



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: 1.2 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 Hologic'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 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 even 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 to the tune 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.