



Biotech Daily

Monday November 28, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PATRYS UP 15%; ACTINOGEN DOWN 10%**
- * **ADHERIUM US FDA 510(k) HAILIE GSK INHALER SENSOR CLEARANCE**
- * **US FDA 'CONDITIONAL APPROVAL' FOR ANTERIS DURAVR STUDY**
- * **LBT RIGHTS RAISE \$502k, \$3m SHORTFALL**
- * **PROBIOTEC CONSOLIDATES NSW SITES; 'UP TO \$105m H1 REVENUE'**
- * **RESPIRI: ARKANSAS HOSPITAL TO USE WHEEZO FOR COPD**
- * **EMYRIA: US NIH EVALUATES MARIJUANA FOR PAIN**
- * **INOVIQ SETTLES WITH DR IRMGARD IRMINGER-FINGER, TONY WALKER**
- * **CRONOS RESOLVES ELIZABETH, DR BENJAMIN JANSEN ISSUES**
- * **MICROBA REQUESTS 'PARTNERSHIP' TRADING HALT**
- * **TELIX TO RELEASE 4.3m VOLUNTARY ESCROW SHARES**
- * **PROBIOTEC AGM 23% OPPOSE 'FULLY VIRTUAL' MEETINGS**
- * **AUDEARA AGM 19% OPPOSE PLACEMENT FACILITY**
- * **IDT AGM 16% OPPOSE DR JANE RYAN, PLACEMENT CAPACITY**
- * **CRESO DIRECTORS' 21m SHARES, 10m OPTIONS, 4m RIGHTS EGM**
- * **AUSBIOTECH, BIO-MELBOURNE NETWORK E-O-Y PARTY**

MARKET REPORT

The Australian stock market fell 0.42 percent on Monday November 28, 2022, with the ASX200 down 30.4 points to 7,229.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and one was untraded. All three Big Caps rose.

Patrys was the best, up 0.3 cents or 15 percent to 2.3 cents, with 8.6 million shares traded. Immutep and Nova Eye climbed more than seven percent; Cynata and Universal Biosensors improved more than four percent; Alcidion, Dimerix and Genetic Signatures were up more than three percent; both Avita and Neuren rose 2.3 percent; Clinuvel, Cochlear and Kazia were up more than one percent; with CSL, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Actinogen led the falls, down two cents or 16.7 percent to 10 cents, with 2.5 million shares traded. Antisense lost 7.4 percent; Resonance fell 6.25 percent; Amplia, Micro-X, Next Science, Pharmaxis and Volpara were down three percent or more; Imugene, Medical Developments, Mesoblast, Orthocell, Polynovo, Proteomics and Starpharma shed two percent or more; Paradigm, Prescient and Telix were down more than one percent; with Emvision down by 0.9 percent.

ADHERIUM

Adherium says the US Food and Drug Administration has granted 510(k) clearance for its Hailie sensor to connect to Glaxosmithkline's inhalers.

In August, the company said it submitted its 510(k) application to the US FDA to connect its next generation Hailie sensors with Glaxosmithkline (GSK) Ventolin, Advair and Flovent pressurized metered dose inhaler, and in July, said it had 510(k) clearance for its Hailie sensor for the GSK Ellipta inhaler (BD: Jul 25, Aug 2, 2022).

Today, Adherium chief executive officer Rick Legleiter said the approval was "the third 510(k) market clearance of the next-generation Hailie sensors capturing physiological data, following the Hailie sensors for Astrazeneca's Symbicort [pressurized metered dose] inhaler and GSK's Ellipta dry powder inhalers enabling even more medication coverage for US remote patient monitoring reimbursement".

"Achieving these significant milestones for the company, we continue to broaden our regulatory footprint to be the drug agnostic, global digital partner of choice on our path toward building a sustainable, cash flow positive business," Mr Legleiter said.

Adherium head of quality, regulatory and clinical affairs Tara Creaven-Capasso said "our objective with each generation of the Hailie sensor is the pursuit of our mission - to be the leading digital solution for remote patient monitoring; integrating devices and data to optimize outcomes for patients, healthcare professionals and payors".

"With [Centers for Medicare and Medicaid Services] focused on providing new and expanded reimbursement options for virtual care management programs, more reimbursement opportunities for doctors are available, which gives access to comprehensive patient data for more effective care delivery, better care coordination, and improved health outcomes," Ms Creaven-Capasso said.

Adherium was up 0.05 cents or 12.5 percent to 0.45 cents.

ANTERIS TECHNOLOGIES

Anteris says the US Food and Drug Administration has "conditionally approved" its Duravr transcatheter heart valve (THV) system for a 15-patient early feasibility study.

Anteris said the US FDA had categorized Duravr THV as a Centers for Medicare and Medicaid Services (CMS) category B device, which allowed the device to be sold during the study pending CMS approval, and had accepted the investigational device exemption application for the study.

The company said the study would evaluate the safety and feasibility of the Duravr THV system in the treatment of 15 patients with symptomatic severe native aortic stenosis, at seven "heart valve centres of excellence" in the US, expected to begin in early 2023.

Anteris chief medical officer Dr Chris Meduri said "the FDA approval to begin the Duravr [study] is a critical milestone for Anteris achieving pre-market approval in the US".

"This study will build upon clinical data from the Duravr first-in-human study recently presented at the Transcatheter Cardiovascular Therapeutics conference in Boston, USA and London Valves in London, England," Dr Meduri said.

Anteris chief executive officer Wayne Paterson said "this study sets up 2023 to be a significant year of milestones and catalysts as we continue to build our remarkable base of evidence amongst patients who have had Duravr implanted".

"In the next year, we will significantly expand the patient population implanted with Duravr, a new class of valve made with a first-in-class, single-piece, native-like valve design built upon our breakthrough Adapt tissue treatment that has years of real-world experience," Mr Paterson said.

Anteris was unchanged at \$23.00 with 43,473 shares traded.

LBT INNOVATIONS

LBT says it has raised \$502,202 of a hoped for \$3.5 million in a one-for-six, rights offer at 6.5 cents a share, and has the option to place the \$2,986,555 shortfall.

In October, LBT said the offer to raise \$3.5 million would provide one option for every three shares subscribed, exercisable at 13 cents, within two years (BD: Oct 25, 2022).

Today, the company said it was exploring funding alternatives, including working with Melbourne's PAC Partners to assist with placing the shortfall.

LBT said the funds would be used for US and European sales and marketing, completion of analysis modules for its Apas automated plate assessment system instrument and working capital.

LBT fell half a cent or 8.3 percent to 5.5 cents.

PROBIOTEC

Probiotec says it will consolidate its New South Wales facilities to a single Sydney site and expects revenue for the six months to December 31, 2022 up to \$105 million.

Probiotec said it had agreed terms with a developer for a 30,000 square metres (322,917 square feet) facility in Kemps Creek in Sydney's Western suburbs to house most of its New South Wales pharmaceutical and packing businesses.

The company said the building was expected to cost between \$7 million to \$10 million, but once fully operational was expected to "deliver cost savings of \$3 million to \$5 million" each year from January 1, 2025, with "increased capacity, capabilities and efficiency".

Probiotec said the site would house its five New South Wales acquisitions since 2019, including Australian Blister Sealing Pty Ltd, Contract Pharmaceutical Services of Australia, Multipack-LJM and H&H Packaging (BD: Aug 1; Dec 11, 2019; Jan 17; Jun 28, 2021).

Probiotec chief executive officer Wes Stringer "the new site will be state-of-the-art and provide an incredible platform for Probiotec to attract new clients, whilst allowing us to significantly expand our capabilities with existing customers to meet future demand".

Mr Stringer told the company's annual general meeting that revenue for the first half of 2022-'23 was expected to be \$100 million to \$105 million with earnings before interest, tax, depreciation and amortization (Ebitda) in the range of \$15.5 million to 16.5 million.

In February, Probiotec said that revenue for the six months to December 31, 2021 was up 100.0 percent to \$85,160,657 with Ebitda of \$14,486,000.

Probiotec was up nine cents or 4.1 percent to \$2.30.

RESPIRI

Respiri says Arkansas Heart Hospital will use its Wheezo remote patient monitoring program to manage heart patients with chronic obstructive pulmonary disease (COPD).

Respiri said that Arkansas Heart Hospital would use the patient management program to "reduce avoidable hospital re-admissions that place a huge healthcare resource and economic burden on medical institutions".

Respiri managing-director Marjan Mikel said "patients with cardiovascular disease are difficult to manage and often have numerous co-morbidities that further complicate their treatment".

"COPD is one such common complication and we are delighted that the Arkansas Heart, a preeminent cardiovascular organization, has chosen to add the Wheezo RPM program to the standard of care for the thousands of [cardiovascular disease] patients with COPD under their care to improve health outcomes and reduce hospital re-admissions," he said.

Respiri was up 0.7 cents or 18.4 percent to 4.5 cents.

EMYRIA

Emyria says the US National Institutes of Health's 'helping to end addiction long-term initiative' will evaluate its marijuana-based EMD-RX7 for pain.

Emyria said its candidates would be used in the pre-clinical screening platform for pain program, in collaboration with the National Institute of Neurological Disorders and Stroke, which focused on "improving prevention and treatment strategies for opioid misuse and addiction, and enhancing pain management" evaluating non-opioid assets.

Emyria managing-director Dr Michael Winlo said "we're delighted to be accepted into this prestigious program to comprehensively evaluate the suitability of our unique, pharmaceutical-grade formulations to address major unmet needs in pain".

"Our compelling real-world data has demonstrated that cannabinoids may be useful amongst sufferers of chronic, non-cancer pain and we saw a need to develop reliable, ultra-pure dose forms, suitable for registration with major regulators," Dr Winlo said.

Emyria was unchanged at 19 cents.

INOVIQ (FORMERLY BARD1 LIFE SCIENCES)

Inoviq says it has settled legal proceedings with founders Dr Irmgard Irminger-Finger and Tony Walker, relating to performance shares for the founders.

Last year, the then Bard1 said that Dr Irminger-Finger and Mr Walker had begun legal proceedings in the Supreme Court of Victoria, over the issue and conversion of performance shares (BD: Feb 24, 2021).

At that time, the then Bard1 said that former director and chief scientific officer Dr Irminger-Finger had resigned from the board and that her consultancy agreement was terminated (BD: Jan 17, 2021).

Bard1 said at that time that the plaintiffs were the original founders and major shareholders of Bard1 AG SA (Bard1 AG), a fully owned subsidiary of the company, acquired from the plaintiffs in 2016.

Today, Inoviq said that it had settled the proceedings to "avoid the costs, inconvenience and the uncertainty of litigation" and would transfer its shareholding in Bard1 AG to Dr Irminger-Finger and Mr Walker.

The company said that Bard1 AG held the intellectual property rights associated with the Bard1 lung cancer test and its lung cancer diagnosis.

Inoviq said that it would retain an entitlement to 10 percent of net sales of any products developed using the lung cancer test intellectual property for the duration of the patents, and five percent following patent expiry.

The company said it would pay Dr Irminger-Finger and Mr Walker a "lump-sum payment of \$1 million" but that the founders had "an obligation to commit \$300,000 to the development of the [lung cancer test] over the next two years".

Inoviq said that the settlement did not involve it "transferring its rights in relation the Bard1 breast and ovarian cancer" intellectual property owned by the company and that the court proceedings would be dismissed with no costs awarded.

Inoviq chair Dr Geoff Cumming said "we are pleased that this matter has settled out of court on what the board believes are reasonable terms considering the significant additional costs of defending a potentially large and complex claim and the uncertainty of a court outcome".

"With the matter finalized, Inoviq can now fully focus on unlocking the significant commercial potential of the Exo-Net and Sub-B2M platforms, as well as progress its other commercial initiatives," Dr Cumming said.

Inoviq fell half a cent or 0.9 percent to 57 cents.

[CRONOS AUSTRALIA](#)

Cronos says it has resolved its issues with Elizabeth and Dr Benjamin Jansen and they will vote their 129,890,570 shares “in accordance with the board’s recommendations”. In September and October, Cronos said that Matua Hasyo Charlie Jansen called for the removal of directors, chief executive officer Rodney Cocks and chief commercial officer Guy Headley; chief medical officer and director Dr Benjamin Jansen had “ceased his position”; and it received a Section 249N notice to appoint Dr Benjamin Jansen as a director (BD: Sep 20, 23, 28, 2022).

In October the company said that Elizabeth Jansen had withdrawn her resolution to appoint Dr Benjamin Jansen a director of the company (BD: Oct 26, 2022).

Cronos previously told Biotech Daily that Dr Charlie Jansen and Dr Benjamin Jansen were founders and former doctors with Cannabis Doctors Australia, which it acquired in 2021 (BD: Sep 14, Dec 16, 2021).

Today, the company said it and co-founder and former director Dr Benjamin Jansen “acknowledge that their previous statements may have caused offence to each other, and both parties regret that the relationship between them had started to erode”.

Cronos said it and Dr Benjamin Jansen were “both committed to seeing the company develop and grow into a global leader in the medicinal cannabis industry and beyond”.

The company said that Elizabeth Jansen “intends to vote her 129,890,570 shares at the ... annual general meeting in accordance with the board’s recommendations”.

“The parties are pleased to have been able to reach a positive resolution to these matters, enabling the board and management to focus on executing the company’s strategic objective,” Cronos said.

Cronos fell 1.5 cents or 2.3 percent to 64 cents.

[MICROBA LIFE SCIENCES](#)

Microba has requested a trading halt “pending the release of an announcement regarding a strategic investment and commercial partnership”.

Trading will resume on November 30, 2022 or on an earlier announcement.

Microba last traded at 22 cents.

[TELEX PHARMACEUTICALS](#)

Telex says it will release 4,312,151 shares from voluntary escrow on December 14, 2022.

According to its most recent filing, Telex had a total of 315,840,778 shares on issue.

Telex fell eight cents or 1.1 percent to \$7.29 with 466,714 shares traded.

[PROBIOTEC](#)

Probiotec says its annual general meeting faced up to 22.91% opposition to the special resolution to amend its constitution to allow for fully virtual meetings.

Probiotec said that the constitution amendment, required 75 percent of the votes to pass and faced 11,582,310 votes (22.91%) against, with 38,982,696 votes (77.09%) in favor.

The company said all other resolutions passed easily, with the executive option plan and the issue of performance rights to chief executive officer Wes Stringer facing five percent opposition.

According to its most recent filing, Probiotec had 81,323,406 shares on issue, meaning that the votes against the amendment of the constitution amount to 14.24 percent of the company, sufficient to requisition extraordinary meetings.

AUDEARA

Audeara says its annual general meeting saw 9,923,474 votes (19.10%) against the 10 percent placement facility with 42,031,005 votes (80.90%) in favor.

Audeara said that all other resolutions passed easily.

According to its most recent filing, Audeara had 74,499,322 shares on issue, with 40,800,678 shares in ASX escrow, meaning the votes against the placement facility amounted to 8.6 percent of the company, sufficient to requisition extraordinary meetings. Audeara was unchanged at 8.8 cents.

IDT AUSTRALIA

IDT says its annual general meeting faced up to 16 percent dissent against the election of Dr Jane Ryan and the 10 percent placement facility.

IDT said the resolution to elect Dr Ryan as a non-executive director was opposed by 12,918,287 votes (16.12%) with 67,212,638 votes (83.88%) in favor, while the placement facility had 12,667,332 votes (15.81%) against and 67,463,774 votes (84.19%) in favor.

The company said all other resolutions were passed easily.

According to its most recent filing, IDT had a total of 240,179,956 shares on issue, meaning the votes against the election of Dr Ryan amounted to 5.38 percent of the company, sufficient to requisition extraordinary meetings.

IDT fell half a cent or 5.3 percent to nine cents with 1.6 million shares traded.

CRESO PHARMA

Creso says its extraordinary general meeting will vote to issue 21,000,000 shares, 10,000,000 options and 4,000,000 performance rights to directors and “ambassadors”.

Creso said it proposed to issue 4,000,000 shares to director James Ellingford, 2,000,000 shares to chair Boaz Wachtel and 15,000,000 shares to Dr Miriam Halperin Wernli, as well 10,000,000 options for Bruce Linton, exercisable at nine cents by January 17, 2024.

Creso said shareholders would vote to issue brand ambassadors Kolby Tullier and Troy Van Biezen 2,000,000 performance rights each, pending revenue hurdles.

The company said the meeting would vote to ratify prior placements, share conversions, the participation of directors, and issue options and shares in relation to an acquisition.

The meeting will be held virtually on December 29, 2022 at 4pm (AEDT).

Creso was unchanged at two cents with 14.5 million shares traded.

AUSBIOTECH, BIO-MELBOURNE NETWORK

Ausbiotech says that with the Bio-Melbourne Network it will host a Melbourne end-of-year party at Docklands on December 14, 2022.

Ausbiotech said that the function will be held at the Chandelier Bar, The General Assembly, 29 South Wharf Promenade, Melbourne.

The industry organization said that the event was free and exclusive to Ausbiotech and the Bio-Melbourne Network, with drinks at bar prices and canapes to be provided.

For more details and to register, go to: <https://bit.ly/3VA6ndp>.