



Biotech Daily

Friday December 22, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX EVEN, BIOTECH UP: CYNATA, DIMERIX UP 9%; CURVEBEAM DOWN 8.5%**
- * **INDONESIA'S PYRIDAM TO BUY PROBIOTEC FOR \$251m**
- * **CLARITY DOSES 1st PHASE III PROSTATE CANCER IMAGING PATIENT**
- * **ISLAND 3rd ISLA-101 COHORT DOSING APPROVED**
- * **RADIOPHARM TO OPEN PHASE I RAD204 NSCLC BRISBANE SITE**
- * **INVEX ENDS PEPTRON PRESENDIN MANUFACTURING CONTRACT**
- * **PHARMAUST FILES \$1.8m FIGHTMND PHASE II/III MONEPANTEL GRANT**
- * **MEDLAB EGM OKAYS ASSET SALES; 32% OPPOSE DR SEAN HALL**
- * **MELODIOL EVERBLU STOCK, LAY OPTIONS, 20:1 CONSOLIDATION EGM**
- * **DIRECTOR ANDREW KROGER REDUCES TO 43% OF CRYOSITE**
- * **LINDMARK TAKES 12.6% OF CRYOSITE**
- * **RICHARD GREEN, JATAYCO, VIKING TAKE 15% OF LBT**
- * **ORTHOCELL LOSES DIRECTOR DR STEWART WASHER**
- * **BIOINTELECT APPOINTS LEAH GOODMAN CEO**
- * **CO SEC PHILLIP HAINS REPLACES ALTERITY CFO KATHRYN ANDREWS**
- * **MELODIOL LOSES CO-CO SEC ERLYN DAWSON**

MARKET REPORT

The Australian stock market fell 0.03 percent on Friday December 22, 2023 with the ASX200 down 2.5 points to 7,501.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Cynata and Dimerix were the best, both up 9.1 percent, to 12 cents and 18 cents, respectively, with 11,140 shares and 1.1 million shares traded, respectively. Neuren was up 6.5 percent; Paradigm climbed 5.4 percent; Atomo and Universal Biosensors were up more than four percent; Impedimed, Next Science and SDI improved more than three percent; with Avita, Clarity, Cyclopharm, Emvision, Mesoblast, Prescient and Pro Medicus up by more than one percent.

Curvebeam led the falls, down three cents or 8.45 percent to 32.5 cents, with 68,490 shares traded. Syntara lost eight percent; Nova Eye shed 7.7 percent; Proteomics fell four percent; Opthea was down 3.2 percent; Antisense and Telix shed more than two percent; 4D Medical, Immutep, Medical Developments, Orthocell and Resmed were down more than one percent; with CSL, Cochlear, Nanosonics and Polynovo down by less than one percent.

PROBIOTEC

Probiotec says it has a binding scheme implementation deed with Jakarta's PT Pyridam Farma Tdk to buy the company at \$3.00 a share, valuing it at \$251.3 million.

Probiotec said that \$3.00 a share offer was a 26 percent premium to the one-month volume weighted average price of \$2.37.

The company said it had 81,323,406 shares on issue and 2,450,000 performance rights. Probiotec said that, without reducing the cash consideration payable to shareholders, it could pay dividends of up to 3.5 cents a share for six months to December 31, 2023 and 4.0 cents a share for the period from January 1 2024 and the earlier of the scheme record date and June 30, 2024, subject to conditions.

The company said the enterprise value of \$326.0 million was the equity value plus net debt of \$74.7 million and its "independent board committee unanimously recommends the scheme ... in the absence of a superior proposal ... and subject to the independent expert concluding ... [it] is in the best interests of Probiotec shareholders".

Probiotec independent board committee chair Jonathan Wenig said the committee was "unanimous in its view that the scheme represents an attractive outcome for our shareholders, as well as stakeholders more broadly, including our customers and employees".

"We are proud of the achievements of the Probiotec business over the years and believe that under its proposed new ownership, [it] will continue to build upon its established place as a leading contract manufacturer and packer for pharmaceuticals and fast-moving consumer goods in Australia, as well as on a more global scale," Mr Wenig said.

Probiotec said there would be two separate scheme meetings, one for chief executive officer Wesley Stringer and chief financial officer and company secretary Jared Stringer, and a separate meeting for all other shareholders, with both meetings required to pass a resolution approving the scheme by the required thresholds.

The company said the agreement included the potential for a break fee or reverse break fee of \$2,513,202 and a scheme booklet would be dispatched by April, the meetings were expected in May, with implementation by June 30, 2024.

The company said that Canterbury Partners was its financial adviser and Arnold Bloch Leibler its Australian legal adviser, with SSEK the Indonesian legal counsel.

Probiotec said that Grant Samuel was the lead financial adviser and Ashurst the Australian legal adviser to Pyridam, with Indonesian financial advice and legal advice provided by PT Mandiri Sekuritas and Armand Yapsunto Muharamsyah & Partners respectively.

Probiotec was up 39 cents or 15.5 percent to \$2.91 with 887,381 shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has dosed the first of up-to 383 patients in its Clarify phase III trial of copper-64 Sar-bis-prostate specific membrane antigen for prostate cancer imaging.

Clarity said dosing took place at Omaha, Nebraska's Urology Cancer Center, and the patient would be evaluated on the day of administration, about 24 hours post-dosing, and followed-up as per protocol, with subsequent patients evaluated in the same manner.

The company said the final study results were intended to provide sufficient evidence to support an application to the US Food and Drug Administration for approval copper-64 Sar-bis- prostate specific membrane antigen as a diagnostic imaging agent in pre-prostatectomy prostate cancer patients.

Clarity was up 2.5 cents or 1.4 percent to \$1.80.

ISLAND PHARMACEUTICALS

Island says it has approval to begin dosing the third cohort of its single-ascending safety study of ISLA-101 for dengue fever and other mosquito-borne diseases.

Last month, Island said it had dosed the first of 24 healthy volunteers in its single-ascending dose study of ISLA-101 (BD: Nov 24, 2023).

Today, the company said a safety review committee review of cohort two concluded that the second dose was safe and well-tolerated and approved the final cohort.

Island said it expected to begin screening and enrolling subjects for the third cohort on January 8, with dosing expected to begin on January 18, 2024.

Island chief executive officer Dr David Foster said the company was “looking forward to moving full-steam ahead with screening cohort three in early January”.

Island was untraded at 8.8 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has completed site initiation at Brisbane’s Princess Alexandra Hospital for its 21-patient, phase I trial of RAD204 for non-small cell lung cancer (NSCLC).

In October, Radiopharm said it had ethics approval for dose-escalation, phase I study evaluating the safety and efficacy of its RAD204 for non-small cell lung cancer and that the trial would be held at Princess Alexandra Hospital (BD: Oct 9, 2023).

Today, the company said the site would be opened on January 4, and it was currently pre-screening eligible patients, with the first patient expected to be dosed in January 2024.

Radiopharm managing-director Riccardo Canevari said the company was “highly encouraged by the initial findings from the pre-clinical studies and phase I imaging data in humans for [RAD204], and as such, we believe this radio-therapeutic agent may be a game changer, as monotherapy or in combination, for the treatment of advanced NSCLC.” Radiopharm was unchanged at 7.1 cents.

INVEX THERAPEUTICS

Invex says it and South Korea’s Pepton Inc have mutually agreed to terminate their manufacturing agreement of Presendin for idiopathic intracranial hypertension, at no cost.

In August, Invex said it closed its phase III trial of Presendin for idiopathic intracranial hypertension due to GLP-1 receptor agonists, like ‘Ozempic’, making Presendin uneconomic as a treatment for the often obesity-related illness (BD: Aug 21, 2023).

Today, the company said it had been awarded investigational new drug (IND) status by the US Food and Drug Administration for the phase III trial on August 18, 2022.

Invex said as part of the termination, the parties would waive the reciprocal regulatory fee that was payable upon either party receiving initial IND status with the FDA.

The company said it would give Pepton “certain regulatory documents associated with the [idiopathic intracranial hypertension] ... trial and ... granted Pepton an exclusive, royalty-free licence to commercialize Presendin ... in [South] Korea and China”.

Invex said it had granted Pepton a first right of refusal for the development rights of Presendin, or exenatide, for idiopathic intracranial hypertension in other jurisdictions.

Invex director Dr Thomas Duthy said after closing the phase III trial “there was no longer a need for Invex to order additional finished drug product and placebo from Pepton”.

“For our traumatic brain injury and glaucoma activities, Pepton’s sustained release formulation of exenatide is not considered an appropriate formulation,” Dr Duthy said.

Invex fell 0.2 cents or 2.4 percent to 8.1 cents.

PHARMAUST

Pharmaust says it will apply to Australia's Fight MND for an up-to \$1.8 million grant to fund its planned phase II study of monepantel for motor neuron disease.

Earlier this month, Pharmaust said it had finished its phase I trial of monepantel for motor neuron disease and applied for US Food and Drug Administration orphan drug designation (BD: Dec 1, 2023).

The company said it expected to be notified of the outcome by July 2024.

Pharmaust said the randomized, placebo-controlled study would evaluate the safety and efficacy of monepantel for motor neuron disease or amyotrophic lateral sclerosis for 48 weeks, but did not state the number of patients expected in the trial.

Pharmaust chief executive officer Dr Michael Thurn said "based on the potential shown to date for monepantel to provide patients ... with a treatment benefit we are excited at our prospects of securing further funding from Fight MND for our adaptive phase II/III study".

Pharmaust fell half a cent or 4.35 percent to 11 cents with 1.45 million shares traded.

MEDLAB CLINICAL

Medlab says its extraordinary general meeting approved the sale of assets with 32.4 percent against the sale of subsidiary Medlab Pty Ltd to director Dr Sean Hall.

Last month, Medlab said investors would vote to approve the sale of its subsidiary Medlab Pty Ltd and intellectual property to director Dr Hall (BD: Nov 23, 2023).

Today, the company said the sale of Medlab Pty Ltd to Dr Hall was opposed by 143,101 votes (32.39%), with 298,742 votes (67.61%) in support.

Medlab said the disposal of its main undertaking was opposed by 141,413 votes (32.01%), with 300,430 votes (67.99%) in favor.

According to its most recent notice, Medlab had 2,283,502 shares on issue, meaning that the 143,101 shares against the sale of its subsidiary amounted to 6.3 percent of the company, sufficient to requisition extraordinary general meetings.

Medlab was in a suspension at \$6.60.

MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

Melodiol proposes to issue 380,886,498 shares and 1,054,589,308 options to Everblu, 200,000,000 options to managing-director William Lay and hold a 20-to-one consolidation. In a 33-resolution extraordinary general meeting notice, Melodiol said investors would vote to issue former Creso chair Adam Blumenthal's advisory company Everblu Capital the shares and options, with Mr Lay's 200,000,000 options be exercisable at 0.6 cents each by November 13, 2028.

Melodiol said it currently had 4,728,824,027 shares on issue, which would become 236,441,201 shares, if the consolidation resolution was passed.

The meeting will be held online on January 23, 2024 at 9.30am (AWST).

Melodiol was unchanged at 0.2 cents with 19.4 million shares traded.

CRYOSITE

Cryosite director Andrew Kroger says he has reduced his substantial shareholding in the company from 22,543,702 shares (46.19%) to 21,043,702 shares (43.11%).

The Melbourne-based Mr Kroger said that on December 20 and 21, 2023 he sold 1,500,000 shares off-market for \$900,000, or 60 cents a share.

Cryosite fell two cents or 3.2 percent to 61 cents.

CRYOSITE

Lindmark Investments Staff superannuation fund says it has increased its holding in Cryosite from 4,654,494 shares (9.54%) to 6,154,494 shares (12.61%).

The Melbourne-based Lindmark said that on December 20 and 21, 2023 it bought 1,500,000 shares off-market for \$900,000, or 60 cents a share (see above).

LBT INNOVATIONS

Richard Green, Jatayco Nominees Pty Ltd, JTCA and Viking BCM Pty Ltd say they have become substantial in LBT with 189,576,792 shares, or 15.09 percent.

The Adelaide-based Mr Green and Jatayco said that on December 8, 2023 they bought 47,800,000 shares for \$239,000, or 0.5 cents a share.

In October, LBT said it hoped to raise \$4.5 million in a one-for-four rights offer at 0.5 cents a share; and later, said it had raised the full amount (BD: Oct 13, Dec 8, 2023).

In the substantial shareholder notice, Mr Green said he had a controlling interest in Jatayco and a relevant interest in the Brisbane-based Viking BCM, which held a further 141,776,792 shares in LBT, or 11.26 percent (BD Dec 20, 2023).

LBT was unchanged at one cent.

ORTHOCELL

Orthocell says former chair Dr Stewart Washer has retired as a director.

Orthocell said Dr Washer had completed the transition from his previous role as the long-standing chair and decided to retire as a director, having served 10 years with the company “to pursue other interests”.

The company said the appointment of two recent directors and chair John Van Der Wielen had prepared it for “the next phase of development and commercialization of its unique medical devices and cellular therapies”.

Mr Van Der Wielen said Dr Washer’s “commitment to the success of Orthocell in the early phase of the company was commendable and I am so appreciative of his assistance in my early days as incoming chair”.

Orthocell chief executive officer Paul Anderson said Dr Washer “was pivotal to the successful initial public offering of Orthocell back in 2014”.

Orthocell fell half a cent or 1.2 percent to 41 cents.

BIOINTELECT

Biointelect says it has appointed Leah Goodman as its chief executive officer.

Biointelect said Ms Goodman had most recently been Bristol-Myers Squibb managing-director, and had “significant experience successfully leading multinational company business transformation ... in Australia and across Asia”.

The company said Ms Goodman held a Bachelor of Science and a Master of Commerce from the University of New South Wales.

Biointelect co-founder Jenny Herz said that Ms Goodman had “strong leadership, diverse healthcare background and strategic experience ... [and would assist the] company growth strategy and execution”.

Biointelect is a private company.

[ALTERITY THERAPEUTICS](#)

Alterity says its company secretary Phillip Hains will replace chief financial officer Kathryn Andrews, effective from January 31, 2024.

Alterity said Mr Hains had been company secretary since 2014, and his experience included about 30 years in corporate secretarial, accounting and general management through the Hong Kong-based professional services firm Acclime, which acquired The CFO Solution.

The company said Ms Andrews had been chief financial officer for nine years and had chosen to leave “to pursue other interests and will continue to support the company during the transition”.

Alterity fell 0.1 cents or 14.3 percent to 0.6 cents with 1.6 million shares traded.

[MELODIOL GLOBAL HEALTH \(FORMERLY CRESO PHARMA\)](#)

Melodiol says that joint company secretary Eryn Dawson has resigned, effective immediately.