



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Impedimed

**By TIM BOREHAM**

**ASX code:** IPD

**Share price:** 5.3 cents

**Shares on issue:** 2,023,093,918

**Market cap:** \$107.2 million

**Chief executive officer:** Dr Parmjot Bains

**Board:** Christine Emmanuel-Donnelly (chair), Dr Bains (M-D), McGregor Grant (CFO), Andrew Grant, Janelle Delaney, Fiona Bones.

**Financials (Year to June 30, 2024):** revenue \$10.3 million (down 9.0%), net loss \$19.8 million (\$20.6 million loss previously), cash of \$24.6 million (down 46%).

**Major shareholders:** Paradice Investment Management 7.1%, Australian Ethical 6%

When we last covered Impedimed in May last year, we opined that the time-honored way of lifting team performance was to replace the coach - a ploy that works about as often as it doesn't.

Back then, Rick Valencia had just replaced the long-serving Richard Carreon as CEO in the top job, with a clear agenda to jazz up the joint.

But all was not oranges, or apples, for Mr Valencia and in November he departed after a boardroom coup that also saw four directors exiting (including subsequent interim CEO David Anderson).

Former Nanosonics CFO, McGregor Grant was appointed interim chair followed by new CEO, Dr Parmjot Bains.

Mr Grant said the changes were made because some shareholders were concerned about corporate costs, the timing of a March 2023 capital raising and the perception the company was not capitalizing on favorable US conditions.

History doesn't repeat, but it sure rhymes.

"When we came into the business, we had a good hard look at that and made a few changes," Mr Grant said.

"We found there was just not enough in the [sales] pipeline.

"We have adjusted the cost base of the business and focused resources on the sales end and we believe we are seeing the results of that work coming through."

Impedimed's Sozo, by the way, is an accurate and non-invasive means of detecting and measuring lymphoedema, caused by the removal of armpit lymph nodes leading to limb-swelling in breast cancer survivors (because of excess fluid), along with the detection of other bodily fluid build-ups.

## **About Impedimed**

Impedimed 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.

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

Before then, the standard-of-care for lymphoedema was before-and-after tape measurements of the swollen limbs which – needless to say – is totally inadequate.

The trouble is, the L-Dex 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.

Last September's board spill saw four incumbents replaced with Mr Grant, the former-long standing CFO of fellow device house Nanosonics, the unrelated Andrew Grant and non-executive directors Christine Emmanuel-Donnelly and Janelle Delaney.

In June 2024, their ranks were bolstered with the appointment of Fiona Bones.

McGregor Grant is also the company's CFO, having replacing long-term numbers man Tim Cruickshank.

Dr Parmjot Bains was anointed interim CEO after the boardroom blitz and was made permanent chief on July 22 this year.

A medical doctor, Dr Bains was joint CEO of Neuren Pharmaceuticals and the unlisted New York based hair-loss house Perseus Therapeutics. She has also held commercial roles at Pfizer and the management consultancy McKinsey.

The board spill motion was passed on fairly slim majorities of 55 to 60 percent, depending on the director subject to appointment or removal. Two directors not subject to the removal petition, Janet West and Dr Michael Seiden, resigned in October and November respectively.

The incumbents argued that removing them would be unnecessarily disruptive and that the agitators lacked the requisite skills. Influential proxy advisers CGI Glass Lewis and ISS also endorsed the status quo, but ultimately (unless you're Donald Trump) you can't argue with the numbers.

## **About Sozo**

Sozo is the only US Food and Drug Administration-cleared device for managing breast cancer-related lymphoedema using bio-impedance spectroscopy (BIS).

Seeing you asked, BIS works by passing low-frequency currents through the cells (whether they be fluid, fat, bone or muscle). The Sozo gathers data from 256 bodily sources.

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.

In May last year, the FDA cleared Sozo Pro, an enhanced version with an updated seat design, a more integrated weight scale and an increased standing weight capacity from 170 kilograms to 220 kilos.

Sozo's efficacy was supported by a 1,200 global clinical trial called Prevent, which assessed the patients' fluid levels over three years. The study showed only 7.9 percent of patients progressed to chronic lymphoedema, compared to 19.2 percent of those assessed with a tape measure.

Since then, Impedimed has cited 'real world' evidence, including supportive research from the New South Wales Health Lymphoedema Program. Of the 1,800 patients assessed, only 75 (4.2%) progressed to chronic lymphoedema compared with 480 (26.7%) with the standard-of-care.

In March 2024, the influential US National Comprehensive Cancer Network (NCCN) designated BIS as the standard-of-care for monitoring all cancer patients susceptible to lymphoedema.

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

Consisting of 33 of the top US cancer centres, the NCCN holds powerful sway in determining a product to be the standard-of-care.

The ruling means health insurers will stump up for BIS tests - which is handy given Sozo currently is the only BIS lymphoedema test.

As at the end of June 2024, 66,000 Sozo tests had been carried out, a three-year compound annual growth rate of 21 percent.

### **It's the economics, stupid**

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.

The company also estimates the size of the lymphoedema prevention market at \$US1 billion for breast cancer, rising to \$US2 billion when non-breast 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.

About 20 percent of breast cancer patients will develop lymphoedema, incurring an average out-of-pocket cost of \$US2,306.

In the US, Impedimed's clinical customers usually pay a monthly licence fee of around \$US1,300 to \$US1,400.

In other markets (including Australia) the clients usually buy the hardware up front, at a cost of around \$A20,000.

The US pricing model is far more attractive: while the rest of the world accounts for about half of the installed Sozo base, it only contributes about 10 percent of revenue.

Mr Grant said the company "went a little hard" on US pricing with a stepped arrangement by which the fee was structured to rise to \$US2,500 by year three.

Not surprisingly, customers queried why they should pay more in what amounted to a reverse loyalty discount.

The structure now has been “flattened”, with more flexibility based on examination volumes and to state-by-state reimbursement.

The US Medicare/Medicaid system reimburses clinicians to the tune of \$US145 per measurement, while private insurers pay anywhere between \$US150 to \$US400. Impedimed takes 30 to 50 percent of the spoils, but clinics don’t need to do too many tests to break even on their investment.

Economically speaking, the company could restrict the number of tests, but more testing means more data to support future extensions and it doesn’t want to deprive patients.

## **Finances and performance**

In the year to June 2024 Impedimed chalked up revenue of \$10.391 million, down 9.0 percent, with a loss of \$19.79 million compared with a \$20.57 million deficit previously.

McGregor Grant says the company has a two-year target for free cash-flow break even “all things being equal”.

The company has targeted a 10 percent reduction in cash burn, mainly from reducing headcount.

Impedimed reports that 38 more Sozos were installed in the June quarter - 23 in the US - taking its global base to 1,083 compared with 997 a year previously. Of these, the US accounts for around 570 units and Australia (around 400 units) accounts for most of the remainder. The churn rate was a low three percent.

The company cites a Texan oncology clinic that ordered another two machines, taking its complement to eight and a national breast surgery group which expanded its take-up from three to eight.

June quarter annual recurring revenue (ARR) was \$11 million, up 10 percent on the March quarter. ARR is the amount of revenue reasonably expected to be booked in the next 12 months, based on existing contracts.

Dr Bains notes that renewal pricing has increased by an average 38 percent, with about one-third of contracts up for renegotiation each year.

At the end of June, Impedimed had cash of \$24.6 million, having raised \$30 million last year in a \$20 million placement and \$10 million in an oversubscribed share plan.

Over the last 12 months, Impedimed shares have ranged between 22 cents (early August last year) and a low of six cents (July 19 this year). Over the company’s listed life, the shares peaked at an all-time high of \$1.68 in mid-2016 and bottomed at four cents in May 2020.

## **Dr Boreham's diagnosis:**

Like the Chinese Communist Party, every company needs a decent manifesto. In the case of Impedimed, management has outlined five goals to be achieved over the next two years.

In oncology, this includes expanding reach into leg lymphoedemic pain, and pelvic melanoma and gynaecological cancers at risk of lymphoedema.

But five-year visions are one thing and near-term performance is another. Biotech history shows that when new boards and management promise sweeping changes, the share price does not move in lock-step and Impedimed shares remain off the pace.

To be fair, the company has been gaining sales traction in that crucial US market - but it is still happening too slowly for some pundits.

A little over a year ago, Mr Valencia said the market was "ours to win or lose" given the supporting reimbursement in the US.

Riffing on the theme of her predecessor, Dr Bains says "both revenue and costs are heading in the right direction".

But the clear message is that like building an underperforming footy team, the change process is a marathon rather than a sprint.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has witnessed too many games where it was 'theirs to lose' for his hapless football team - and indeed it did.***