



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Microba Life Sciences

By TIM BOREHAM

ASX Code: MAP

Share price: 31 cents; **Shares on issue:** 344,136,473 (48,031,314 in ASX escrow)

Market cap: \$106.7 million

Chief executive officer: Dr Luke Reid

Board*: Pasquale Rombola (chair), Prof Ian Frazer (deputy chair), Prof Gene Tyson, Dr Hyungtae Kim, Richard Bund, Jacqueline Fernley

* Dr Caroline Popper resigned in mid-June 2023 for personal reasons

Financials (March quarter 2023): revenue \$1.01 million (up 61%), receipts \$1.24 million, loss of \$5.9 million, cash of \$35.4 million, quarters of available funding: six

Major shareholders: Sonic Healthcare 19.99%, Perennial Value Management 11.7%, SA Microba Holdings (Mr Bund) 9.2%, Tiga Trading 7.17%, MacroGen Inc 5.2%, Boysenholz Pty Ltd 5%, Gingko Bioworks Inc 4%

Inside the human gut, trillions of bacteria are doing their job and contrary to common belief it's not all about forcing their chunderous host to reach for the bucket.

On the contrary, the complex ecosystem is vital for maintaining human health in terms of digestion and boosting immunity. In the words of Luke Reid, the head of the only ASX-listed microbiome-testing outfit Microba, they are crucial to maintaining health and treating or preventing a range of chronic conditions.

The science of how the bugs do this has not been well understood, although knowledge is increasing rapidly in areas such as treating irritable bowel disease (IBD).

The smart bugs are also known to produce neuro-transmitters that can affect the brain, as well as metabolites that work systemically through the body and impact various organs and systems.

Microbiome companies are attracting hot commercial interest and since listing just over a year ago, testing outfit Microba has seen a proliferation of deals and partnerships in the sector.

In the past six months the US Food and Drug Administration (FDA) has also approved two microbiome-based drugs, both to treat *Clostridium difficile* (a germ that causes colon inflammation).

The latest in a number of big-ticket partnerships, Microba and Sonic Healthcare last November sealed a deal by which the ASX-listed pathology giant sells Microba's kits across its extensive global network.

This week, the parties agreed to sell Microba's infectious diseases platform (called Metapanel) in Australia. Adding to the intrigue, Merck & Co has just snapped up the irritable bowel disease and Crohn's disease specialist Prometheus Biosciences for \$US10.8 billion (\$16.2 billion).

From a germ of an idea

Microba was formed in 2017 based on intellectual property acquired from the University of Queensland.

Also involved were the University of California Berkeley, Massachusetts Institute of Technology and the Joint Genome Institute.

Microba listed on April 5, 2022 at a subscription price of 45 cents, with the initial public offer raising \$30 million.

Microba's tech was developed by co-founders Prof Philip Hugenholtz and Prof Gene Tyson.

The latter is an executive director and the former chairs its scientific advisory board.

CEO Dr Reid was an associate director of Uniquist Pty Ltd and, before that, held roles at plant geneticist Dupont Pioneer.

Dr Reid met the two professors at Uniquist while working on unrelated tech and the rest - as they say - is history.

The company's deputy chair, Prof Ian Frazer needs no introduction as the co-inventor of the Gardasil and Cervarix cervical cancer vaccines.

The guts of the company

Microba has three arms: microbiome services (testing), drug development and a proprietary database of 1.2 million microbial genomes covering 5,000 species.

The company launched its first product, Microba Insight, in Australia in July 2018. Consumers buy the test online for \$349 and send back a stool sample, for which they receive a summary of their gut microbiome.

Patients outside a healthy range are provided with advice including dietary recommendations.

In 2019, the company followed up with a gut microbiome measuring product, Metabiome, for healthcare professionals in Australia and New Zealand through a distribution partnership.

Consumers aside, users of the test include healthcare practitioners and research entities (such as biotechnology and food companies).

In late February this year the company launched three test variants under the new brand Co-Biome: Metaxplore, Metaxplore GI and - you guessed it – Metaxplore GI Plus.

Pitched at clinicians, these tests are designed to be interpreted shortly before the patient appointment. The Metaxplore tests include tweaks such as the ability to identify nine specific pathogens and to provide a microbiome profile of more than 28,000 species.

“We can also analyse published data, put it through algorithms and identify novel parts of the microbiome,” says Microba therapeutics head, Prof Trent Munro.

Central to Microba’s story is the geographically diverse microbiome databank, which the company has accumulated over the last four years.

This bug library will help the company to pin down “novel and therapeutic leads not identified by others”.

Take your partners

Microba is chuffed about the partners with which it has drawn a dance card.

Sonic Healthcare aside, Microba has partnerships with sector leader Genova Diagnostics, North America’s biggest gastrointestinal pathology providers.

Others are Synlab, Europe’s biggest pathology lab chain, the Nasdaq-listed Illumina and the New York-listed, Bill Gates-backed Ginkgo Bioworks. Microba has also just signed a Middle Eastern compact with artificial intelligence outfit G42.

Dr Reid describes the distribution model as “very high margin and very scalable”.

Under the “Intel inside” model, the company delivers the raw data underpinning the clinical reports. The partners do the sales, marketing, distribution and processing.

“Early on we decided we didn’t have to own every customer in every market and that it was better to work with the best leaders with deep channels into markets,” he says.

Via these partners, Microba has access to 35 countries. Of these, 13 have been “operationalised” compared with the eight promised by June 2023.

News you can use

Dr Reid says the company’s tests emphasise “actionable information”.

The reports are designed to be simple, so that a clinician can glean the key information five minutes before the patient visit.

From the report, patients can be advised of corrective actions such as a change of diet or a prescription of good ol’ antibiotics to treat a known pathogen.

“We have always been rigorous and conservative with what we bring to individuals,” he says.

As well as providing patient-specific results, Microba curates and grades all the relevant available clinical literature and this also determines the actions available to the patient.

In the clinic

The company has just launched a phase I trial for lead drug candidate MAP 315 for the inflammatory bowel disease of ulcerative colitis.

In June, the company enrolled the first of 32 healthy patients, 24 of them on active treatment over 14 days and eight on placebo.

The results are expected to be announced in December this year and - if successful - will lead to a phase II efficacy study.

Microba chose ulcerative colitis because there’s a significant unmet need, with patients suffering frequent flare-ups.

Other potential targets are colon cancer, diabetes, non-alcoholic steato-hepatitis (Nash or fatty liver disease), Alzheimer’s disease, rheumatoid arthritis, anxiety and depression.

On the immune-oncology front, the company is interested in using microbiomes to enhance the efficacy of approved checkpoint inhibitors.

Pre-clinical microbiome mouse melanoma models - and do excuse the alliteration - showed a “significant reduction in tumor size” when Microba’s “therapeutic leads” were used in combination with a checkpoint inhibitor.

“As pharma companies look at ways to differentiate their immunotherapy products, we believe Microba presents a compelling opportunity as a combination therapy,” Dr Reid says.

Meanwhile, Microba and Ginkgo are targeting the development of novel therapies for three autoimmune disorders.

A poo-nami of approvals pending?

In November 2022, the FDA approved Ferring Pharmaceuticals and Rebiotix’s Rebyota, a “microbiota restorative therapy” for irritable bowel disease sufferers.

In late April, the agency gave the nod to two *Clostridium difficile* therapies: Seres Therapeutics and Nestle’s SER-109, now called Vowst.

Has everyone finished eating? Great!

A key downside of the two approved products is that they are based on faecal donations: the poo of healthy subjects.

The procedure has been made more elegant by freeze-drying the faeces and encapsulating the material but - let’s face it - the procedure is always going to have some image problems, given they are rectally administered.

The technique also involves significant manufacturing challenges and it is not exactly scalable.

“There’s no doubt oral therapy will be better efficacy-wise,” Prof Munro says.

Finances and performance

At the time of the Sonic Healthcare deal, management said the resulting revenues from the partnering deals should become apparent in the second (June) half of the current financial year.

Lo and behold, the March quarter showed revenue of a tad over \$1 million, 60 percent up year-on-year.

The company also lost close to \$6 million, but still has \$35 million in the bank.

Success in the US market is always a key factor for a diagnostics outfit. In that respect, Dr Reid says the company has a “thoughtful” US reimbursement strategy and investors should expect some news “in the not-too-distant future”.

In the meantime, he says, there’s a “significant sizable” local market for both testing products.

As part of last year’s deal, Sonic Healthcare invested \$17.8 million to acquire a 19.99 percent holding in Microba - the maximum allowable stake without launching a takeover offer.

The Microba register is chock-full of institutions including Thorney Investments (Tiga Trading) and Perennial Value Management.

Since listing Microba shares have traded between 14 cents (mid-October last year) and 42 cents (mid-February this year).

Safe but useless?

There’s plenty of hype in the supplements industry about probiotics: micro-organisms that are claimed to benefit the gut when ingested.

Typically derived from dairy sources, most of these pills and potions are ‘generally recognized as safe’ category: they will not kill you, but may not necessarily benefit you.

The poor disclosure opens an opportunity for Microba to enter the sector with products that are properly scientifically validated.

Probiotics aren’t sourced from the natural gut microbiome because they can’t tolerate oxygen, so are harder to make. A key aspect of Microba’s smarts is being able to handle and replicate the bacteria in the lab.

“We have a role to play in supplements but from a very scientifically-validated perspective,” Dr Reid says.

Dr Boreham’s diagnosis:

Most biotechs talk about their hopes and intentions for big-ticket partnering deals, which we take with the proverbial grain of sodium chloride seasoning.

With its Sonic and Genova tie-ups, Microba is looking the real deal. Bear in mind the company has no intention of going all the way on its own, either down the testing or drug development paths.

Ultimately, Dr Reid expects microbiome testing to become as routine as blood testing and will treat a range of inflammatory and mental health disorders.

“Our vision is [that] in the not-too-distant future this should become like a routine blood test,” he says.

Not surprisingly, investors often probe management on the virtues of the testing side of the business vis-a-vis the nascent therapeutics side.

“If we nail therapeutics, it would be significantly larger than testing,” Dr Reid says. “But the testing business in its own right could be really significant.”

Given that, Microba is like one of those trillions of bacteria: a small bug in a very large pond but that leaves all the more room to grow.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He works by gut feeling alone.