# Biotech Daily

Friday June 16, 2023

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: PHARMAXIS UP 6%; STARPHARMA DOWN 8%**

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

*** FTI TO LIQUIDATE ELLUME (AUSTRALIA)**

*** AUSTCO $7.4m ST PAUL'S HOSPITAL VANCOUVER DEAL**

*** CORRECTION: CANN GROUP**

*** CANN GROUP: HALEON CANCELS SATIPHARM MARIJUANA TRIAL DEAL**

*** USCOM BUYS-BACK 11.3m SHARES FOR $620k**

*** REGAL TAKES 14% OF IDT**

*** HARRY HALL REPLACES NEXT SCIENCE M-D JUDITH MITCHELL, ON $655k**

*** AVITA APPOINTS DAVID O'TOOLE CFO**

*** GENETIC SIGNATURES APPOINTS KARL PECHMANN CFO, COO, CO SEC**

*** INCANNEX APPOINTS IHL-42X APNOEA TRIAL INVESTIGATORS**

## MARKET REPORT

The Australian stock market was up 1.06 percent on Friday June 16, 2023, with the ASX200 up 75.9 points to 7,251.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and one was untraded.

Pharmaxis was the best, up 0.3 cents or 6.4 percent to five cents, with 302,648 shares traded. Alcidion, Mesoblast, Next Science and Orthocell climbed more than five percent; Pro Medicus and Telix were up more than four percent; Impedimed improved 3.3 percent; Actinogen rose 2.2 percent; Avita, Dimerix, Imugene, Next Science and Proteomics were up more than one percent; with Cochlear up by 0.8 percent.

Starpharma led the falls, down three cents or 7.7 percent to 36 cents, with 926,368 shares traded. Atomo and Uscom lost more than six percent; Cyclopharm was down 5.8 percent; Patrys fell 4.55 percent; 4D Medical, Cynata, Emvision and Prescient were down more than three percent; Kazia, Neuren and Resonance shed more than two percent; Amplia, Clinuvel, Genetic Signatures, Nanosonics, Paradigm and Polynovo were down one percent or more; with CSL, Medical Developments and Resmed down by less than one percent.

# DR BOREHAM'S CRUCIBLE: LUMOS DIAGNOSTICS

**By TIM BOREHAM**

**ASX code:** LDX

**Share price:** 1.2 cents; **Shares on issue:** 300,420,080; **Market cap:** $3.6 million

**Chief executive officer:** Doug Ward

**Board:** Sam Lanyon (executive chair), Bronwyn Le Grice, Lawrence Mehren, Catherine Robson

**Financials (March quarter 2023):** unaudited revenue $US2.0 million, ($A2.94 million) operating outflows $US2.84 million, cash balance $US4.33 million, quarters of available funding*****: 2.5

***** includes $US2.67 million of undrawn convertible notes

**Identifiable major holders:** Planet Innovation Holdings 23.3%, GZ Family Holdings 9.1%, Perennial Value Management 8.0%, Ryder Capital 6.8%.

The ASX biotech sector is replete with hard-luck stories, but nothing tops the rapid valuation demise of the point-of-care diagnostics house which is now trading well under its cash backing.

Lumos means 'light' and the idea was that the company would shine brightly after its July 5, 2021 pandemic-era share market debut, which raised a chunky $63 million.

Lumos specializes in rapid point-of-care (POC) tests to help healthcare professionals diagnose and manage medical conditions more accurately.

Lumos offers customized assay development and manufacturing services for third-party POC tests, as well as proprietary digital reader platforms.

Sadly, Lumos shares have lost 99 percent of their value since the IPO. The key (but certainly not the only) culprit was last year's US Food and Drug Administration decision to decline marketing approval for the company's viral-versus-bacterial test, Febridx.

Is there a way forward for the company which at least has revenue and solid contracts in place?

CEO Doug Ward, who replaced Rob Sambursky a year ago, maintains Lumos is hiding its light under a bushel.

Mr Ward says Lumos had spent large wads of the initial public offer funding but was not seeing the results: "I saw they had products that could get there, just a bit differently."

## Problems solved?

Mr Ward says even before he clocked on to the top job, the company had already “course corrected and made a bunch of really difficult decisions”.

Still, new management quickly identified that Lumos was over-emphasizing the product side of its business and neglecting the services side that contributes most of its revenue.

Meanwhile, the cash-strapped Lumos has entered an unusual tie-up with the Massachusetts-based women’s’ health specialist, Hologic.

Announced in mid-March, the deal involves Hologic buying some of Lumos’s manufacturing equipment at its Carlsbad, California facility and renting it back to the company. This resulted in a $4.4 million cash injection.

Hologic’s involvement is not exactly arbitrary: Mr Ward was business development manager for Hologic and Hologic was one of Lumos’s biggest customers for its services.

“The reader technology is probably best-in-class and the key reason for Halogic’s interest,” Mr Ward says.

## A quick recap

Googlers beware: Lumos is also the name of several other healthcare related programs, including a New South Wales survey of “patient healthcare journeys” a University of Sydney brain tumor program and an “open-source device for wearable spectroscopy research”.

Lumos’s ASX debut came amid a flurry of big-ticket life sciences initial public offers, including Trajan Scientific and Australian Clinical Laboratories.

Lumos is a spin-off from the Melbourne based Planet Innovation, which has developed quite a reputation for medical device design and development. Planet Innovation retains a 23 percent shareholding in Lumos and remains a guiding - er - light via Lumos chair (and Planet Innovation CEO) Sam Lanyon.

In Planet Innovation’s hands, Lumos was engorged via the acquisition of Nplex, which held crucial electronic reader technology. In 2019, Lumos merged with the Florida-based Rapid Pathogen Screening (RPS), developer of the Febridx test to distinguish between viral and bacterial infections.

Dr Sambursky co-founded RPS.

To truncate a lengthy yarn, the wheels quickly fell off the Lumos cart and the board moved to replace Mr Sambursky and trim the workforce.

The company’s Sarasota, Florida premises - a legacy of RPS - was closed and all manufacturing, research and commercial activities were relocated to California.

## Lifting the hex on Febridx

Lumos's former flagship product, Febridx, is a finger-prick blood test that can distinguish between viral and bacterial within 10 minutes.

The kits are lateral flow, which means the sample flows horizontally over a strip containing the test reagents (about two-thirds of all POC tests are designed as lateral flow).

In what Mr Ward dubbed as "not the outcome the company was seeking" last July the FDA rejected Lumos's marketing approval application under the 510(k) device pathway, deeming Febridx as not substantially equivalent to the predicate device.

In effect, the agency feared false negative Covid (viral) tests.

Febridx previously had been approved in the UK, Europe, Canada, Brazil, the United Arab Emirates and - lest we forget - Australia.

The company appealed the decision, but the agency held firm. Following a meeting with the FDA in January this year, the company submitted a proposal for a revised usage under the 510(k) pathway.

This Plan B involves Febridx following other tests for Covid or the 'flu has been deployed.

If Febridx reads positive for a bacterial infection then - and only then - it is off to the doc for antibiotics.

Mr Ward says FDA approval would have been a "no brainer" had it not been for Covid, given the plague made the agency "over-the-top sensitive" about tests returning false negatives. The company expects to hear back from the regulator by the end of 2023.

Mr Ward says Lumos would partner to bring the diagnostic to market: "You just have to be realistic and a little bit humble."

## Other products

Despite the emphasis on the services side of the business, Lumos does have its own products.

As an extension of Febridx, the company is developing Uridx for urinary tract infections and Sepsidx for the often-fatal blood infection sepsis.

On the commercial side, Lumos is working on assay development and customizing readers for pharmaceutical and medical device companies.

It is also working on novel tests for infectious and inflammatory diseases.

Lumos also developed its own Covid-19 assay called Covidx, a fingerprick rapid antigen test more comfortable than the 'brain stab' nasopharyngeal swab test.

In February last year, Lumos announced a deal with the Victoria Government to co-invest in a $17 million Covid rapid antigen test manufacturing facility, but this one went nowhere.

The company is also hoping the FDA will grant emergency use application for Viradx, a three-in-one rapid antigen assay for Covid, influenza A and influenza B. Management recently provided more information to the agency and is awaiting an approval decision.

Over the border, Health Canada has granted interim authorization and the company is filling initial orders.

We should also mention is that Lumos avails of plastic cassettes supplied by Atomo Diagnostics, which listed on the ASX in April 2020, on the back of its HIV rapid antigen tests.

## Finding niche markets

Mr Ward says the reality of product development is that a company the size of Lumos is simply too small. Given that, Lumos will look for further partnerships to get its tests to market.

The company certainly does not intend to compete with the likes of Roche, Siemens and Johnson & Johnson in core respiratory or cardiac markets.

“We will find niche areas, such as [sexually transmitted infections] and cardiac health,” he says.

“We don’t have to build the market or create something that does not exist. We just have to create something that is a little bit better [than what is on offer].”

To date, POC tests typically have been used for glucose and cholesterol measurement, pregnancy tests, cardiac issues and faeces-based blood tests (for bowel cancer).

## Finance and performance

In the March 2023 quarter Lumos gleaned $US2 million ($3 million) of revenue, 13 percent less than in the December 2022 quarter and mainly from the services business (diagnostic test development and contract manufacturing).

The company recorded receipts of $US1.07 million, down 17 percent, with cash outflows of $US2.84 million.

“Orders for Febridx from our distributors in four European markets remained relatively modest, but are starting to gain momentum,” the company said.

Lumos ended the quarter with cash of $US4.33 million, courtesy of the sale and leaseback deal that netted $US4.2 million.

In December 2022 shareholders voted in favour of an $8 million convertible note issue to two US institutions, in two equal tranches. The first $4 million was drawn down immediately, with the remainder available “subject to Lumos’s capital needs and mutual agreement between Lumos and the investors”.

The Lumos IPO raised $63 million, including $30.4 million from the issue of new shares and $20 million from the sale and transfer of existing shares. In June 2022, the company raised a further $11.2 million in a rights offer.

Issued at $1.25 apiece, Lumos shares peaked at $1.18 in mid-August 2021 and after a mini rally they are just above last Friday’s nadir of 1.2 cents.

**Dr Boreham’s diagnosis:**

Lumos investors must fondly remember the pandemic - so to speak - given the company’s revenue blip from $A8 million in 2019-’20 year to $A21 million in 2021-’22.

Undeterred, Mr Ward is striving to make Lumos a $US100 million-plus revenue company.

He says the services business should not amount to a “science experiment” in that products should emerge as well.

“Services and products are hand-in-glove if you do it right,” he says. “If you have a platform and can launch a portfolio of products then you have a winning combination.”

These days, aged care facilities, local councils and libraries are giving Covid tests away. This speaks volumes about the post-pandemic hangover faced not just by Lumos, but ASX peers including Atomo, Genetic Signatures and the substantive Australian Clinical Laboratories.

In the case of the unlisted Ellume the hangover has proved to be more than headache and nausea: the company yesterday called in the administrators after a rescue deal fell through, reportedly leaving creditors short of $200 million and more than 40 jobs in peril.

On the positive side, Lumos argues, the pandemic has accelerated the adoption of POC testing more generally.

Also, the problem of antibiotic resistance remains unchecked and Lumos has a key role to play in ameliorating what the World Health Organization describes as one of the globe’s top 10 health threats.

Meanwhile, the Hologic sale and leaseback deal shows some admirable commercial nous, but more initiatives will be needed to restore the Lumos glow and ensure the company does not run out of funds.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Having failed to find the winning combination of higher income and lower expenses, he is constantly at risk of running out of funds.***

## ELLUME, FTI CONSULTING

Administrators, FTI Consulting say that Ellume has been placed into liquidation following the unsuccessful completion of the Hough deed of company arrangement.

Biotech Daily understands that Ellume's US subsidiary, Ellume USA LLC, was not in liquidation and would continue its operations, which included a $US231.8 million contract with the US Department of Defense (see below) and the pursuit of further contracts.

Biotech Daily understands that of the money owed to creditors, about $65 million is owed to trade creditors with a further about $100 million in convertible notes.

In 2019, Ellume chief executive officer Dr Sean Parsons said the company hoped to list on the ASX to commercialize its range of respiratory diagnostics, including licences with Glaxosmithkline for an influenza test and Qiagen for an upgrade to the Cellestis-developed Quantiferon Gold test for tuberculosis (BD: Apr 9, 2019).

Dr Parsons told Biotech Daily at that time that the company had developed fluorescent immune-assays using a quantum dot system which could simplify blood tests, and instead of using an enzyme linked immunosorbent assay (Elisa) the Ellume system analyzed a signal over time and could provide accurate results in 20 minutes, without the need for the samples being sent to a pathology laboratory.

In December 2020, Ellume said its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) home test was "96 percent accurate" and received US Food and Drug Administration "emergency use" approval (BD: Dec 10, 16, 2020).

Two months later, Ellume said the US Government will provide $US231.8 million ($A302.8 million) to produce its Sars-Cov-2 home tests but in October recalled a "specific product lots of [Sars-Cov-2] tests" after they reported false-positive test result rates higher than was observed in clinical testing (BD: Feb 2, Oct 7, 2021).

Biotech Daily understands the recall cost Ellume $37 million, not including lost sales.

Last September, Ellume said it had appointed John Park and Joanne Dunn of FTI Consulting as voluntary administrators, who later said the company had $140 million in liabilities, assets included $1.5 million in cash, $37 million in plant and equipment, with inventory to be confirmed, with liabilities including $89 million for convertible noteholders, $49 million for creditors and $1.69 million in employee entitlements for a "headcount" of 215 staff, but the US business was not subject to the voluntary administration and would continue to trade its business as usual until further notice (BD: Sep 1, 13, 2022).

In December, FTI said that the Burleigh West, Gold Coast, Queensland-based Hough Consolidated Pty Ltd proposed to buy Ellume for $US38 million ($A56.2 million) through a deed of company arrangement (Doca) which was supported by a second creditors meeting on December 20 (BD: Dec 13, 21, 2022).

This week, FTI said Hough had been unable to provide $1.25 million to the deed administrators nor demonstrate it had sufficient funds to pay the short-term funders despite several extensions by 4pm on June 13, 2023 and the deed of company arrangement "was automatically terminated".

"The company has been placed into liquidation and a wind-down of the operations has begun," FTI said.

The administrators said that company operations were ceasing and "we have issued communications to certain suppliers for the closure of the accounts set up during the administration and Doca periods".

"There are some suppliers who have been separately advised to continue supply or services during the liquidation," FTI said.

FTI said it would report to creditors on the estimated return within three months.

Ellume was a public unlisted company.

## AUSTCO HEALTHCARE

Austco says Vancouver's St Paul's Hospital has paid its Canada subsidiary Austco Marketing & Service $7.4 million to supply its Tacera alarm management software.
Austco said the contract was its largest contract award, covering 1,100 Tacera patient stations, 1,200 clinical workflow terminals and webservices interfaces.
The company said the 548-bed St Paul's Hospital was under construction and expected to open in 2026.
Austco said that with the application stations installed at the facility, critical messages including medical emergency notifications, would be delivered "ensuring staff are promptly notified and can act quickly".
Austco chief executive officer Clayton Astles said "this is the largest contract win in the company's history and demonstrates our growing sales momentum and the increasing reputation of our flagship product Tacera as the most advanced clinical workflow solution available today".
Austco was up 3.5 cents or 25 percent to 17.5 cents with 2.15 million shares traded.

## CORRECTION: CANN GROUP

Last night's edition incorrectly reported that Cann Group hopes to raise $11.7 million in a four-for-one rights offer at 12 cents a share. It is a one-for-four rights offer.
The company said it would issue two million options to PAC exercisable at 24 cents each within 36 months, as well as a two percent management fee on the rights offer and a six percent selling fee for the shortfall.
The Thursday sub-editor said that although their add-ups and subtracts were "pretty fair", they had always had difficulties with "timeses and stuff" (multiplication and division) and has been sent to Price Waterhouse Coopers for re-programming.
Cann Group was unchanged at 12.5 cents.

## CANN GROUP

Cann Group says Haleon Australia Pty Ltd will terminate the clinical trial option and evaluation agreement for its schedule 3 over-the-counter Satipharm cannabidiol (CBD).
In January, Cann said preliminary analysis of its more-than 212-patient, randomized, blinded, controlled phase III trial of Satipharm CBD capsules for sleep disturbances had "not shown a statistically superior response compared to placebo" (BD: Jan 22, 2023).
Today, the company said the Haleon termination would take effect on September 7, 2023 and that during the termination period it would continue discussions with Haleon "regarding other potential opportunities".

## USCOM

Uscom says it has bought back 11,266,885 shares for $619,679 or 5.5 cents each.
In May, Uscom said it intended to buy-back up to 19,676,833 shares at 5.5 cents a 37.5 percent premium to the volume weighted average price of 4.0 cents on May 5 "to rationalize shareholdings as a further step to optimize shareholder value and [was] looking at a range of national and international corporate activities" (BD: May 8, 2023).
Uscom said that there were 198,635,884 shares on issue prior to the buy-back.
The company's buy-back booklet said the shares would be cancelled, leaving 187,368,999 shares on issue.
Uscom fell 0.3 cents or 6.25 percent to 4.5 cents.

## IDT AUSTRALIA

Regal Funds says it has increased its substantial shareholding in IDT from 26,360,286 shares (10.94%) to 43,578,939 shares (14.30%).
Sydney-based Regal said it bought and sold shares between August 1, 2022 and June 13, 2023, with the single largest purchase of 18,904,248 shares for $1,228,776 or 6.5 cents a share on June 13.
Last week, IDT said it had “firm commitments” to raise $5.0 million in a placement at 6.5 cents a share with a $2.0 million share plan to follow (BD: Jun 5, 2023).
IDT fell 0.1 cents or 1.5 percent to 6.4 cents.

## NEXT SCIENCE

Next Science says Harry Hall IV will replace managing-director Judith Mitchell, effective from July 10, with Ms Mitchell to remain with the company until July 31, 2023.
Next Science said Mr Hall had been an executive at Johnson & Johnson’s DePuy Synthes responsible for a $US3.2 billion ($A4.68 billion) platform.
The company said Mr Hall held a Bachelor of Science and a Master of Science from the South Carolina’s Clemson University and a Master of Business Administration from Philadelphia’s Pennsylvania State University.
Next Science chair Prof Mark Compton said the company thanked Ms Mitchell “for the pioneering work she has done for Next Science in establishing its position as a listed medical device company and building its business such that many thousands of patients have already been assisted by the unique and highly effective products that stem from our Xbio technology”.
The company said that Mr Hall would be located in Jacksonville, Florida and have a base salary of $US450,000 ($A654,663) a year, along with $US500,000 in performance rights, pending shareholder approval and short-term cash incentives.
Next Science was up one cent or 1.9 percent to 54 cents.

## AVITA MEDICAL

Avita says it has appointed David O’Toole as its chief financial officer, effective from June 15, 2023.
Avita said Mr O’Toole had more than 30 years of experience in biotechnology and life sciences companies, including as chief financial officer of Opiant Pharmaceuticals and Soleno Therapeutics.
The company said Mr O’Toole held a Bachelor of Science from the University of Arizona.
Avita was up nine cents or 1.8 percent to $4.99 with 558,471 shares traded.

## GENETIC SIGNATURES

Genetic Signatures says it has appointed Karl Pechmann chief financial officer, chief operating officer and company secretary, effective from June 26, 2023.
Genetic Signatures said Mr Pechmann had been an executive at companies, including Oncosil Medical, Kyckr and Immutep.
The company said Mr Pechmann’s appointment followed the resignation of previous chief financial officer and chief operating officer Peter Manley, and would succeed the interim chief financial officer and company secretary Anthony Rule.
Genetic Signatures fell one cent or 1.9 percent to 52 cents.

## INCANNEX HEALTHCARE

Incannex says it has appointed Dr John Hudson and Dr Russell Rosenberg as principal investigators for the phase II/III trial of IHL-42X for obstructive sleep apnoea.

According to the Incannex website, IHL-42X was a composite of tetrahydrocannabinol (THC), acetazolamide (a carbonic anhydrase inhibitor) and dronabinol (a synthetic marijuana).

Incannex said it planned to recruit about 45 sites for the trial, with the facilities of the Austin, Texas-based Dr Hudson and the Atlanta, Georgia-based Dr Rosenberg to serve as the first clinical trial sites for submission to the US Food and Drug Administration and ethics approval.

The company said Dr Hudson worked for the Austin-based Future Search trials, with facilities in Austin and Dallas, and had supervised more than 300 clinical trials over the past 20 years.

Incannex said Dr Rosenberg was chief scientific officer and chief executive officer of Atlanta's Neuro Trials Research, with more than 35 years of experience in clinical sleep medicine and research, and had been investigator in more than 300 trials.

Incannex fell half a cent or 4.35 percent to 11 cents with 1.5 million shares traded.