# Biotech Daily

Tuesday April 30, 2024

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: ACTINOGEN UP 19%;**
**- MEDICAL DEVELOPMENTS DOWN 10%**

*** AROA RECEIPTS UP 21% TO $60m**

*** IMEX Q1 RECEIPTS UP 9% TO $4.8m; ONE QUARTER CASH**

*** CANN 9-MONTH RECEIPTS UP 33% TO $13m; 0.3 QUARTERS CASH**

*** MESOBLAST 9-MONTH RECEIPTS $8.6m**

*** IMPEDIMED 9-MONTH RECEIPTS DOWN 3% TO $8.5m**

*** BIOXYNE 9-MONTH RECEIPTS UP 363% TO $7.2m**

*** CURVEBEAM 9-MONTH RECEIPTS: $5.2m**

*** ACRUX 9-MONTH RECEIPTS DOWN 41% TO $5m**

*** RESPIRI PLACEMENT RAISES $1.6m**

*** CLARITY 1st CU-67-SAR-BIS-PSMA PATIENT 'COMPLETE RESPONSE'**

*** ENA: FDA OKAYS PHASE Ib INNA-051 TRIAL**

*** NYRADA, WALTER REED NYR-BIO3 BRAIN INJURY RAT STUDY**

*** TRIVARX REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** EBR 1.6m CEO, 982k DIRECTOR OPTIONS AGM**

*** INHALERX 2m CHAIR SEAN WILLIAMS OPTIONS AGM**

*** GENETIC SIGNATURES LOSES 21-YEAR CEO DR JOHN MELKI**

*** DIRECTOR JANE BELL REPLACES MESOBLAST CHAIR JOSEPH SWEDISH**

*** MELODIOL LOSES DIRECTOR JODI SCOTT**

## MARKET REPORT

The Australian stock market climbed 0.35 percent on Tuesday April 30, 2024, with the ASX200 up 26.7 points to 7,664.1 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and one was untraded. All three Big Caps were up.

Actinogen was the best, up 0.6 cents or 18.75 percent to 3.8 cents, with 11.4 million shares traded. Curvebeam climbed 15.15 percent; Clarity was up 9.4 percent; Imugene and Syntara improved more than six percent; Paradigm was up 5.9 percent; Atomo and Emvision rose more than three percent; Amplia, Nova Eye, Orthocell, Proteomics and Resonance were up more than one percent, with Cochlear, CSL, Resmed and Volpara up by less than one percent.

Medical Developments led the falls, down 5.5 cents or 10.4 percent to 47.5 cents, with 449,091 shares traded. Mesoblast lost 8.8 percent; Starpharma fell 7.4 percent; Impedimed was down 5.6 percent; Percheron fell 4.2 percent; Immutep, Opthea, Telix and Universal Biosensors were down three percent or more; 4D Medical and SDI shed more than two percent; Alcidion, Clinuvel, Dimerix and Micro-X were down more than one percent; with Avita, Cyclopharm, Genetic Signatures, Neuren and Pro Medicus down by less than one percent.

## AROA BIOSURGERY

Aroa says receipts from customers for the year to March 31, 2024 were up 20.9 percent to $NZ65,675,000 ($A59,808,000), compared to the previous corresponding period.
Aroa said receipts were from sales of its Myriad products and Ovitex bio-scaffold for soft tissue regeneration, with active US Myriad sales accounts up from 205 in the three months to December 31, 2023 to 218 at March 31, 2024.
Aroa said it had reduced its three-monthly cash burn by 71 percent to about $NZ1 million.
The company said it had a positive cash flow of $NZ271,000 for the three months to March 31, 2024, with cash and cash equivalents of $NZ29,522,000 at March 31, 2024 compared to $NZ44,722,000 at March 31, 2023.
Aroa was up 1.5 cents or 3.1 percent to 50 cents.

## IMEX HEALTH SYSTEMS

Imex says receipts from customers for the three months to March 31, 2024 were up 9.4 percent to $4,801,000, compared to the previous corresponding period.
Imex said receipts from contracts for its medical imaging platforms, with 511 sites in 14 countries having processed 2.4 million studies using its platforms in the three months to March 31, 2024, generating annualized recurring revenue of about $9.3 million.
The company said it had a cash burn of $1,431,000 for the three months, with cash and cash equivalents of $1,389,000 at March 31, 2024 compared to $2,041,000 at March 31, 2023, leaving it with about one quarters cash.
Imex said it had completed a conditional placement of $250,000 and that increased revenue had “consumed significant working capital and will drive cash receipts” in the three months to June 30, 2024.
Imex was untraded at 57 cents.

## CANN GROUP

Cann says receipts from customers for the nine months to March 31, 2024 were up 33.2 percent to $13,178,000, compared to the previous corresponding period.
Cann said receipts were from sales of its medical marijuana products.
The company said it had a cash burn of $3,851,000 for the three months, with cash and equivalents of $753,000 at March 31, 2024 compared to $1,240,000 the prior year, leaving it about 0.3 quarters cash and it was “in the process of securing additional funding”.
Cann was in a suspension and last traded at 6.2 cents.

## MESOBLAST

Mesoblast says receipts from customers for the nine months to March 31, 2024 slipped 0.2 percent to $US5,632,000 ($A8,620,000), compared to the prior corresponding period.
The company said receipts were from royalties on sales of its mesenchymal stem cell products for graft versus host disease.
Mesoblast said it had a three-month cash burn $US11,645,000, with cash and equivalents of $US76,364,000 at March 31, 2024 compared to $US48,799,000 the prior year.
Mesoblast fell 9.5 cents or 8.8 percent to 99 cents with 19.2 million shares traded.

## IMPEDIMED

Impedimed says receipts from customers for the nine months to March 31, 2024 were down 3.0 percent to $8,523,000, compared to the previous corresponding period.
Impedimed said receipts were from sales of its Sozo bio-impedance spectroscopy technology for lymphoedema, heart failure and protein calorie malnutrition.
The company said it had a cash burn of $6,278,000 for the three months, with cash and equivalents of $30,682,000 at March 31, 2024 compared to $21,363,000 the prior year.
Impedimed fell half a cent or 5.6 percent to 8.4 cents with 2.2 million shares traded.

## BIOXYNE

Bioxyne says receipts from customers for the nine months to March 31, 2024 were up 363.4 percent to $7,182,000, compared to the previous corresponding period.
The company said receipts were from sales of medical marijuana products, with results constrained by a delay in receipt of product, with demand remaining “high in Australia”.
Bioxyne said it had a three-month cash burn of $970,000, with cash and equivalents of $749,000 at March 31, 2024 compared to $3,375,000 the prior year, leaving it with 0.8 quarters cash, but revenue should improve and it raised $1.45 million cut-off date.
Bioxyne fell 0.2 cents or 25 percent to 0.6 cents with 19.8 million shares traded.

## CURVEBEAM AI (ARTIFICIAL INTELLIGENCE)

Curvebeam says receipts from customers for sales of its musculo-skeletal medical imaging scanners for the nine months to March 31, 2024 were $5,188,000.
Last year, Curvebeam said it had $8,055,193 in revenue for the year to June 30, 2023 (BD: Aug 23, 2023).
The company said that it had a cash burn of $4,475,000 for the three months with cash and cash equivalents of $11,779,000 at March 31, 2024 compared to $5,157,621 at June 30, 2023.
Curvebeam was up 2.5 cents or 15.15 percent to 19 cents.

## ACRUX

Acrux says receipts from customers for the nine months to March 31, 2024 were down 40.8 percent to $4,945,000, compared to the previous corresponding period.
Acrux said receipts were from sales of its topically applied generic pharmaceuticals.
Acrux said it was $912,000 cash flow positive cash flow for the three months, with cash and equivalents of $5,328,000 at March 31, 2024 compared to $8,727,000 the prior year.
Acrux was up 0.8 cents or 13.1 percent to 6.9 cents.

## RESPIRI

Respiri says it has raised an additional $1.6 million in a placement at three cents a share, a 14.3 percent discount to its last closing price of 3.5 cents on April 29, 2024.
Last year, Respiri said it had commitments to raise $6.5 million in a placement at 3.0 cents a share, and a $20 million facility with Principal Wealth Group (BD: Dec 14, 2023).
Today, the company said it had received the placement funds in advance and they would be used for its acquisition of Access Managed Services and for working capital.
Respiri fell 0.3 cents or 8.6 percent to 3.2 cents with 1.1 million shares traded.

## CLARITY PHARMACEUTICALS

Clarity says the first prostate cancer patient treated with two doses of 8.0GBq of copper-67 Sar-Bis-prostate specific membrane antigen (PSMA) has had a “complete response”.
In 2022, Clarity said it has treated the first of up-to 30 patients in its ‘Secure’ phase I/IIa trial of copper-67 Sar-bis-PSMA for metastatic non-resectable prostate cancer at the GU Research Network’s Urology Cancer Center in Omaha, Nebraska (BD: Oct 7, 2022).
Last year, the company said it had treated the first six-patient cohort in its phase I/IIa trial of its copper-67 radioisotope therapy for prostate cancer and would increase the dose to 8GBq (gigabecquerels) in cohort two (BD: May 24, 2023).
Today, Clarity said the patient had received his first dose while in cohort two of its phase I/IIa trial and a second dose under the US Food and Drug Administration’s extended access program.
The company said the patient remained with undetectable levels of prostate specific antigen using its copper-64 positron emission tomography imaging for “almost six months, following the administration of the second dose of copper 67 Sar-bis-PSMA”.
Clarity said prostate specific antigen decline was “an independent prognostic indicator of improved overall survival following radioligand therapy”.
The company said adverse events were reported as relating to treatment including “drug mouth, altered tase, thrombocytopenia, fatigue and anaemia”, but at last follow-up were considered “non-clinically significant”.
Clarity chair Dr Alan Taylor said the company was “very excited with this incredible response of the very first patient ever to be dosed twice at what we would consider a therapeutic dose”.
“Seeing a patient that has gone through so many prior therapies now have undetectable disease with few side effects is extremely inspiring,” Dr Taylor said.
“Especially as we have now entered our first multi-dose cohort of the … trial, cohort four, at a dose level of 12GBq, where we have already seen incredible benefits in patients that have failed so many lines of therapy,” Dr Taylor said.
“We hope to replicate this remarkable result in many patients and confirm the favorable safety profile of this agent,” Dr Taylor said.
Clarity was up 24 cents or 9.4 percent to $2.80 with 2.3 million shares traded.

## ENA RESPIRATORY

Ena says the US Food and Drug Administration has approved an investigational new drug approval application for a phase Ib study of its dry powder formulation INNA-051.

Ena chief executive officer Dr Christophe Demaison told Biotech Daily that the trial would investigate up to 30 healthy volunteers.

“Due to its [mechanism of action] INNA-051 is expected to show efficacy against the most common respiratory viral infections, including Covid, ’flu and the common cold caused by rhinovirus or [respiratory syncytial virus],” Dr Demaison said.

“This is supported by pre-clinical studies in Sars-Cov-2, influenza (seasonal H3N2 and H1N1) and rhinovirus animal challenge models,” Dr Demaison said.

The company said INNA-051 was a virus-agnostic, intra-nasal, anti-viral host defence immune-modulator and was an “agonist of toll-like receptor 2/6 (TLR2/6) which plays a key role in recognizing pathogens and triggering the innate immune response”.

Ena said a phase IIa proof-of-principle study had shown that liquid formulation of INNA-501 led to viral clearance and local stimulation of anti-viral host defences in laboratory models of influenza.

The company said it had developed an improved dry powder formulation to take into further clinical development.

Ena said it had submitted ethics approval for a phase Ib study in Australia, which was expected to begin in “mid-2024, with the aim to assess the safety, tolerability, pharmaco-dynamics, and pharmaco-kinetics of the dry powder formulation of INNA-051 in older adults”.

Dr Demaison said the company was “pleased that the FDA has cleared our [investigational new drug application] for our dry powder formulation of INNA-051, which is expected to provide extended shelf life at room temperature”.

“FDA clearance is a significant milestone for the company as it supports late-stage clinical development of INNA-051,” Dr Demaison said.

Ena is a private company.

## NYRADA INC

Nyrada says it has begun a rat study of NYR-BIO3 for traumatic brain injury at Washington DC’s Walter Reed Army Institute of Research.

Nyrada said the study would assess the effectiveness of NYR-BI03 in a model of traumatic brain injury which emulated a severe traumatic brain injury.

The company said as part of the study, test animals would undergo a penetrating traumatic brain injury procedure and be treated with either NYR-BI03 or a control vehicle.

Nyrada said the study would assess neuro-protection and mitochondrial function using biomarker and magnetic resonance imaging analysis, with the analysis to be undertaken at Sydney’s University of New South Wales.

The company said it expected to begin a separate first in-human phase I clinical trial of NYR-BI03 before 2025.

Nyrada chief executive officer James Bonnar said the trial was “an exciting next step on the journey to assess the efficacy and tolerability of NYR-BI03”.

“Nyrada is currently targeting NYR-BI03, which brings a novel mechanism of action, as a therapy for both stroke and moderate to severe [traumatic brain injury],” Mr Bonnar said.

“Moderate and severe [traumatic brain injury] is considered an orphan indication by the US Food & Drug Administration designating NYR-BI03 as potentially eligible for an accelerated regulatory pathway,” Mr Bonnar said.

Nyrada fell 0.4 cents or 4.1 percent to 9.4 cents with one million shares traded.

## TRIVARX (FORMERLY MEDIBIO)

Trivarx has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on May 2, 2024, or on an earlier announcement.
Trivarx last traded at 2.6 cents.

## EBR SYSTEMS

EBR says its annual general meeting will vote to issue 1,590,000 options to managing-director John McCutcheon and 981,822 options to its chair and directors.
EBR said Mr McCutcheon’s options were subject to service-based vesting conditions, were part of his long-term incentive plan, exercisable at 55 US cents (84 Australian cents) each and were in addition to his $US525,000 ($A803,700) yearly salary.
The company said chair Allan Will and directors Karen Drexler, Trevor Moody, Dr David Steinhaus, Dr Bronwyn Evans and Dr Christopher Nave would receive 163,637 options each, exercisable at 55 US cents and in addition to their respective board fees.
EBR did not state an expiry date for the options.
The company said investors would vote to re-elect directors Ms Drexler, Dr Nave and Dr Steinhaus, ratify the prior issue of Chess depository interests, approve the 10 percent placement capacity and approve the issue of securities under its equity incentive plan.
The meeting will be held online on May 30, 2024 at 9am (AEST).
EBR fell 1.5 cents or 1.6 percent to 94 cents.

## INHALERX

Inhalerx says its annual general meeting will vote to issue chair Sean Williams 2,000,000 options as part of its incentive entitlement plan.
Inhalerx said the options would be exercisable at 15 cents each within three years from the issue date and were in addition to his $76,650 yearly salary.
Inhalerx said investors would vote on the remuneration report, to elect James Barrie and Mr Williams as directors, approve the 10 percent placement capacity and the appointment of related party Ingenu CRO Pty Ltd as contract research organization.
The meeting will be held online on May 30, 2024 at 3pm (AEST).
Inhalerx was untraded at 3.2 cents.

## GENETIC SIGNATURES

Genetic Signatures says chief executive officer Dr John Melki has “stepped down”, with director Dr Neil Gunn appointed in the interim, effective from April 30, 2024.
Genetic Signatures said Dr Melki had been with the company since 2003 and helped it achieve “several significant milestones including the successful launch of various commercial products, its ASX listing, and positioned the company for the prospective launch of its first [US Food and Drug Administration]-approved product in the US”.
The company said it had begun a search process to recruit a replacement chief executive officer in anticipation of the commercialization of its 3base product in the US.
Genetic Signatures said Dr Gunn was a “highly experienced diagnostics executive” and would act as interim chief executive officer until a replacement was found.
The company said Dr Gunn would be paid $400,000 in yearly salary, inclusive of his $US60,000 ($A91,800) annual director fees.
Genetic Signatures fell half a cent or 0.7 percent to 69.5 cents.

## MESOBLAST

Mesoblast says it has appointed director Jane Bell as non-executive chair, effective from today, replacing Joseph Swedish.
Mesoblast said Mr Swedish had “chosen to transition from chair and will remain on the board until completion of his term at the annual general meeting later this year”.
In 2022, the company said Ms Bell had replaced Shawn Tomasello as an independent non-executive director (BD: Aug 18, 2022).

## MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

Melodiol says director Jodi Scott has resigned, effective immediately.
Melodiol thanked Ms Scott “for her contributions to the company during her tenure and wish her well in her future endeavors”.
Melodiol was up 0.1 cents or 33.3 percent to 0.4 cents with 1.1 million shares traded.