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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Cyclopharm

By TIM BOREHAM

ASX code: CYC

Share price: 95 cents

Shares on issue: 68,636,501

Market cap: $65.2 million

Chief executive officer: James McBrayer

Board: David Heaney (chairman), James McBrayer, Vanda Gould and Tom McDonald

Financials (June first half): revenue $6.06 million, net loss $1.43 million, underlying earnings before interest taxation depreciation and amortization $861,000, dividend 0.5 cents, cash $10.62 million.

Identifiable holders: ASX listing: CVC Ltd (Alexander Beard) 13.8%, Australian Ethical 7%; Nasdaq: Anglo Australian 19.3%, Barings Acceptance 16.75%, Chemical Trustees 11.72%.

A quirk of Cyclopharm's lung imaging technology is that it's been around for 30 years and is sold in 55 countries, with 1,500 units purchased by hospital nuclear medicine departments.

While Cyclopharm's core product Technegas is the diagnostic of choice to detect pulmonary embolism in these countries, it's not yet approved or sold in the US: the biggest nuclear medicine market and the land of the spluttering masses.

Cyclopharm is striving to right this glaring omission with an approval submission to the US Food and Drug Administration, a process that requires a $US7 million trial.

“Half the nuclear medicine departments are in the US and we are already servicing the other half,” says chief executive officer James McBrayer.

He is buoyed by Cyclopharm’s success in Canada, where Technegas now accounts for most of the market and has displaced traditional imaging, based on the isotope xenon-133.

In September, Cyclopharm bought its distributor in the Benelux countries, IC Medical for EUR200,000 ($A314, 000) plus another EUR200,000 in performance payments.

It is hoped this purchase will expand the use of Technegas to new indications by providing access to respiratory physicians and also expand commercialization of a new product, Ultralute.

Potted history

Cyclopharm was founded in 1986, with the technology developed by Australian National University’s Dr Bill Burch.

A component of nuclear medicine, the Technegas process involves the patient breathing radioactive particles that, when ensconced in the lung, are read by traditional imaging equipment.

At the core of the process is a generator: the isotope technetium-99 in liquid form is heated in a carbon crucible to 2,700 degrees Celsius, to form a gas-like particle that is then inhaled by the patient.

The nano-particles have a six-hour radioactive life, after which they are eventually dispersed through normal lung excretion processes.

The process is more reliable than the standard of care, based on the isotope xenon-133.

“Its hallmark is simplicity,” says Cyclopharm chief James McBrayer.

“It only takes few breaths to get a read-out on lung ventilation.”

Technegas also has the advantage of producing three-dimensional (3D) images.

While inhaling a lungful of radioactive isotopes sounds as unhealthy as chugging on a full-strength Marlboro, Mr McBrayer notes there has never been an “attributable adverse event” with patients.

Since 1987, more than 3.8 million patients have been diagnosed using Technegas, including 200,000 in 2016. Technegas has also chalked up $83 million in sales over this period.

While the company derives 60 percent of its revenues from Europe, Canada is the biggest country market and the best harbinger of what's in store in the US.

Currently, the US lung diagnostic market is shared by xenon-133 and another Technetium-99 based agent called DTPA, which is an abbreviation of a very long name.

Okay: it's diethylenetriaminepentacetate (as in: diethylene-triamine-pent-acetate).

DTPA is actually meant for renal imaging but is used off-label for pulmonary embolisms. Based on a wet aerosol, DTPA can cause blotchy imaging that hides underlying issues.

Annually, four million Americans are diagnosed for pulmonary embolisms, but Mr McBrayer estimates an addressable sub-market of 600,000.

In the US, computed tomography pulmonary angiography (CTPA) is the main way to diagnose pulmonary embolisms.

But nuclear medicine is used for in-patients who are contra-indicated: in other words, the procedure could harm them in other ways. For instance, they may have renal impairment or be pregnant, in which case the radiation is unhelpful indeed.

This sub-market may be a mere drop in the ocean of respiratory misery, but it's still a diagnostic market worth $US90 million a year.

Clinical trial: enrolling now

To support its US Food and Drug Administration application, in September the company started enrolling the first of 240 patients across 15 sites, initially at the Washington University in St Louis, Missouri.

At last count, 31 were enrolled with results expected by October 2018.

The trial compares Technegas against xenon-133. Being a non-inferiority trial, all the trial needs to do is to prove Technegas works as well as the standard-of-care.

Unusually, the FDA will allow a preliminary read of 40 patients to support a mini submission by April. This will give a useful official steer on trial design.

Happily, Cyclopharm has stored some nuts away already, having raised $7 million in June last year to fund the trial.

Intriguingly, the rights offer was underwritten by major holder Australian Ethical, which eschews nuclear bombs, but doesn't mind nuclear medicine.

Cyclopharm's other priority is to expand Technegas for use in bigger markets of asthma detection, chronic obstructive pulmonary disease (COPD) and patient management. COPD alone is 30 times the size of the pulmonary embolism market.

"We are now seeing a resurgence in new applications as the respiratory medicine world expands its thinking on patient care," Mr McBrayer says.

Why not sooner?

An obvious question is that if Technegas is so superior, why is it yet to be approved in the US?

"It's been a combination of things," Mr McBrayer says. "We are a unique product and the FDA didn't know whether to classify us as a drug or a device."

In the end the agency decided Technegas was both.

Another issue was that the FDA would have preferred a technetium-99 based trial to be compared with another technetium-99 based product. But with DTPA used off-label for pulmonary embolism, there was no formal clinical data to enable this.

But given Technegas has special protocol assessment status with the FDA, the company and regulator are singing from the same hymnal, hopefully with melodious results.

You beaut, Ultralute

Cyclopharm is also about to launch a second product called Ultralute, to expand the useful life of generators that produce the nuclear materials in hospitals by about 50 percent.

Without sounding like a nuclear physicist – or Homer Simpson – molybdenum-99 decays into technetium-99, the isotope used in 80 percent of all medical diagnostic procedures.

There was a global supply issue with molybdenum-99 in 2009, because most of North America was supplied by an ageing Canadian reactor the Canuck government still wants to close.

Currently, supply is okay, but it can't be relied on. Hence the need for more reactors to produce moly generators to get as much bang for their buck as possible.

Oddly enough, Cyclopharm is not in a position to build a nuclear reactor, but it can make the existing supply chain more efficient. That is where Ultralute comes in handy.

So much so that the International Atomic Energy Association is working with the company to see if the technology can be made available to developing countries.

Cyclopharm expects to launch Ultralute commercially early this year.

Printer-and-cartridge model

Cyclopharm adheres to what Mr McBrayer dubs “the printer-and-cartridge model”: Eighty percent of revenue is derived not from the generators themselves, but consumables and service.

Cyclopharm has a track record of profitability, with the half-year deficit of $1.43 million attributed to $1.58 million of FDA trial expenses.

In other words, ignore this one-off cost and the company made a slender profit.

Unusually, Cyclopharm also has a dividend paying record, dispensing half a cent for the interim dividend for the six months to June 30, 2017. The company reports its full year to December 31, 2017 numbers next week.

Cyclopharm also has no debt and more than $10 million of cash.

Excluding a large Chinese order in 2016 that creates a skewed comparison, the board expects “modest growth in underlying Technegas volumes” for the 2017 year.

Dr Boreham’s diagnosis:

Cyclopharm investor prezzos are usually accompanied by testimonials from enthralled practitioners, usually Canadian ones ruing the misfortune of their cross-border colleagues who cannot yet access the device.

No doubt the makers of xenon-133 and rival angiogram products will claim that Technegas is not the bee’s knees for whatever reasons.

But this faux practitioner is convinced, if only because Cyclopharm has a solid revenue track record.

Cyclopharm shares have meandered between 70 cents and $1 over the last year. The current circa $65 million market cap does not seem extravagant and should see a decent spurt when the FDA says yes.

Of course, expect the opposite if the agency issues a surprise rejection.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He once won a spelling bee because he was not asked to spell diethylenetriaminepentacetate.