



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## 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 Inflammatrix

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, Inflammatrix 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.***