Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: EMVISION UP 9.5%; PATRYS DOWN 10%**

*** DR BOREHAM'S CRUCIBLE: CLEO DIAGNOSTICS**

*** PROBIOTEC REVENUE UP 17% TO $214m; PROFIT DOWN 20% TO $11m**

*** AUSTCO REVENUE UP 17% TO $42m; PROFIT DOWN 3% TO $2.3m**

*** CRYOSITE REVENUE UP 1.5% TO $12m; PROFIT UP 3% TO $1.4m**

*** ACRUX LICENCE REVENUE UP 392% TO $8.6m; LOSS DOWN 92% TO $764k**

*** ARC $86m FOR 200 EARLY-CAREER RESEARCHERS**

*** AND HEALTH $18.75m FOR 5 BIOTECHS**

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*** CITIGROUP TAKES 29% OF BIONOMICS**

*** ARUN, SUSMITA SINGH TAKE 12.8% OF CURVEBEAM**

*** NANOSONICS APPOINTS EX-CSIRO DR LARRY MARSHALL DIRECTOR**

*** BOTANIX COO DR HOWIE MCKIBBON PROMOTED TO CEO, ON $624k PA**

MARKET REPORT

The Australian stock market fell 0.93 percent on Friday August 25, 2023, with the ASX200 down 66.9 points to 7,115.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, three traded unchanged and five were untraded.

Emvision was the best, up 14.5 cents or 9.5 percent to $1.67, with 46,924 shares traded. Actinogen climbed eight percent; Paradigm was up 7.6 percent; Prescient improved 5.6 percent; Alcidion, Micro-X and SDI were up more than four percent; Immutep, Kazia and Telix climbed three percent or more; Nova Eye rose 2.1 percent; with 4D Medical, Clinuvel, Nanosonics and Resmed up by less than one percent.

Patrys led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 446,188 shares traded. Impedimed fell 7.7 percent; Atomo, Genetic Signatures and Medical Developments lost more than six percent; Mesoblast and Orthocell fell more than five percent; Cyclopharm and Universal Biosensors were down more than three percent; Avita and Imugene shed more than two percent; Dimerix, Polynovo and Proteomics were down more than one percent; with Cochlear, CSL, Neuren, Next Science, Pro Medicus and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: CLEO DIAGNOSTICS

By TIM BOREHAM

ASX code: COV

Share price: 20.5 cents; **Shares on issue:** 128,500,001; **Market cap:** $26.3 million

Chief executive officer: Dr Richard Allman

Board: Adrien Wing (chair), Dr Allman, Dr Andrew Stephens, Prof Tom Jobling, Lucinda Nolan

Financials (December half 2023): income $5,386, loss $421,412

Major shareholders: Wing Investment Holdings (Adrien and Michelle) 11.09%, Loumea Investments (Richard Vom) 7.10%, Hudson Institute of Medical Research 5.84%.

For all the advances in cancer diagnostics, some iterations of the cheeky disease continue to evade accurate forms of detection.

That is certainly the case with ovarian cancer, the seventh-most prevalent cancer and with one of the highest mortality rates.

Because a pap smear does not pick up ovarian tumors, there is no early detection test. The diagnosis is made at the time of surgical ovary removal - which obviously is less than ideal.

Enter Cleo Diagnostics, which debuted on the ASX on Tuesday this week, having raised $12 million.

The funds are earmarked to support the commercialization of up to three diagnostic tools, starting with an application to the US Food and Drug Administration for a triaging tool (see below).

"There is no accurate pre-surgical method to diagnose ovarian cancer or to accurately differentiate between cancerous [tissues], versus the much more common benign disease," says Cleo chief executive Dr Richard Allman.

"This is simply not good enough."

Cleo hopes to succeed where many an ovarian diagnostics developers have stumbled.

"Ovarian cancer has been a hard area to be in. The number of scientific discoveries has been small in the past 20 to 40 years," Dr Allman says.

"But we wouldn't risk doing an IPO in the current climate if our story wasn't strong."

About ovarian cancer

It is estimated that 445,700 women globally will be diagnosed with ovarian cancer annually by 2040, a 42 percent increase on 2020. According to Cancer Australia, the current Australian incidence is 11 in 100,000 women.

Ovarian cancer is one of the deadliest cancers because it tends to be undetected until the advanced stages. Only 30 percent of women diagnosed at advanced stage will survive beyond five years. But survivability increases to 94 percent if detected early.

“By and large you don’t find out you have ovarian cancer until you are at a late stage, because of the location of the tumours deep inside the body,” Dr Allman says. “It also tends to be asymptomatic or with very general symptoms such as tiredness or abdominal pain.”

By late stage, the patients have hundreds of tumors around the abdomen, which means treatments - ‘debulking’ surgery and/or chemo - are not usually successful.

Currently, the standard-of-care diagnoses are trans-vaginal ultrasounds and assays based on the biomarker CA-125, which is overexpressed by ovarian tumors (as well as some other cancers).

Dr Allman says the effectiveness rate of the existing tests is no better than 50 percent: a toss of a coin would be just as useful.

The brains behind Cleo

Cleo was incorporated in November 2021, based on the assets acquired from the Hudson Institute. The Hudson Institute sprung from the 2014 merger of the Prince Henry and Monash medical research institutes.

As with all good medical discoveries, serendipity was involved: Hudson’s Dr Andrew Stephens was looking at immune responses in tumors and discovered the bio-marker CXCL-10. The test is backed by more than 10 years of research at the Hudson Institute.

An inflammatory molecule, CXCL-10 is evident only on malignant ovarian tissue and develops very early in pre-cancerous lesions. Cleo continued probing the data and ultimately struck a deal with Hudson for an exclusive worldwide licence.

An epidemiologist, Dr Allman was the chief scientific officer for Genetic Technologies, where he helped to develop the company’s second-generation breast cancer risk tool. Before that, he had an academic career in the UK.

Dr Allman also carried out due diligence for ASX blood test peer, Rhythm Biosciences, which recently won UK Conformity Assessment approval for its bowel cancer test. He then did similar work for Cleo and was convinced enough to join the company full-time.

Accountant and corporate adviser Adrien Wing founded Rhythm and he is now Cleo’s chair and biggest shareholder.

Fellow Cleo director Prof Tom Joblin is a gynaecological oncology surgeon and founder of the Ovarian Cancer Research Foundation (OCRF).

Another director, Lucinda Nolan, would be familiar to Victorians, having risen to assistant commissioner in the police force. She was then CEO of the Country Fire Authority where she faced political bushfires on all fronts, before heading to the OCRF.

Meanwhile, Dr Stephens is now Cleo's chief scientific officer.

Clinical head start

Cleo is working off the building blocks of two trials carried out by the Hudson Institute, under the auspices of Dr Stephens.

The first trial in 2020 enrolled 275 patients and assessed the ability of the test to distinguish malignant and benign tumors (triaging). The test had a sensitivity rate of 90 percent and a specificity of 91.7 percent. Sensitivity is the ability to avoid false negatives while specificity relates to false positives.

Carried out in 2022, the second trial assesses 271 patients with an elevated risk of ovarian cancer as part of a broader biomarker panel. It was able to detected malignancies at an early stage with more than 90 percent accuracy, with the "potential" to do so at a pre-cancerous stage. More work is required.

Meanwhile, Cleo expects a medical journal to publish its findings on academic data.

Targeting triage

Yet unnamed, the Cleo assay is a non-invasive in-vitro blood test to determine the presence and recurrence of ovarian cancers.

The targeted CXCL-10 is over-expressed on ovarian cancers - but not the more common benign tissue. The test consists of an immune-assay, control proteins and algorithms.

Cleo is working on three uses, but the primary commercial focus is on a pre-surgical triage test for symptomatic women.

"They may have had abdominal pain or an abnormal ultrasound, but the doctor still doesn't know whether it is an ovarian cyst or a tumour," Dr Allman says.

The only way of finding out is to excise the suspicious matter with surgery - but 90 percent of the time the lump will be benign.

Under the FDA's 510(k) route, the company merely would have to prove the product is not inferior to the existing diagnostics. Cleo notes there already are two FDA approved products targeting the CA-125 biomarker. But any commercial Cleo test most likely would be multi-panel, in that CA-125 would also be targeted for maximum efficacy.

Other applications

Cleo is also eyeing a mass screening test for non-symptomatic women and a post-surgery recurrence test to gauge whether cancer has returned. With recurrence, the CA-125 based assays have been found wanting.

“There’s more clinical complexity and uncertainty around timelines with this one, because the patients might have a recurrence after several weeks or months,” Dr Allman says.

With screening, all women aged over 50 would - or should - be eligible.

“We are de-risking this one by carrying out our first study in high-risk women with a BRCA [gene] mutation or a strong family history of ovarian cancer,” Dr Allman says.

Given that, a shorter trial with fewer patients is possible.

Finances and performance

Post IPO, Cleo has 128,500,001 shares on issue, compared with 45,000,001 previously (to be exact). The public offer consisted of 60 million shares at 20 cents apiece, plus 16 million convertible notes - part of a seed capital round - converted at 50 cents apiece.

Dr Allman says the company has enough funding to bring the triage test to market, “with a little bit of fat to initiative the recurrence and screening studies.” These secondary studies are expected to start next year.

Getting a screening test to market would require more funding, but the company will not go back to market until it has runs on the board with the FDA triage application.

In the US, about one million patients will have an abnormal ultrasound result each year, requiring referral to a specialist.

Similar triage type tests are reimbursed at about $US890 ($A1,390) which implies a $US1 billion-plus addressable market.

In the hands of the Hudson Institute, the technology was backed to the tune of $5 million by the National Health and Medical Research Council and the Ovarian Cancer Research Foundation (mainly the latter).

If the test is approved in the US, the UK, Europe or Japan, Cleo needs to pay $1.5 million to the Hudson Institute.

Given the joyousness of such a landmark occasion, we’re sure investors wouldn’t mind this modest impost.

Cleo shares ranged between 19.5 cents and 23 cents immediately after Tuesday’s debut and the last time we looked they were trading at par with the 20-cent issue price.

Check out the competition

The Cleo prospectus lists six developers of blood-based ovarian cancer assays, three of which have products on market. To be honest, the competitive landscape is blurred.

The Texas-based Aspira Women's Health has a multi-biomarker test called Ovasuite, including a triage function. Pennsylvania's Fujirebio Diagnostics also has a combination tool called Roma.

The roll-call includes the ASX listed Inoviq, which has been focused on breast cancer but is developing an ovarian cancer diagnostic for patients already diagnosed or in remission. This assay targets the CA125 biomarker. Inoviq is also tapping its separate exosome platform, Exo-Net as a broader screening tool.

We would be remiss not to mention the ASX listed Healthlinx, which tried to develop a multi-marker blood test called Ovplex. Healthlinx morphed into a social media company - never a good sign - before disappearing from the ASX boards altogether

Cleo is also keen to avoid the experience of Rhythm Biosciences, which made an "incorrect regulatory move" resulting in a surprise rejection by Australia's Therapeutic Goods Administration.

"There are learnings to be had from other peoples' hiccoughs, but there are bigger learnings to be had from successful companies," Dr Allman says.

In the non-cancer space, he cites Cellestis, which developed a niche antibody diagnostic for tuberculosis and was acquired by China's Qiagen for a tidy $355 million in 2011.

Dr Boreham's diagnosis:

Management has set a clear target of FDA approval within 24 months for the triage test, with commercial sales in the US six months thereafter.

"Two and a half years is very ambitious. I'm not aware of another Australian biotech that has delivered on a timeline like that," Dr Allman says.

Given that the Hudson has worked on the test for 10 years, Dr Allman says his goal is achievable, because management has focused on risk reduction every step of the way. In other words, the company is not chancing the FDA process by presenting half-baked data.

"It would be easy to build a black box research company around a diagnostic, with no clear line of sight to a commercial product," he says.

"We have worked hard at de-risking the company, not just from a science perspective but an investor perspective."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His idea of optimal risk management is not to get out of bed in the morning, but that is not always practical.

PROBIOTEC

Probiotec says revenue for the year to June 30, 2023 was up 17.4 percent to $214,028,475, with net profit after tax down 19.6 percent to $11,018,186.
Probiotec said its revenue increase was “driven by recovery of virus-related markets together with pricing uplifts to recoup inflationary cost pressures”.
The company said revenue came from sales of its manufactured and packaged “pharmaceuticals, consumer health and fast-moving consumer products”.
Probiotec said it would pay a fully-franked dividend of 3.5 cents a share for holders at the record date of September 1, to be paid on September 8, 2023, equal to the previous year.
Probiotec said it would not provide formal guidance but that it had significant additional manufacturing capacity through “the integration of state-of-the-art new pharmaceutical manufacturing and packing equipment coming online” by the end of the year 2023.
The company said that its diluted earnings per share fell 22.2 percent to 13.3 cents and it had cash and equivalents of $14,050,414 at June 30, 2023 compared to $22,203,568 at June 30, 2022.
Probiotec was up three cents or 1.1 percent to $2.70.

AUSTCO HEALTHCARE (FORMERLY AZURE HEALTHCARE)

Austco says revenue for the year to June 30, 2022, was up 17.0 percent to $41,978,000 with profit after tax down 3.0 percent $2,258,000.
Austco said its revenue came from sales of its Tacera and Pulse branded healthcare communications and clinical workflow systems.
The company said having “observed a material build-up in our confirmed orders as site access restrictions and supply chain challenges hampered our ability to convert sales into revenue” it had “materially delivered on the backlog of orders [in 2022-’23]”.
Austco said no dividend had been declared for the year to June 30, 2023, retaining the funds for “organic and inorganic growth” and last year it paid a 0.3 cents a share dividend.
Austco said that diluted earnings per share fell 5.1 percent to 0.775 cents, net tangible assets per share was up 2.2 percent to 6.00 cents, and it had cash and cash equivalents of $4,673,000 at June 30, 2023, compared to $7,628,000 at June 30, 2022.
Austco fell two cents or 10.5 percent to 17 cents.

CRYOSITE

Cryosite says revenue for the year to June 30, 2022 was up 1.5 percent to $11,935,000 with net profit after tax up 3.3 percent to $1,409,000.
Cryosite said revenue was from its “specialist temperature-controlled storage, logistics and distribution services, and associated process management services for clinical trials medicines, scheduled medicines and biological” as well as its long-term storage for cord blood and tissue samples.
The company said it expected to “continue to deliver an increase in revenue, [but] inflationary pressure is increasing the cost of consumables, transport, energy and talent”.
Cryosite chief executive officer John Hogg said “while we are not immune to the macro-economic environment or geo-political tensions, we have worked hard to safeguard against future challenges and will continue to operate with resilience”.
Cryosite said diluted earnings per share rose 3.6 percent to 2.89 cents, net tangible asset backing per share was up 47.6 percent to 5.86 cents, and it had cash and cash equivalents of $4,731,000 at June 30, 2023 compared to $5,341,000 at June 30, 2022.
Cryosite was untraded at 65 cents.

ACRUX

Acrux says revenue for the year to June 30, 2023 was up 392.3 percent to $8,551,000, primarily from a single licence, with net loss down 92.2 percent to $764,000.
Acrux said it was developing “a pipeline of topically applied generic pharmaceutical products for commercialization through licensees and with an emphasis on the US market”.
Earlier this year, the company said the Budapest-based Gedeon Richter PLC would buy the future royalties of its Lenzetto oestradiol transdermal spray for menopause symptoms for EUR4.10 million ($A6.41 million) (BD: Jan 23, 2023).
Last year, Acrux said revenue for the year to June 30, 2022 was $5,103,000 and this year it said revenue for the year to June 30, 2023 was $11,928,000, but in both cases it claimed about $3.4 million of Federal Research and Development Tax Incentives as revenue.
Acrux said it had not declared a dividend for the year.
The company said diluted loss per share fell 92.2 percent to 0.27 cents, net tangible asset backing per share was unchanged at 3.0 cents a share, and it had cash and cash equivalents of $6,232,000 at June 30, 2023 compared to $5,831,000 at June 30, 2022.
Acrux fell 0.2 cents or 4.35 percent to 4.4 cents.

AUSTRALIAN RESEARCH COUNCIL

The Australian Research Council says $86 million has been provided for 200 research projects in its Discovery Early Career Researcher Award (Decra) scheme.
Australian Research Council chief executive officer Judi Zielke said the funding was “a strong investment into the growth of Australia’s research and innovation capacity”.
“Increasing Australia’s research and innovation capacity generates new knowledge and results in the development of new technologies, products and ideas, the creation of jobs, economic growth and an enhanced quality of life in Australia,” Ms Zielke said.
For a full list of funded Decra projects, go to: www.bit.ly/3YNfuKT.

AND HEALTH (AUSTRALIA’S NATIONAL DIGITAL HEALTH INITIATIVE)

AND Health says it will provide five companies with up-to $3.75 million each along with assistance to help commercialize and scale their businesses.
AND Health said the program was funded by the Federal Government through the Medical Research Future Fund and the successful applicants were Atmo Biosciences, Eugene, Humanetix, Immunosis and Metabolic Health Solutions.
The organization said the companies would be supported by a “project support team and a multi-sectoral, multi-disciplinary panel of senior executives”.
According to their websites, Atmo Biosciences was developing an ingestible gas-sensing capsule to provide insights into gut health and microbiome function.
Eugene said it made genetic tests for reproductive and preventative health.
Humanetix’s website said it sells care management software.
Immunosis said it had developed a blood test for immune dysfunctions that integrated gene expression signatures and mutation information.
According to the Metabolic Health Solutions website, it runs clinics and health programs for weight loss, monitoring metabolic health and obesity related diseases.
AND Health chief executive officer Bronwyn Le Grice said companies from the first cohort five years ago had raised more than $148 million in funding and generated revenues in excess of $49 million.

CYCLOPHARM

Cyclopharm says it will receive $700,000 in a cash settlement from its legal proceedings against Landauer Australia and David Rundell.
Cyclopharm said the payment was a partial settlement of its ongoing legal action in Australia and Germany, and followed a separate $570,000 receipt from a judgment in Germany against Bjorn Altmann and Almedis Altmann GmbH in December 2022.
The company said it continued its legal action against the remaining Australian and German defendants, and expected to return to the New South Wales Supreme Court during 2023 and Germany in 2024.
Cyclopharm said that it was “confident of a favorable outcome to these legal proceedings”.
Cyclopharm managing director James McBrayer told Biotech Daily “the proceedings began in 2018 and relate to the use of intellectual property”.
Cyclopharm fell eight cents or 3.4 percent to $2.30.

GENETIC SIGNATURES

Genetic Signatures says its Easyscreen respiratory pathogen detection kit is not consistently detecting influenza B “in a small portion of low viral concentration samples”.
Genetic Signatures said minor changes to the assay design had been shown to restore detection of low viral concentration influenza B-positive samples.
The company said that it had advised the regulatory authorities of the reported detection inconsistencies and its ability to implement a solution in a relatively short timeframe.
Genetic Signatures said in the interim Easyscreen sales had been impacted and it expected forecast revenue to be about $2 million for the three months to October, with no expected impact in the following three-month periods.
Genetic Signatures fell three cents or 6.1 percent to 46 cents.

CLARITY PHARMACEUTICALS

Clarity says it has begun dosing the highest dose level in its trials of copper-67 Sartate for neuroblastoma and copper-67 Sar-bis-PSMA for prostate cancer.
Clarity said the first patient in the fourth and final cohort of its up-to 34 patient, open label, non-randomized phase I/IIa trial of copper-67 Sartate for neuroblastoma had received the highest dose of 375MBq/kg (mega-becquerels/kg).
The company said the aim of the trial was to determine the optimal dose of copper-67 Sartate for treating high-risk neuroblastoma, and once found it would progress to the dose expansion phase of an additional 10 participants.
Clarity said some participants from previous cohorts had received additional therapy cycles of copper-67 Sartate in addition to the single therapy cycle administered under their specific dose escalation phase.
Clarity said the first patient in the third and final cohort of its phase I/II trial of copper-67 Sar-bis-PSMA (prostate-specific membrane antigen) for treating metastatic, castrate-resistant prostate cancer had received the highest dose of 12GBq (giga-becquerels).
The company said the aim of the trial was to assess single doses of copper-67 Sar-bis-PSMA, to be followed by a multi-dose cohort pending a safety evaluation.
Clarity was up six cents or 5.8 percent to $1.10.

MICROBA LIFE SCIENCES

Microba says it has dosed all 32 participants in its phase I trial of MAP315 for inflammatory bowel disease, with early data indicating the drug is “well tolerated”.
Earlier this year, Microba said it had dosed the first patient in its randomized, double-blind, placebo-controlled phase I study of its live biotherapeutic MAP315 in healthy adult participants (BD: Jun 28, 2023).
Today, the company said the trial was conducted in two cohorts of 16 participant which were randomized three-to-one to receive MAP315 or placebo, with both cohorts completed as planned.
Microba head of therapeutics Prof Trent Munro said that once all participant visits in the coming weeks were complete and the total dataset was collected, final data would be available in December.
“This takes us another step forward as we look to develop MAP315 as a new treatment for inflammatory bowel disease sufferers,” Prof Munro said.
Microba was unchanged at 35 cents.

AVECHO BIOTECHNOLOGY

Avecho says it has requested a suspension following Wednesday’s trading halt “regarding a capital raising” (BD: Aug 23, 2023).
Trading will resume on the release of an announcement.
Avecho last traded at 0.9 cents.

BIONOMICS

The ASX says that Bionomics has requested a suspension from quotation “to facilitate its removal from the official list of [the] ASX”.
In July, Bionomics said it would delist from the ASX to focus on its Nasdaq listing, minimize ASX costs and leverage its US investor base (BD: Jul 25, 2023).
Bionomics last traded at one cent.

BIONOMICS

Citigroup Global Markets Australia Pty Ltd says it has increased its substantial holding in Bionomics from 423,033,300 shares (28.8026%) to 452,849,940 shares (30.8326%).
Citigroup said it held the additional 29,816,640 shares “acting as depositary under [Bionomics] existing American depositary receipts programs”.

CURVEBEAM AI (ARTIFICIAL INTELLIGENCE)

Arun and Susmita Singh say they have become substantial in Curvebeam with 41,082,279 shares or 12.83 percent of the company.
On Wednesday, Curvebeam listed on the ASX following its $25 million initial public offer at 48 cents a share to commercialize its imaging systems (BD: Aug 23, 2023).
Today, Mr Singh said that on August 16, 2023, he bought 1,041,667 shares at 48 cents a share and received 25,404,077 shares “as top-up merger consideration” with Ms Singh receiving 7,842,037 shares “as top-up merger consideration”.
According to the Curvebeam prospectus Mr Singh is an executive director, chief operating officer, chief technology officer and the head of the US division.
Curvebeam was up two cents or 5.1 percent to 41.5 cents.

NANOSONICS

Nanosonics says it has appointed former CSIRO chief executive officer Dr Larry Marshall as a non-executive director, effective from October 3, 2023.

Nanosonics said Dr Marshall had been the Commonwealth Scientific and Industrial Research Organisation chief executive officer for more than eight years.

The company said that Dr Marshall had been the managing-director or chief executive officer of six companies over the past 30 years, including Arasor and Southern Cross Venture Partners.

Nanosonics said Dr Marshall held a Bachelor of Science and a Doctor of Physics from Sydney's Macquarie University.

Nanosonics was up three cents or 0.7 percent to $4.20 with one million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has promoted chief operating officer Dr Howie McKibbon to chief executive officer, on a base salary of $US400,000 ($A623,500) a year, effective from today.

Botanix said prior to his role as chief operating officer Dr McKibbon had been its chief commercial officer, and previously was Dermavant Science's head of worldwide commercial operations and Anacor Pharmaceutical's head of sales and marketing.

The company said Dr McKibbon held a Bachelor of Arts from the Tampa-based University of South Florida as well as a Master of Business Administration and Doctor of Pharmacy from the Macon, Georgia-based Mercer University.

Botanix said Dr McKibbon would receive a fixed remuneration of $US400,000 ($A623,500) a year, with performance based short term incentives of 35 percent of remuneration and a long-term incentive of up-to 56 million share rights pending a series of performance hurdles.

Botanix was unchanged at 18.5 cents with 2.7 million shares traded.