



Biotech Daily

Friday May 5, 2023

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Impedimed

By TIM BOREHAM

ASX code: IPD

Share price: 17.5 cents; **Shares on issue:** 1,787,664,914; **Market cap:** \$312.8 million

Chief executive officer: Richard Valencia

Board: Donald Williams (chair), Mr Valencia, David Anderson (executive director), Prof Robert Graham, Amit Patel, Jan West

Financials (March quarter 2023): revenue \$2.7 million, receipts \$3.21 million, net cash outflows \$2.79 million, cash of \$21.3 million, quarters of available funding: eight

Major shareholders: Paradise Investment Management 8.4%, Australian Ethical 7.1%, (founding CEO) Greg Brown 2.0%.

In team sports, the time-honoured way of lifting performance is to replace the coach - a ploy that tends to work about as often as it doesn't.

With investors laser-focused on commercial results rather than vague promises, a number of ASX biotechnology companies have taken the same approach of supplanting long-serving CEOs with those perceived to be more financially-oriented.

Coincidentally, the companies that have done so tend to be US-focussed, such as Avita Medical, Volpara Health Technologies, Lumos and Impedimed.

In the case of Impedimed, Rick Valencia replaced long-serving Richard Carreon in the top job with a clear change agenda.

“When I came to the business, I observed a company that was not functioning at the level it needed to in order to succeed,” says the California-based Mr Valencia.

“I was hired to identify the company’s focus, get it commercialized and get to cash break-even.”

Mr Valencia also has a more personal motivation for furthering sales of Impedimed’s Sozo devices for detecting lymphoedema, caused by the removal of armpit lymph nodes leading to limb-swelling in breast cancer survivors (because of excess fluid).

“My wife is a cancer survivor and she experienced a lot of the issues we address,” he says.

Finally, Impedimed’s 20-year history of setbacks has taken a dramatic turn for the better.

In a “transformative moment” for Impedimed, on March 24, the US National Comprehensive Cancer Network (NCCN) designated bio-impedance spectroscopy (BIS) as the standard-of-care for monitoring all cancer patients susceptible to lymphoedema.

Surprisingly, the guidelines included not just breast cancer but other cancers that might result in lymphoedema, such as skin, gastric and genital cancers.

The relevance is that health insurers will stump up for BIS tests and - get this! - Sozo currently is the only BIS lymphoedema test.

About Impedimed

Bio-impedance spectroscopy (the BIS) non-invasively measures, monitors and manages the fluid patient’s fluid status.

BIS is all about passing low-frequency currents through the cells (whether they be fluid, fat, bone or muscle). The Sozo gathers data from 256 bodily sources.

The company was founded by biotech doyen Dr Mel Bridges in 1999 and listed in October 2007 at 72 cents apiece - poor timing given the global financial crisis was about to erupt.

Impedimed is based in Pinkemba, Queensland but most of the activity takes place at its Carlsbad, California digs.

Mr Valencia has 30 years in the healthcare sector, having been the interim chairman and CEO of glucose monitoring device maker Waveform Diabetes.

Before that he was on the board of Tandem Diabetes Care and a senior vice-president at Qualcomm Incorporated. Both these companies are Nasdaq-listed.

Mr Carreon had been CEO for more than a decade.

Sozo measures up better

Somewhat laughably, the standard-of-care for lymphoedema has been before-and-after tape measurements of the swollen limbs. Under current care guidelines, clinicians have not been obliged to monitor the condition at all.

Initially, Impedimed introduced the L-Dex U400, which assessed breast cancer patients for lymphoedema.

The trouble is, the test took about 30 minutes and required the use of gel-backed electrodes on a prostrate patient. So Impedimed devised Sozo, a wirelessly connected unit that looks like a cross between scales and an exercise bicycle.

Sozo doesn't require electrodes and can accurately measure fluid in 30 seconds.

Impedimed's clinical piece-de-resistance was its Prevent trial, which measured lymphoedema in 1,200 breast cancer patients over three years, across 10 mainly US sites.

The trial met its primary endpoints and was statistically significant, showing 92 percent of early detection patients did not progress to chronic lymphoedema.

Sozo is approved for use in the US, Europe and Australia for lymphoedema, as well as other indications including heart failure and protein calorie malnutrition.

But Mr Valencia has made it clear that while the company is interested in these non-cancer markets, it will focus on the US lymphoedema opportunities.

Becoming the standard-of-care

Consisting of 33 of the top US cancer centres, the National Comprehensive Cancer Network (NCCN) holds powerful sway when it sets its clinical guidelines, because they become the standard-of-care for the whole market.

"You don't want to be the insurer not paying for what is considered standard-of-care," Mr Valencia says.

Nonetheless, the company was surprised at the swift manner in which the insurers agreed to review their policies to cover BIS testing.

While there are around 1,000 US health insurers, most are subsidiaries of 63 companies accounting for 80 percent of the market.

At last count, 47 of these had agreed to review their policies. All but two have made this decision 'out of cycle', which means they won't wait for their regular review meetings.

"This is unusual and means they have taken it very seriously," Mr Valencia says. "The NCCN guidelines are very powerful and that has caused them to react very quickly."

Sizing up the market

The company estimates the size of the US lymphoedema treatment market at \$US10 billion (\$A15 billion) - a cost borne by insurers or the health system.

“Lymphoedema is a horrible disease, but you can stop it in its tracks before it becomes a lifelong chronic disease, simply by wearing compression garments and doing some exercises,” Mr Valencia says.

The company estimates the size of the lymphoedema prevention market at \$US1 billion for breast cancer, rising to \$US2 billion when the other cancers are included.

Impedimed’s selling point to the insurers is that spending \$US2 billion makes sense if it means avoiding outlaying \$US10 billion over time.

Hmm - makes sense.

Currently, Impedimed charges a subscription of around \$A1,500 a month per client, for each of the 500 machines currently used in the US. Post reimbursement, the company expects to be able to charge \$2,500 per month, rising to \$4,000 per month for all four relevant cancers.

Elsewhere there are also about 500 machines - notably in Australia - but they yield much less because the deals tend to be on a ‘capital sale’ basis: the clinics buy the machine rather than a subscription.

Under the ‘all you can eat’ subscription model the clinics can do any number of tests and receive a current US Medicare/Medicaid rebate of \$US140 per measurement. With private reimbursement, this is expected to rise to \$US200 to \$US220 per test.

The clinics pocket this payment, but as a general rule, the vendors (such as Impedimed) enjoy an economic benefit of 30 to 50 percent of the reimbursed amount.

Testing volumes currently are a modest 50,000 per quarter (for high-risk patients).

Mr Valencia says it’s possible the company could introduce a cap on testing under the subscription model, but it doesn’t want to deter testing.

That’s not just because of the obvious patient benefit, but because more testing means more data accrual to support other uses for Sozo.

Finances and performance

In the March 2023 (third) quarter Impedimed posted revenue of \$2.7 million, flat on the year previously and five percent down on the December 2022 quarter.

The company also claimed record receipts of \$3.2 million.

Net cash outflows of \$2.79 million compared with a deficit of \$6.5 million in the December quarter.

Annual recurring revenue (ARR) was \$8.7 million, up 28 percent. ARR is the amount of revenue reasonably expected to be booked in the next 12 months, based on existing contracts.

Based on built-in price escalators pertaining to the 500 US units, this ARR is expected to rise to \$10.2 million in the 2023-'24 financial year (and eventually to \$13 million).

During the quarter, new contracts with a total value of \$3.2 million were inked, 44 percent higher than previously.

Meanwhile, customer churn was less than two percent.

The company's cash balance stood at \$23 million, 12 percent down year-on-year.

But management is confident of achieving cash-flow break even with its existing capital, which is based on 300 more machines being sold in the US.

Broker Morgans estimates the company will be profitable in the 2024-'25 year, to the tune of \$2.7 million.

Over the last year Impedimed shares have traded between 19 cents on April 26, 2023 and five cents (July 2022). They peaked at an all-time high of \$1.68 in mid-2016 and bottomed at four cents in May 2020.

What's next?

Impedimed had been carrying out trials in relation to end-stage renal failure and heart failure.

These programs remain of interest but have been "semi parked" in favor of commercializing the oncology tests.

In the renal sphere, the dialysis blood-cleansing process involves fluid being removed and this has to be done using an accurate baseline.

The current measurement is by "clinical estimate" - also known as a rough guess. If the machine removes too much liquid, the patient can dehydrate. Too much fluid can cause heart failure.

Today, the company said the FDA had approved its tweaked Sozo Pro device under the 510(k) pathway.

Sozo Pro includes a medical-grade weight-scale of up-to 220 kilograms and has extra features to improve patient workflows and data collection.

Dr Boreham's diagnosis:

Mr Valencia says the company's long-standing (or long suffering?) shareholders might wonder what comes next, but he dubs the NCCN edict as a "once in a lifetime opportunity".

He says the "endless possibilities" for Sozo have been both a blessing and a curse for the company, given that the multiple development programs have detracted from the company's focus.

While newbie 'coaches' usually enjoy a honeymoon period, Mr Valencia acknowledges he has no excuses, given the company's commercial tailwinds in the US.

"This a market that is ours to win or lose," he says. "We are the only company that can execute into the NCCN guidelines."

One could say there's no impediment to success now ...

Mr Valencia says the company will be "very intentional" with its market pronouncements and "lead with the facts" - which sounds like one of your columnist's grumpy former editors.

The fact is, Impedimed's fortunes always rested on the willingness of US public and private payors to stump up for the tests.

Now that's happening, Team Impedimed is poised to shrug off its past setbacks and prevail in the premiership quarter.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. This column contains nothing but facts, albeit some people occasionally try to tell us alternative ones.