Biotech Daily

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Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.17 percent on Friday July 16, 2021, with the ASX200 up 12.2 points to 7,348.1 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell and 12 traded unchanged.

Proteomics was the best, up 8.5 cents or 8.5 percent to $1.08, with 439,551 shares traded. Neuren climbed 5.2 percent; Cynata improved 4.1 percent; Kazia and Optiscan rose two percent or more; Pharmaxis and Pro Medicus were up more than one percent; with Avita, CSL and Resmed up by less than one percent.

Yesterday's 17.65 percent best, Alterity, led the falls, down 0.5 cents or 12.5 percent to 3.5 cents, with 30.6 million shares traded. Medical Developments lost 5.7 percent; Mesoblast and Prescient fell more than four percent; Cyclopharm, Nova Eye, Patrys and Universal Biosensors were down more than three percent; Amplia and Opthea shed more than two percent; Genetic Signatures, Immutep, Imugene, Paradigm, Polynovo, Starpharma and Volpara were down one percent or more; with Clinuvel, Cochlear, Next Science and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: LUMOS DIAGNOSTICS

By TIM BOREHAM

ASX code: LDX

Share price: $1.27; **Shares on issue:** 150,152,413; **Market cap:** $190.7 million

Chief executive officer: Dr Rob Sambursky

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

Financials: (December half 2020): revenue $11.5 million (up 200%), net loss $5.63 million (previously $6.28 million deficit), cash of $15.3 million (pre $63 million IPO)

Identifiable major holders: Planet Innovation Holdings 26.7%, RPS Diagnostics 10.4%, Perennial Value Management 7.81%, Acorn Capital 5.98%, Ellerston Capital 5.43%.

From the cluttered pipeline of initial public offers (IPOs) in the life sciences sector, another star is born.

Lumos listed on July 1 after a $63 million fund raising, displacing recent ASX debutantes Trajan Scientific (scientific instruments), Argenica (neuroprotective therapeutics) and Australian Clinical Laboratories from the centre stage.

"Everyone wants to be the new song," chirps the company's Florida based chief executive, Rob Sambursky.

Lumos is singing the virtues of its point-of-care (POC) diagnosis for viral and bacterial acute respiratory infections - and being able to distinguish between the two key maladies is a useful attribute at a time when the world is ridden with pestilence.

In the past, POC tests have typically been used for glucose and cholesterol levels, pregnancy tests, cardiac issues, pregnancy detection and faecal-based blood tests (for bowel cancer). Lumos also develops digital readers to interpret the sample strips.

But can Lumos - which means 'light' - continue to shine on a crowded stage?

Off the Planet

Lumos sprung from the loins of the Melbourne based Planet Innovation, which designs and develops devices for numerous life science companies. (In May, Prime Minister Scott Morrison popped in for a look-see. How good was that?)

Lumos was founded within Planet Innovation in 2015 and was then engorged via the acquisition of Nplex Pty Ltd (which held electronic reader technology).

In 2017, Lumos acquitted Kestrel Biosciences which owned adjunct technology pertaining to rapid diagnosis. After this, Lumos - which actually wasn't called Lumos - changed its name to Lumos.

In 2019, Lumos merged with the Florida based Rapid Pathogen Screening (RPS), which was developing the Febridx test. So, in effect RPS brought the product side of Lumos to the table.

"A commercial guy trapped in a doctor's body," Dr Sambursky is a medical doctor with advanced training in ophthalmology and infectious diseases. He went on to co-found RPS.

As his title suggests, Lumos executive chair Sam Lanyon takes a hands-on role, but his day-job is actually running Planet Innovation which has lofty aspirations of its own.

Lumos carries out its manufacturing, research, development and commercialization activities from facilities in Carlsbad, California and Sarasota, Florida. But its official HQ is in Melbourne, Australia (not to be confused with Melbourne, Florida).

Just the product for testing times

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

Febridx is approved and sold in Canada, the UK and Europe, while the US Food and Drug Administration currently is mulling the company's 510(k) device submission.

Here, Lumos has Therapeutic Goods Administration assent, but selling in Australia is challenging, where much of the testing is hospital-based, along with centralized pathology laboratories.

So far, however, Lumos has gleaned most of its revenue from the commercial services side of the business. In effect a white labelling arrangement, the company undertakes customized assay and digital reader development and manufacturing for other parties with the desire (but not ability) to develop a test.

"We have clients in Europe, Asia and the US," Dr Sambursky says. "We have eight to 10 of them at any given time. Some are more active than others but we are happy to have diversity of clients."

Biden time away in the US of A

Not surprisingly, Lumos's key focus is on the US market, which accounts for just over half of all rapid diagnostic tests sold. This is driven not just by the size of the market, but a sympathetic reimbursement system that resulted in the tests being used routinely.

“It’s harder to enter the US market from a regulatory perspective, but easier from a commercial perspective,” Dr Sambursky says.

Fear has also been a motivating factor, in that doctors will always opt for a test rather than risk a patient death and then a letter from an ambulance-chasing lawyer.

They also make money out of the tests - which cost about $US20 ($AUD26) per patient - and that’s not always the case.

Lumos initially submitted its FDA paperwork as a de novo (new) application, which is more complicated than a standard 510(k) job. On its own volition, the regulator allowed it through as 510(k), which means the company can use data from a previous trial rather than undertaking a new one.

“All of the data is in,” Dr Sambursky says. “We are playing a waiting game but are confident of the decision will be favorable in light of the fact we achieved the critical milestones.”

What’s next?

Lumos cites a pipeline of complementary products that will tap into the established distribution channels and underlying technology. Some will provide a potential entrée into home testing, especially for the assays that produce a simple yes or no answer.

As extension products 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’s also working on non-infectious medical conditions such as gut complaints, allergies and immune system maladies.

The mandatory Covid bit

Lumos is developing its own Covid-19 (well, actually severe acute respiratory syndrome coronavirus-2, or Sars-Cov-2) assay called Covidx, which is a specific antigen POC test.

“As a fingerprick test it’s much more comfortable than the ‘brain tickle’,” Dr Sambursky says. (The good doc is of course referring to the ubiquitous naso-pharyngeal swab test, also cruelly referred to as the ‘brain stab’).

Lumos is also working on an extension assay called Viradx, which can simultaneously detect influenza A and B and Covid.

In the meantime, Febridx has been used as a patient triage tool to separate those with a virus, a bacterial infection or nothing at all (the test is 99 percent accurate in detecting the negative cases). Only the virus-positive patients need to undergo a specific Covid test.

The Covid plague also increased demand for Lumos's commercial services, via new agreements with large healthcare providers such as Italian based diagnostics giant Diasorin.

Finances and performance

In the December half of 2020, the then private Lumos increased revenue by 238 percent, from $3.4 million to $11.5 million. Most of the revenue - $9.8 million – was derived from the services side of the business. But Dr Sambursky expects products sales will account for most of the company's revenue within two to three years.

Management is confident enough to forecast revenue of $23.8 million for the year to June 30, 2021. Understandably, management won't predict performance for the current year or future years.

The revenue growth was spurred by new distributor appointments and Febridx sales gaining traction in the UK and other key markets.

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. Also, $25.3 million of convertible notes issued last year were converted into ordinary shares.

The IPO funds will be used to support "infrastructure and capacity expansion, developing the test pipeline and tech platform development".

Post listing, existing Lumos holders account for 66.4 percent of the register. Of these 75.4 million shares, 75 percent are escrowed for up to two years.

Lumos lost $5.6 million during the December half and does not expect to be profitable this year.

"We have flirted with profitability for several months in the past year," Dr Sambursky says. "We could have throttled back but we decided to raise capital and grow the business, which increases the expenses."

Summing up the rivals

Mr Sambursky cites the company's key competitors as Israeli start-up Memed and Inflammatix

Memed recently raised $US75 million to develop a device which deploys the body's immune system to distinguish between viral and bacterial diseases.

A private US company, Inflammatix is developing molecular diagnostics-based tests for acute diseases including sepsis.

Dr Sambursky says the key difference between these companies and Lumos is that Febridx targets outpatient applications (such as doctors' clinics), based on a model of single usage and high throughput.

"The competition has much more of a desktop reader approach. They are also still years away [from] coming to the market," he says.

Life science IPO watchers would be familiar with Atomo Diagnostics, which listed on the ASX in April 2020, on the back of its rapid diagnostic test focused on HIV. Lumos and Atomo are not so much in competition as 'co-opetition': the latter provides the plastic cassette 'hardware' for the Lumos tests.

Dr Sambursky says: "We make the tests strips and the chemistry and everything that makes Febridx what it is but we run it in their plastic housing."

Dr Boreham's diagnosis:

Ultimately, Lumos is tackling an emerging health crisis which on the World Health Organisation's reckoning will kill 10 million of us a year by 2050 if nothing is done.

We're not talking about Covid-19, which has 'only' cost four million lives so far. The bigger problem is antibiotic resistance, which the WHO (the organisation, not the band) rates as one of the globe's top 10 health threats.

According to the US Center for Disease Control, 30 percent of outpatient antibiotic prescriptions are unnecessary.

Dr Samburksy says only 18 percent of patients front up to their doc with a bacterial complaint, but 55 percent are prescribed antibiotics. That's because the medics are scared of missing a bacterial infection, or they're being pressured by the patient to prescribe something … anything. The Febridx can tell the doctor whether the infection is viral (no antibiotics) or bacterial (try antibiotics).

"We can slow the development of drug resistance and save unnecessary costs," Dr Sambursky says.

According to research house Markets and Markets, the global point-of-care diagnostics market is worth just shy of $US30 billion a year, with infectious diseases accounting for $US2.9 billion.

The addressable market in North America and Europe - the company's key target markets - are worth $US19 billion ($US1.8 billion for infectious diseases).

With the pandemic still raging it's a case of so far, SAR(s) good for Lumos in its early life on the ASX stage. but expanding its songbook would be desirable.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He was tempted by a lucrative musical career after realizing audiences would pay him not to sing.

MEDICAL DEVELOPMENTS

Medical Developments says it expects last year's net profit after tax of $379,000 to be turned to a loss of $4.2 million to $5.2 million, pre-impairment.

Last year, Medical Developments said that its revenue for the year to June 30, 2020 was up 10.6 percent to $23,640,000, with net profit after tax down 63.5 percent to $379,000 (BD: Aug 19, 2020).

The company said at that time that the Covid-19 pandemic led to a decline in sports activities and reduced population movements and consequently a reduction in emergency service use of its Penthrox inhaled methoxyflurane analgesic.

Medical Developments said that its respiratory device sales were "an all-time high", up 61 percent for the year to June 30, 2020 and "partly attributed to Covid-19 related purchasing, but predominately related to new product launches and new pharmacy channel success in multiple markets".

Today, the company said that it expected "to recognize a non-cash charge of $7.5 million to $8.5 million after tax within … [its] accounts" related to both its respiratory business and the continuous flow technology.

Medical Developments has previously said it was working with the Commonwealth Scientific and Industrial Research Organisation on its continuous flow technology for the production of active pharmaceutical ingredients s (BD: Jun 5, 2017; Oct 29, 2019).

Today, the company said the respiratory business was "adversely impacted in 2020-'21 by the Covid-19 pandemic, moderating our growth outlook and resulting in an impairment of the associated intangible assets".

Medical Developments said that its flow technology would deliver long-term value beyond the manufacture of Penthrox, but it had "not yet unlocked this value".

"As such, the asset has been impaired," the company said.

Medical Developments said it would "continue to pursue licencing and other opportunities for the technology".

Medical Developments fell 25 cents or 5.7 percent to $4.12 with 474,229 shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says customer receipts for the six months to June 30, 2021 were up 36.3 percent to $US3,193,000 ($A4,295,663) compared to the prior corresponding period.

Visioneering said customer receipts from the sales of its Naturalvue multifocal contact lenses for the three months to June 30, 2021 was up 50.9 percent to $US1,634,000.

The company said its cash burn for the three months to June 30, 2021 was $US2,105,000 with cash and equivalents of $US15,078,000.

Visioneering fell 3.5 cents or three percent to $1.115.

NOVA EYE MEDICAL

Nova Eye says it has established a share sale facility for holders of unmarketable parcels of shares, worth less than $500.

Nova Eye said that the facility for holders of 1,587 shares or fewer, was based on 31.50 cents a share at the record date of July 8, 2021.

The company said that 1,429 of its 3,691 shareholders would be eligible for the facility which would allow shareholders to sell shares without brokerage or handling costs and allow the company to reduce administrative costs.

Nova Eye said the closing date for the facility would be August 30, 2021.

Nova Eye fell one cent or 3.2 percent to 30 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its 2,008-sample study with Janssen found a “significant reduction” in the Promarkerd risk scores of type 2 diabetes patients taking canagliflozin.

Proteomics said the study with Johnson & Johnson’s Janssen Research and Development LLC examined the association between canagliflozin, a sodium-glucose transport protein 2 (SGLT2) inhibitor diabetes drug, and the Promarkerd score over three-years.

The company said the study measured the blood samples from the patients at the start of the trial and three years later showing that the average Promarkerd risk score of patients taking canagliflozin reduced, while the average risk score increased in patients who took the placebo.

Proteomics managing director Dr Richard Lipscombe said the findings “further illustrate the benefits of the Promarkerd test by showing that we can also identify patients who are asymptomatic for diabetic kidney disease, and that canagliflozin improves their renal risk profile as well”.

“For the first time, we are confirming that the SGLT2 inhibitor class of diabetes drug is associated with lowering a patient's Promarkerd risk score, and that there is a potential treatment for the at-risk patients identified by the test,” Dr Lipscombe said.

Proteomics was up 8.5 cents or 8.5 percent to $1.08.

INCANNEX HEALTHCARE

Incannex says it has hired Procaps SA to formulate its marijuana and hydroxy-chloro-quine IHL-675A for a range of inflammatory diseases.

Incannex said the Barranquilla, Colombia-based Procaps provided formulation, clinical trial supply and commercial manufacture, and had developed more than 500 formulations for pharmaceutical and nutritional products for more than 50 countries.

The company said Procaps’ Unigel technology encapsulated capsules or other solid dosage forms within capsules.

Incannex was up one cent or 3.7 percent to 28 cents with 2.8 million shares traded.

MGC PHARMACEUTICALS

MGC says it has applied to the Slovenian Intellectual Property Office for a patent covering its “self-nano-emulsifying drug delivery system” for marijuana molecules.

MGC said the patent, titled ‘Cannabinoids-Ionic complex self-nanoemulsifying concentrate and method for preparation thereof’ would protect its “self-nano-emulsifying cannabinoids-ionic complex concentrate drug delivery system”, its formulation, method of manufacture and capacity for enhancing stability, solubility and bioavailability.

The company said its drug delivery system could administer higher cannabidiol concentrations at 100-200mg/ml for the treatment of neurological conditions.

MGC said that the molecule emulsified “immediately at the oral mucosa epithelium, resulting in instant bio-trade into the blood plasma”.

The company said the claims covered the manufacture of cannabinoids concentrate in liquid (oral mucosal spray, drops) or solid (powder, gelatin capsule) forms.

MGC said its drug delivery system was based on type IV oil-free nano-technology which had a globular molecule size below 50 nano-metres enabling it to pass through the blood brain barrier, for the treatment of neurological diseases.

MGC was up 0.1 cents or 2.6 percent to four cents with 6.6 million shares traded.

CRESO PHARMA

Creso says it has launched its marijuana-based Cannadol gel products for sports in Switzerland.
Creso said it launched Cannadol Boost for use before sports activity and Cannadol Recovery to be used after physical activity to enhance recovery, developed using its hemp, cannabidiol tea-based technology.
The company said Cannadol Boost contained a formula of caffeine, taurine, vitamins and minerals for energy boost while Cannadol Recovery contained lemon balm, curcumin, vitamins and minerals.
Creso was up half a cent or 3.7 percent to 14 cents with 62.8 million shares traded.

AROA BIOSURGERY

Aroa says that 118,047,131 shares held in voluntary escrow will be released on July 23, 2021.
Aroa said Movac Fund 3 LP and Movac Sidecar Fund LP held 21,480,975 shares or 7.1 percent of the company and following the release from escrow would undertake an "in-specie distribution" of a minimum of 16,063,983 shares or about 5.3 percent of the company, reducing its holding to below the five percent substantial level.
According to July 7, 2021 notice to the ASX, Aroa had 301,076,111 shares on issue.
Aroa was up one cent or 0.8 percent to $1.24.

LIVING CELL TECHNOLOGIES

Living Cell says it has appointed chair Prof Bernie Tuch as interim chief executive officer following the resignation of Dr Ken Taylor, effective from today.
Living Cell said Dr Taylor joined the company in February 2014 as its chief executive officer and was appointed to the board in August 2018.
Prof Tuch said the board was "extremely grateful for [Dr Taylor's] contribution and leadership during his time with the company".
"Living Cell has benefited greatly from his experience and international connections," Prof Tuch said.
Living Cell was unchanged at 1.4 cents with 1.7 million shares traded.