



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Somnomed

**By TIM BOREHAM**

**ASX code:** SOM

**Share price:** \$2.35

**Shares on issue:** 82,759,315

**Market cap:** \$194.5 million

**Chief executive officer:** Neil Verdal-Austin

**Board:** Guy Russo (chair), Mr Verdal-Austin, Amrita Blickstead, Hilton Brett, Hamish Corlett, Michael Gordon, Karen Borg

**Financials: (year to June 30 2021):** revenue \$62.7 million (up 9%), underlying earnings before interest, tax depreciation and amortization \$3.9 million (down 17%), net loss after tax \$1.2 million (previous \$438,000 deficit), cash \$21.1 million (down 30%), debt \$2.35 million (down 68%)

**Identifiable major holders:** TDM Growth Partners 26.8%, Australian Ethical 11.07%, Dottie Investments (Peter Howarth) 7.9%, Fidelity 7.6%

Somnomed chief Neil Verdal-Austin readily concedes the established treatment for obstructive sleep apnoea (OSA) is highly effective, which may seem a strange message from the world's biggest supplier of the (mouthguardy) alternative technique.

The reason is that compliance rates for the standard-of-care, continuous positive airways pressure (CPAP) is notoriously low with 70 percent of patients discarding the requisite pumps and masks within months.

So, it's a bit like saying that anti-Covid masks work well when they're not dangling under one's chin (no judgments, not at all. Not here.)

Unlike CPAP, Somnomed's continuous open airway therapy, or COAT, does not require unwieldy masks and pumps.

"Somnomed's plan is to grow that sector so that a far greater number of patients are treated for OSA," Mr Verdal-Austin says.

But how? Somnomed's master strategy to increase adoption revolves around a mystery new technology platform due to be unveiled by the end of the year.

Aimed at winning over US insurers, the "transformational technology" will enable Somnomed to better position oral appliances against CPAP.

Mr Verdal-Austin describes it as an "integrated automated tech platform that creates a data driven ecosystem."

Um - we're none the wiser either. But we shouldn't have long to wait, with an investor tell-all planned before the year is out.

## **Emerging from the shadows of the pandemic**

The Covid-19 scoreboard shows that most life sciences companies weathered the pandemic reasonably well, or else they benefited because they were part of the solution (such as testing and vaccines).

Somnomed was not one of them: the sleep sector was affected enormously because patients were denied access to sleep physicians, the company's key source of referrals.

Meanwhile sleep physicians, who are respiratory doctors (pulmonologists, if you must) were being shifted to deal with emergency Covid patients.

Unlike CPAP giant Resmed, Somnomed didn't have air pumps which it could convert to ventilators to keep critically ill Covid patients alive.

"A healthcare device company doesn't do to well during a pandemic," Mr Verdal-Austin says.

"It's been a tough time, there's no doubt about that. You can see and read it in the communications from ourselves and others in the market."

## **Sleepers, awake!**

Now, the first rays of recovery are emerging, as evidenced by the company's second (June) half revenue rebound (see 'finances and performance' below).

Mr Verdal-Austin describes the North American recovery as “outstanding”, while the company is also emerging from access issues in Europe (where the sleep docs are hospital-based rather than in private practice).

In the US, a product recall from CPAP provider Philips Respironics has benefited Somnomed, but has also created chaos for US sleep clinics.

He describes conditions as “unpredictable and lumpy as things change week to week”, but increased vaccination rates are likely to contain the risks and spur sales growth.

Indeed – we’re all hoping on the power of the vaccine to restore some semblance of normality.

### **A COAT of many colors**

Somnomed’s COAT device is a mandibular advancement splint that moves the lower jaw slightly forward, keeping the airway open at all times.

Think of it as a posh mouthguard.

Somnomed sells in 28 countries and has treated 620,000 patients, including failed CPAP users and previously untreated users.

Somnomed listed in August 2004, raising \$12 million at 30 cents apiece.

The company initially was based on a device called the Somnomed MAS (mandibular advancement splint), invented by Sydney retired consultant orthodontist and champion rower Dr Richard Palmisano, who died in 2009.

Somnomed underwent several strategy iterations, most notably a hasty and costly retreat from its chain of direct-to-patient US sleep diagnostic centres, Renew Sleep Centres (RSS).

Somnomed opened its first RSS centre in December 2016 but abandoned the strategy in December 2018, having opened only four of the intended 16 outlets.

The core problem, in short, was a change to health insurance policies that increased patients’ out-of-pocket expenses and reduced reimbursement rates for Somnomed

The RSS fiasco saw the departure of US-based CEO Derek Smith, who was replaced by Mr Verdal-Austin, the company’s long time CFO and chief operating officer.

Somnomed’s chairman Guy Russo is a revered figure in retail land, having run the Kmart and Target chains and McDonald’s Australia. He currently chairs the Mexican food chain Guzman y Gomez so there’s never a shortage of takeaway burritos at board meetings.

## **Putting the bite on distribution**

As evidenced by the RSS experiment, the problem for sleep appliance makers is that distribution channels are inherently indirect.

The sleep physicians do the diagnosing and prescribing, but the dentist does the fitting and invoices the customer.

With the exception of mouthguards for teeth grinding (bruxism), the dentist doesn't initiate the sale.

Given mouth appliances are much cheaper than CPAP and just as effective in many cases, the vexing question is why COAT accounts for only eight to 10 percent of the obstructive sleep apnoea (OSA) market.

"It's fraught with complication because there are myriad variables," Mr Verdal-Austin says.

"History shows that doctors default to CPAP and sometimes it's been the only treatment. They didn't consider the patient versus the treatment."

He says the situation is changing because of raised awareness and education and continuing research to highlight the virtues of COAT.

Somnomed, meanwhile has built a network of around 25,000 dentists who are wise to the virtues of COAT.

## **What's next?**

Somnomed is now in second-generation stage with its appliance called Herbst Advance, which is more comfortable and lasts longer than Advant 1.0.

The mouthguard works with a titration action (the moving forward of the jaw) and is made of a soft inner liner material, rather than hard acrylic.

In Europe patients pay around EUR1,000 (\$A1,390), which includes diagnosis and fitting.

In the US this 'all in' cost is more like \$US2,000 to \$US3,000, while in Australia it's more like \$A1,800.

Somnomed itself receives about 500 for each device and by 500 we mean Euros, US dollars or Aussie dollars.

So, there's a fair bit of margin in the whole treatment chain that Somnomed doesn't receive.

Despite this, the cost is still well below that of CPAP treatment.

## **Finances and performance**

Somnomed's full-year performance was a tale of two halves, in that the first (December) half turnover declined seven percent because of pandemic lockdowns, especially in the US. But second (June) half revenue rebounded 33 percent, with the June quarter in particular boding well for the current year.

Europe and Australasia revenues rose 20 percent and 17 percent respectively.

Underlying earnings declined to \$2.7 million from \$4.7 million in the previous year, with a reported net loss of \$1.2 million.

Management confidently predicts a 15 percent revenue uptick for the current year, "assuming that Covid does not get worse in any of the 28 markets in which we trade."

Underlying earnings will be flat, reflecting an expected \$8 million spend on the new tech platform.

Over the last year Somnomed shares have ranged between a somnolent \$1.65 (early March 2021) and \$2.58 (early October last year). The shares hit a historic high of \$4.86 in October 2004.

## **Rivals ride the COAT tails of Somnomed**

Somnomed reckons it accounts for 40 to 55 percent of the COAT market globally, with a 60 to 65 percent share in Europe. In the US the company accounts for 20 to 25 percent of the market while in Australia it's more like 40 to 45 percent.

In the US, Somnomed competes directly with Prosomnus Sleep Technologies: "a formidable competitor who we watch very carefully". In Australia, the competitors are more like independent laboratories that make devices for dentists who distribute directly.

We also must mention the ASX-listed Oventus, which sells a device with a vent (duckbill) to enable mouth breathing when the nose is blocked.

Somnomed argues these nasal blockages should be addressed as part of the treatment.

Who nose which philosophy is right, but we merely note that Oventus last year recorded modest revenue of \$1.1 million, albeit 160 percent higher.

About eight years ago Resmed dabbled in the COAT sector by buying a French outfit called Narval, which had 90 percent of the Gallic market. Resmed expanded Narval into the US and Canada, but eventually surrendered.

Mr Verdal-Austin says the foray was like a train company deciding to become an airline because it was in the transportation business.

But no submarine-building analogies, fortunately ...

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

Your columnist last got his teeth into Somnomed in the halcyon pre-Covid days of August 2019.

At the time, the shares traded at \$2 and the company was valued at \$125 million, with full-year revenue of \$59 million.

On that basis the company has merely marked time, although back then it reported a \$15.8 million loss.

Some 1.36 billion people suffer from obstructive sleep apnoea, 900 million mildly and 400 million moderately to severely. But it's hard to know because they don't exactly stay awake to hear themselves snoring - and increasingly don't share their bed with anyone but a dog to alert them to their rumblings.

Of the mild sufferers - of most interest to Somnomed - 54 million are in the US.

Snoring is also endemic in kranski-munching Germany (26 million), beef bourguignon - loving France (23 million) and even the leaner denizens of Japan (22 million).

Evidently something is amiss when seven out of 10 CPAP patients do not use the prescribed product obtained at great expense.

Mind you, Resmed is a hugely successful global company with turnover of \$US3.2 billion and Somnomed bears a \$150 million market valuation.

But like China in the 1970s, the sleeping giant could be about to wake as COAT increasingly proves its credentials over CPAP.

"Our message is that you cannot ignore compliance and that aspect will start to move the dial for oral appliances," Mr Verdal-Austin says.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. As far as he knows he doesn't suffer from obstructive sleep apnoea but has been known to bore people to snores in waking hours.***