

Wednesday, 29 July 2008

SomnoMed Limited (SOM)

SomnoMed has surpassed our expectations and recorded an operating profit in the US

SomnoMed has made outstanding progress in the US market with its SomnoDent MAS devices. From a virtual "standing start" in the US just over two years ago the Company's patented mandibular advancement splint (MAS) business recorded an operating profit of A\$198,000 for the three months ended 30 June 2008. This result was gained from total revenue of A\$874,000. Unit sale of over 1,500 for the quarter were up 140% on the PCP. The gross operating profit margin for the June quarter was 56% on sales revenue.

From the Company, "This is a milestone event for our US subsidiary. The excellent performance of our US operations in the last quarter is consistent with the build up we have seen over the last 12 months. SomnoMed sales are constantly gaining momentum in the most important market in the world. North America is expected to contribute increasing profit in the 2009 year. It took over two years for our US operations to reach profitability. We are confident that Europe, where we commenced operations in November 2007 will become profitable in a shorter period of time. "

Investors will recall that SomnoMed developed and patented a mandibular advancement splint (MAS), an oral appliance effective in the treatment of obstructive sleep apnea and snoring. SomnoMed owns the intellectual property and patents associated with this product. The patents have been granted in Australia, USA and New Zealand. Patent applications are pending in Canada, Europe, Hong Kong, Japan and South Korea.

Global sales for the June quarter 2008 (including the US) totaled 2.323 units, a 114% increase on those of the pcp. Total Group sales revenue for the three months was A\$1.27m.

When we add the unit sales for the first half to the third and fourth quarter sales we see that the total sales for the June 2008 year were 7,048 MAS units. This is an impressive performance and is an 80% increase on unit sale for the 2007 year.

Background

SomnoMed's oral device is effective in treating up to 80% of patients suffering from snoring and obstructive sleep apnea (OSA).

□ Overview

- Half of all adult men and a third of women snore;
- Snoring is a symptom of a medical condition, -sleep apnea that can cause serious medical conditions;
- SomnoMed's oral device is a first-line treatment for obstructive sleep apnea, (OSA).
- The Company has established a marketing presence in Europe, North America and the Asia Pacific region and has sufficient funds to develop the business potential in these markets.

In Brief

Recommendations

Short Term:	Buy
Long Term:	Buy
Risk:	Medium
Price:	3.0 cents
12 Month Target Price:	n/a

Snapshot

Monthly Turnover	\$495,000
Market Cap	\$23.8m
Shares Issued	767.6m
52 Week High	4.4 cents
52 Week Low	1.3 cents
Sector	Healthcare Equipment & Services

Business Description

SomnoMed Limited produces a mandibular advancement splint (MAS), an oral appliance effective in the treatment sleep related breathing disorders (SRBD). The oral device is first-step treatment for obstructive sleep apnea (OSA). The Company owns the intellectual property and patents associated with its lead product, SomnoMed has developed a significant marketing network in Europe and the US, the two largest markets for its products.

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The author of this note holds shares in SomnoMed

The SOM oral MAS is unobtrusive when worn



Quote, Source; American Academy of Sleep, February 2006

“Oral appliances can be used as the first-line therapy for patients with mild to moderate obstructive sleep apnea. Previous guideline recommended continuous positive airways pressure (CPAP) systems as a first-line treatment for OSA. But research suggests that in mild to moderate cases, from 10 to 30 interruptions per hour, oral appliances are just as effective in reducing respiratory interruptions.”

SomnoMed is confident that its mandibular advancement splint (MAS), can be effective in reducing snoring and apnea in approximately 80% of patients. In most cases the use of MAS reduces the sleep interruptions to between 5 and 7 interruptions an hour, which is considered normal for most adults.

□ **Background on sleep disorders**

The study of the sleeping sequence is a relatively new field of scientific study. The exact effects of not getting enough sleep aren't as yet, fully understood. However, it is very obvious that when we do not get our usual daily quota of sleep our bodies and mental abilities become sluggish. During sleep a person breathes in a slow rhythmic pattern, the heart rate slows and most of the body muscles relax. Therein lies the problem. The relaxed tissue around the throat including the palate, the uvula and the tonsil relax and vibrate against the back of the throat during breathing. The uvula is the central tag-like structure hanging down from the edge of the soft palate. Snoring is simply the noise created as the relaxed soft tissues flap against each other.

□ **A period of real growth is at hand**

The MAS device is a two-piece acrylic splint similar to a footballer's mouth guard for oral use. The MAS fits over the upper and lower teeth, **but unlike a mouth guard is a precision-made clinically-tested device.** It is important that the initial template made from a patient's tooth configuration and the final fittings are made by a qualified dentist who has experience in dental occlusions and the associated oral structures. This is one of the fundamental differences between the SomnoMed advancement splint (MAS), and similar products on the market. The SomnoMed product is a precision device where even very small adjustments (0.17mm) in relative positioning of the lower jaw can make a significant difference in the product's effectiveness. It has been claimed in overseas markets that given a splint's good dental fit and skillful adjustment up to 88% of snoring and the resulting sleep apnea can be reduced to approximate normal levels. These points highlight the fact that the SomnoMed device was developed by a multi-disciplinary medical and dental team that was fully aware of technical and medical issues involved.

□ **A three pronged marketing programme**

Over the last 12 months SomnoMed has embarked on a marketing strategy that involves building a global distribution network. The Company has established a three pronged approach to the potential global market which is currently estimated to be approximately 1.5 million sleep-assist units per annum. As mentioned earlier the study of the sleeping sequence and obstructive sleep apnea is a relatively new field of scientific study. It is now suggested that as this area of medical research advances and the life

threatening consequences of untreated sleep apnea becomes more widely recognized, the demand for sleep-related systems and devices will grow at approximately 15% per annum.

To capture the potential in this expanding Global market SomnoMed intends to sell direct to dentistry practitioners where appropriate, sell to third party distributors and service partners and thirdly, establish a limited number of licensed partnerships with large companies servicing the dental industry.

□ **The first step into Europe**

In June 2007 the Company entered into an agreement with the German company Orthosleep to become its Central European laboratory. Orthosleep is one of Germany's leading dental laboratories for sleep-related dentistry. It is envisaged that Orthosleep will play a co-ordinating role in licensing of partners across the continent. This Company will train dentistry professionals in the skills necessary to gain an accurate template for the MAS and then to correctly fit and adjust the finished product. SomnoMed plans to establish partnerships in every country in Europe to achieve full coverage before the end of calendar 2008. Europe has a population of more than 300 million people and is the second most important market in the world.

□ **Building on its footprint in the US**

In December 2007 SomnoMed announced that it had signed a license agreement with US-based Dental Service Group (DSG). This is SomnoMed's first license agreement in the world. DSG will manufacture, market and distribute the SomnoMed MAS in the US and Canada. DSG operates 31 full service dental laboratories across North America. There has been a series of training programmes related to the MAS device for the dentistry professionals working within the DSG network. Other more recent license agreements have been undertaken in the US and Europe. The sales growth in the US evident in the June 2008 quarter reflects the well on the Company's efforts in the US.

□ **Looking Ahead**

We note that the Company stated that the net cash consumed (cash burn) during the June 2008 quarter was \$361,000. This figure is a substantial reduction on the \$605,000 cash burn in the March 2008 quarter. As at 30 June SomnoMed had cash reserve of \$5.4m. Given the rate of revenue growth and the resulting internal cash flow it appears that the Group has ample cash to finance its near term growth objectives. It is now widely accepted that laboratory fabricated custom-made adjustable splints have an important first-step role to play in treating Obstructive Sleep Apnea (OSA). The advantages of utilising a relatively cheap oral device with a success rate approaching 80% is an attractive first approach for medical practitioners, individuals and Health Funds.

The estimate, mentioned earlier, that approximately half of all adult men and a third of women snore gives an indication of the potential market for an unobtrusive corrective device. We believe that over the next few years SomnoMed will grow rapidly and reward shareholders accordingly.

We have a BUY recommendation on the stock.

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