Biotech Daily

Monday December 4, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: COMPUMEDICS UP 56%; CYNATA DOWN 12%**

*** MESOBLAST PLACEMENT, RIGHTS OFFER FOR UP-TO $97m**

*** MEMPHASYS RAISES $2.1m; RIGHTS OFFER FOR $2.1m MORE**

*** COMPUMEDICS: FDA CLEARS SOMFIT AT-HOME SLEEP TEST; GUIDANCE**

*** MICROBA $924k FLAVORS & FRAGRANCES ALLERGY RESEARCH DEAL**

*** S&P: 4D MEDICAL DEMOTED FROM ALL TECHNOLOGIES INDEX**

*** DOHERTY DEVELOPING SAFE SKIN TREATMENTS, IN MICE**

*** BOTANIX FDA OKAYS SOFDRA NDA RESUBMISSION**

*** STH KOREAN APPROVES AMPLIA AMP945 PANCREATIC CANCER TRIAL**

*** ADHERIUM BEGINS TEVA-HAILIE PRODUCTION**

*** BTC TO DISTRIBUTE EUROSETS' LIFE SUPPORT SYSTEMS**

*** ALTERITY ATH434 'IMPROVES PARKINSON'S FUNCTION', IN MONKEYS**

*** INHALERX COMPLETES PHASE I MARIJUANA IRX211 DOSING**

*** VITURA: FEDERAL COURT ORDERS ON CDA CLINICS 'HISTORIC ADS'**

*** NEUROTECH EXTENDS NTI164 MARIJUANA AUTISM TRIAL TO ADULTS**

*** CURVEBEAM RELEASES 19.8m ASX ESCROW SHARES**

*** GOODBYE PHARMAXIS, HELLO SYNTARA**

*** GENETIC SIGNATURES APPOINTS STEPHANE CHATONSKY DIRECTOR**

*** CANN CFO, CO SEC DEBORAH AMBROSINI GOES; STEVEN NOTARO CO SEC**

*** EPSILON'S CUI CALLS EGM TO OUST BEASLEY; FEW DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.73 percent on Monday December 4, 2023, with the ASX200 up 51.5 points to 7,124.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 18 fell, four traded unchanged and one was untraded. All three Big Caps rose.

Compumedics was the best, up nine cents or 56.25 percent to 25 cents, with 1.8 million shares traded. Prescient climbed 16.7 percent; Atomo was up 9.5 percent Clarity rose 8.8 percent; Dimerix improved 7.1 percent; Resonance climbed 6.6 percent; Avita was up 5.6 percent; Immutep improved 3.3 percent; Amplia and Volpara rose two percent or more; Nanosonics, Orthocell, Paradigm, Resmed and SDI were up more than one percent; with Cochlear, CSL, Neuren, Polynovo and Pro Medicus up by less than one percent.

Cynata led the falls, down 1.5 cents or 12 percent to 11 cents, with 173,208 shares traded. Curvebeam and Next Science lost more than six percent; Antisense shed five percent; Actinogen, Alcidion and Imugene fell four percent or more; 4D Medical, Genetic Signatures, Medical Developments, Nova Eye and Starpharma were down more than three percent; Proteomics and Universal Biosensors shed two percent or more; Clinuvel and Telix fell more than one percent; with Emvision and Cyclopharm down by less than one percent.

MESOBLAST

Mesoblast says it hopes to raise up-to $36 million in an institutional placement and $61 million in a one-for-four retail and institutional entitlement offer, at 30 cents a share.
Last week, Biotech Daily was told that Mesoblast intended to raise up-to $97.7 million at 30 cents a share, a 25.9 percent discount to the last trading price (BD: Dec 1, 2023).
Today, the company said Bell Potter Securities was the sole lead manager and sole bookrunner to the raise, and the funds would be used for its adult phase III trials for graft versus host disease and chronic lower back pain, as well as general corporate purposes.
The company said the institutional rights offer closed today, with the retail offer record date December 6, opening on December 8 and closing on December 19, 2023.
Mesoblast was in a trading halt and last traded at 40.5 cents.

MEMPHASYS

Memphasys says it has “firm commitments” for a $2.1 million placement at one cent a share and with a two-for nine rights issue hopes to raise about $4.23 million.
Last week, Memphasys said that it hoped to raise up-to $4 million, with details to be released “in due course” (BD: Nov 30, 2023).
Today, the company said that the placement would include a conversion of $511,747 of debt into equity, and that participants would receive one option for every two shares bought, exercisable at two cents each within two years of issue.
Memphasys said former directors Andrew Goodall and Alison Coutts had subscribed for $224,642 and $14,193, respectively, with Canaccord Genuity Ltd as lead manager.
The company said the funds would be used for commercial opportunities with Felix, drive development activities, settle debts and creditors and providing working capital.
The company said that the rights offer was fully underwritten by Canaccord, with $380,458 in sub-underwriting commitments from Mr Goodall, had a record date of December 8, would open on December 13, 2023 and close on January 2, 2024.
Memphasys was unchanged at 1.2 cents with 2.6 million shares traded.

COMPUMEDICS

Compumedics says it has US Food and Drug Administration approval to market its Somfit device for at-home sleep testing.
Compumedics said the approval marked “the achievement of another significant milestone for the Somfit technology platform in one of the world’s largest sleep markets”.
The company said since the commercialization of Somfit in Australia in July 2023, it had generated $1.2 million of sales orders to date.
Compumedics said the “significant strategic milestone” meant it could begin its commercialization activities in the US.
The company said it would target to achieve between 10 and 30 percent of the up to $US180 million US market during the next two years and it had appointed a number of sales’ staff in the US to commence sales activities.
Compumedics said that it had reaffirmed its 2023-’24 guidance of more than $44 million in revenue.
The company said that it expected earnings before interest, taxation, depreciation and amortization (Ebitda) to be more than $5 million.
Compumedics was up nine cents or 56.25 percent to 25 cents with 1.8 million shares traded.

MICROBA LIFE SCIENCES

Microba says it will be paid $924,150 by New York’s International Flavors & Fragrances Inc to develop microbiome-based treatments for multiple forms of allergy.
Last year, Microba said it had begun a joint discovery program with International Flavors and Fragrances to identify allergy treatments by using its databank of more than 15,000 gut microbiome samples and associated health data, and that it had hit its first milestone after delivering its first data package as part of the partnership (BD: Jul 4, 2022).
Today, the company said it had completed the identification of lead species from which International Flavors and Fragrances was entitled to select for a second stage project.
Microba said the goal of stage two was the successful isolation of strains from the selected project species and characterization of those strains.
Microba said International Flavors and Fragrances had an exclusive option to licence the strains for development and commercialization.
The company said that it expected a final project report to be submitted on or about October 2024.
Microba was unchanged at 22 cents.

STANDARD AND POOR’S DOW JONES INDICES, 4D MEDICAL

Standard and Poor’s says 4D Medical has been removed from the ASX All Technology Index, effective from December 18, 2023.
Previously, Standard and 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.
Last Friday, 4D Medical was up 105.6 percent to $331 million for the month of November on US reimbursement and a second FDA approval (BD: Dec 1, 2023)
4D Medical fell 3.5 cents or 3.6 percent to 93.5 cents.

THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

The Doherty Institute says a mouse model shows how to treat autoimmune diseases without impacting the skin's protective tissue-resident T-cells.

The Doherty Institute said the research with the University of Melbourne showed ways to remove immune cells that caused skin autoimmune diseases without affecting protective cells that fought infection and cancer.

The Institute said the protective cells, called tissue-resident T-cells, stayed in place to fight infections and cancerous cells in the skin, but when not controlled properly could contribute to autoimmune diseases, such as psoriasis and vitiligo.

The Doherty Institute said researchers found distinct ways of controlling different types of immune cells, enabling them to selectively eliminate 'problematic cells' and reshape the skin's immune landscape.

The Institute said the study selectively eliminated 'problematic' cells that could drive autoimmune disorders, while preserving cells essential to maintain protective immunity.

The Doherty Institute said given the study showed the successful removal of specific skin T-cells in mice, further research was necessary to validate the efficacy of these strategies in human subjects.

The Doherty Institute said the research, titled 'Divergent molecular networks program functionally distinct CD8+ skin-resident memory T cells' was published in Science and was available at: https://www.science.org/doi/10.1126/science.adi8885.

Co-author and University of Melbourne researcher Dr Simone Park said the research was "the first to describe the unique elements that control various types of skin [tissue-resident T-cells] cells in animal models, offering precise targets for potential treatment strategies".

"Specialized immune cells in our skin are diverse [and] many are critical to prevent infection and cancer, but others play a big role in mediating autoimmunity," Dr Park said.

"We discovered key differences in how distinct types of skin T-cells are regulated, allowing us to precisely edit the skin's immune landscape in a targeted way," Dr Park said.

University of Melbourne senior research officer and co-author of the study Dr Susan Christo said the discoveries "could advance efforts to treat skin disease".

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has approved it to resubmit its new drug application for its sofpironium bromide gel, Sofdra, for excessive sweating.

Earlier this year, Botanix said the US Food and Drug Administration has denied its new drug application of sofpironium bromide for excessive sweating, requesting printed instruction changes (BD: Sep 26, 2023).

Today, Botanix said the FDA had confirmed that the planned content of materials it proposed would be acceptable for the resubmission of the Sofdra new drug application package, which was expected to be submitted early next year.

The company said the materials were limited to the revised patient instructions for use, revised human factors validation study protocol and report, updated use-related risk analysis and updated draft prescribing information, carton and container labels and the 'Sofdra' name submission.

Botanix said it would also bring forward the annual safety update to the FDA, which included a pharmacovigilance report from Japan and any other published safety findings.

The company said all the materials were either already prepared or would be finalized in preparation for the planned resubmission.

Botanix was up one cent or 6.1 percent to 17.5 cents with 10.6 million shares traded.

AMPLIA THERAPEUTICS

Amplia says the Korean Ministry of Food and Drug Safety has approved its up-to 50-patient, phase II trial of AMP945 with standard-of-care for pancreatic cancer.
In October, Amplia said the 14-patient phase Ib trial of oral focal adhesion kinase (FAK) AMP945, or narmafotinib, for pancreatic cancer with gemcitabine and nab-paclitaxel, showed it was safe, well-tolerated with "very encouraging" activity (BD: Oct 31, 2023).
Today, the company said the phase IIa trial was designed to assess the efficacy of the triple drug combination of AMP945, gemcitabine and Abraxane, using an AMP945 dose determined by the phase Ib trial.
Amplia said the primary endpoint was objective response rate, with secondary endpoints including progression free survival, overall survival, safety and tolerability.
The company said with approval it would open five preselected clinical trial sites in South Korea and begin enrolling patients.
Amplia said having opened six sites in Australia for the phase Ib trial would help "optimize the recruitment and management of patients" in the trial.
Amplia managing-director Dr Chris Burns said that Korea's clinical trial capability was "world class and recruitment into pancreatic cancer trials has been historically strong".
Amplia was up 0.2 cents or 2.7 percent to 7.5 cents.

ADHERIUM

Adherium says it has begun producing Hailie devices with a physiological data capturing sensor for Teva Pharmaceutical Industries' Proair HFA albuterol sulphate inhaler.
Adherium said the Proair hydro-fluoro-alkane (HFA) broncho-dilator was a pressurized metered dose inhaler, and that its Hailie monitoring device's additional sensor could capture physiological data such as inhalation flow rate.
The company said the sensor supported respiratory-focused hospitals, medical groups and payors to manage respiratory disease for improved health outcomes, enabling reimbursement and saving healthcare costs through remote patient monitoring.
Adherium was unchanged at 0.3 cents.

BTC HEALTH

BTC says it will sell and distribute the Medolla, Italy-based Eurosets' range of cardio-pulmonary and extra-corporeal life support systems in Australia and New Zealand.
BTC said Eurosets was a manufacturing company and supplier of oxygenators for cardiac surgery bypass procedures as well as systems for extra-corporeal life support, a technique of providing prolonged cardiac and respiratory support to patients whose lungs and heart are unable to provide adequate amount of gas exchange or blood perfusion.
The company said the Eurosets' systems, called Ecmolife and Colibri, were already approved by the Australian Therapeutic Goods Administration and available for sale.
BTC said the agreement was held by its wholly-owned investee company BTC Cardio Pty Ltd and did not state the commercial terms.
BTC chair Dr Richard Treagus said "this is a decisive step for BTC Cardio, our recently formed investee company, as we establish and build a strong presence in this highly specialized field of medical care".
BTC was up 0.1 cents or 1.9 percent to 5.3 cents.

ALTERITY THERAPEUTICS

Alterity says a study of ATH434 for Parkinson's disease showed the drug "reduced motor impairment and improved general functions" in five Macaque monkeys.

Alterity said the study compared daily oral doses of ATH434 at 3.0mg/kg and 10mg/kg compared to placebo for 12-to-14 weeks after the monkeys showed Parkinsonian symptoms.

The company said the monkeys were assessed using a Parkinson's scale before, during and after dosing, and at 12 weeks found all five evaluable monkeys had stable or improved scores from a baseline compared to two of three placebo monkeys not showing improvement or developing worsened symptoms.

Alterity said the "favorable Parkinsonian outcomes observed in each of the ATH434-treated monkeys were associated with lower iron in the right substantia nigra".

The company said the monkeys with improved scores "had higher right dorsal striatal synaptophysin, indicating functional recovery of nerve endings in this critical motor pathway".

Alterity said the study was presented in a poster, titled 'Effects of ATH434, a Clinical-Phase Small Molecule with Moderate Affinity for Iron, in Hemiparkinsonian Macaques', at the Future of Parkinson's Disease Conference in Austin, Texas from November 30 to December 3, 2023.

Alterity managing-director Dr David Stamler said the data showed "for the first time that ATH434 can reduce Parkinson's symptoms in a higher order animal, the monkey".

"Importantly, the improvements in motor skills and general functioning that parallel human parkinsonism were associated with reductions in iron in affected brain regions, validating the approach we are using in our ongoing clinical trials," Dr Stamler said.

"The data from this study improve our ability to predict clinical outcomes and increases our confidence level in our ongoing phase II clinical trials in multiple system atrophy, a parkinsonian disorder with similar underlying pathology to Parkinson's disease," Dr Stamler said.

Alterity was unchanged at 0.4 cents with 41.3 million shares traded.

INHALERX

Inhalerx says it has completion dosing its up-to-32 participant, phase I trial of marijuana-based IRX211 to evaluate its safety and pharmaco-kinetics.

Inhalerx said the trial at Melbourne's Nucleus Network, would assess the pharmaco-kinetics, safety and tolerability of single escalating doses of IRX211 in healthy participants, and the results would guide the design of further trials.

The company said that IRX211 was delivered by inhalation in a fixed dose designed to provide rapid onset analgesia for patients with episodic bursts of breakthrough pain.

Inhalerx chief executive officer Darryl Davies said dosing was "a significant milestone".

"The drug-delivery efficiency data coupled with the low side effect profile is particularly exciting to the company as we pursue the goal of providing a safe, effective, and fast acting non-opioid drug to the market," Mr Davies said.

Inhalerx said the randomized, controlled, single-ascending-dose study originally planned for four cohorts of eight participants, but data from the first three cohorts was "definitive enough … to make an informed decision regarding the choice of dosing strength to enter phase II without incurring the further cost and time requirements …[of a] fourth cohort".

The company said that the clinical study report was expected by May 2024.

Inhalerx fell 0.3 cents or 8.1 percent to 3.4 cents.

VITURA HEALTH

Vitura Health says the secretary of the Federal Department of Health and Aged Care has filed proceedings in Brisbane against its subsidiary CDA Clinics Qld Pty Ltd.
Vitura said the proceedings related to alleged contraventions of section 42DLB of the Therapeutic Goods Act 1989 by CDA Clinics with regard to “historic advertisements of products on a website associated with a legacy business which was known as CDAexpress”.
In 2021, the then Cronos said it would acquire the acquire Varsity Lakes, Gold Coast, Queensland-based CDA Health (formerly Cannabis Doctors Australia), for up to 439,784,282; and later that year, received shareholder approval and completed the acquisition (BD: Sep 14, Dec 16, 2021).
Today, the company said director Dr Benjamin David Nghauhui Jansen, who was appointed a director following the acquisition, was a respondent to the proceedings.
Vitura said the matter predated the merger and CDA Clinics Qld was a dormant company that did not operate its CDA Clinics operation, had no assets, no debts and no operations.
Vitura said it was seeking legal advice concerning the proceedings.
Vitura fell half a cent or 1.7 percent to 29 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has ethics approval to extend its up-to 54-patient, phase II/III clinical trial of its marijuana-based NTI164 for autism spectrum disorder to adult patients.
Neurotech said the ethics committee approval allowed the child patients with autism spectrum disorder in the trial to remain on treatment after turning 18 years of age, for up-to 54 weeks of total treatment.
The company said the double-blind, randomized and controlled-to-open-label study would study the efficacy of up-to 20mg/kg daily doses of NTI164 on the severity of spectrum disorder in child autism patients.
Neurotech said the trial’s primary endpoint was clinical global impression-severity, which showed a clinician’s impression of severity of illness on a seven-point scale.
Neurotech director Dr Thomas Duthy said with recruitment trial expected to be completed by the end of the year, the company expected results by April 2024.
Neurotech was up 0.1 cents or 1.75 percent to 5.8 cents with 1.5 million shares traded.

CURVEBEAM AI

Curvebeam says it released 19,881,718 shares from ASX escrow on October 31, and November 10, 2023 with 6,749,541 of the shares remaining in voluntary escrow.
A Curvebeam spokesperson told Biotech Daily that the company had a total of 320,138,492 shares, with 117,392,779 shares still in ASX escrow.
Curvebeam fell two cents or 6.1 percent to 31 cents.

PHARMAXIS, SYNTARA

Pharmaxis says it has formally changed its name to Syntara Ltd and is in the process of changing its ASX ticker code from PXS to SNT.
Last week, Pharmaxis said its annual general meeting voted 98.32 percent in favor of its name change to Syntara (BD: Nov 28, 2023).
Pharmaxis was unchanged at three cents.

GENETIC SIGNATURES

Genetic Signatures says it has appointed Stephane Chatonsky as non-executive director, effective from today.
Genetic Signatures said Mr Chatonsky previously was an executive at Lazard, McKinsey & Co, Macquarie Bank and Leapfrog Investments and had held directorships and advisory positions for pathology, healthcare and technology companies.
According to his Linkedin profile, Mr Chatonsky held a Master of Business Administration from the Wharton School of the University of Pennsylvania.
Genetic Signatures fell two cents or 3.7 percent to 52 cents.

CANN GROUP

Cann Group says chief financial officer and company secretary Deborah Ambrosini has resigned for personal reasons, effective from December 22, 2023.
Cann Group said it would appoint a replacement chief financial officer, with head of legal and regulatory affairs Steven Notaro appointed company secretary, effective immediately.
Cann was up 0.75 cents or 7.5 percent to 10.75 cents.

EPSILON HEALTHCARE

Epsilon says chair Xiao (Josh) Cui has called an extraordinary general meeting to remove founder and deputy chair Alan Beasley and appointed John Few as a director.
In November, Epsilon (then The Hydroponics Co) founder Mr Beasley requisitioned an extraordinary general meeting to replace director Stuart Cameron and chair Xiao (Josh) Cui, citing “the governance of the board” (BD: Nov 21, 2023).
The following day Epsilon responded to a detailed ASX query relating to the company’s finances and noting a number of discrepancies and separately said that says it “terminates Mr Peter Giannopoulos as the role of the Chief Executive Officer … effective immediately at 3:35pm November 21, 2023” (BD: Nov 22, 2023).
On November 23, the company said that in calling the extraordinary general meeting under section 249CA of the Corporations Act 2001 Mr Beasley had not followed “the due procedures”, an accusation Mr Beasley rebutted (BD: Nov 23, 2023).
On Friday, Epsilon said it had received a section 249D notice from Mr Cui’s Watercrest Asset Management Pty Ltd to remove Mr Beasley from the board of directors.
Epsilon said that Mr Cui was Watercress’s “sole director and company secretary”.
In a separate announcement the company said it had appointed John Few as a non-executive director company effective 30 November 30, 2023.
The company said that Mr Few had been the director of Sydney’s East West Advisory since February 2015, and previously worked for IBM Australia.
Epsilon said that Mr Cui had been appointed as executive chair, effective from November 30, 2023 and would be paid $264,000 a year plus from December 1, 2023.
Epsilon fell 0.3 cents or 10.7 percent to 2.5 cents.