked for Australia New Zealand (ANZ) Bank, Union Bank of Switzerland (UBS) and Ord Minnett and consulted to companies on governance, finance and corporate structure.
Alterity said Ms Macnish Niven held a Bachelor of Commerce and Bachelor of Science from the University of Western Australia.
Alterity fell 0.1 cents or 25 percent to 0.3 cents with 2.8 million shares traded.

ONCOSIL MEDICAL

Oncosil says Peter Hall has elected not to join the board as a non-executive director, due to “personal family issues”.

Earlier this year, Oncosil said it had appointed Mr Hall as a non-executive director, effective by “the end of August 2024”; and later, said that due to “unforeseen personal family issues” the effective date of his appointment had been delayed to October 1, 2024 (BD: Jul 15, Sep 2, 2024).

Today, the company said the board respected Mr Hall’s decision and “wishes him and his family well”.

Oncosil fell 0.1 cents or 6.7 percent to 1.4 cents with 30.5 million shares traded.