Wilson HTM INVESTMENT GROUP | *A Leading Wealth Manager and Adviser to Emerging Companies*

10 September 2013

SOMNOMED LIMITED (SOM)

BUY | HOLD | SELL

ACTION & RECOMMENDATION

We recommend accumulating SomnoMed stock over FY14, a year that is likely to see further "medical initiative" investments made in the USA. Although it will take years for treatment penetration rates in that country to match oral appliance adoption rates in Europe, there are prospects for nearer-term catalysts as those foundations are built. The managed care offering being developed in America already has traction and can develop more. We provide a mini-review of recent randomised controlled trials that support the wider adoption of oral appliances in the treatment of sleep apnoea. We upgrade the rating to BUY with a new price target of $1.34 per share.

FY14 – further investment in market development

Company Update

What's Changed

- **Upgrading to BUY, price target $1.34 per share** – while we expect that it may take time for SomnoMed's US "medical strategy" to generate incremental sales volumes, we are encouraged by the recent proliferation in the medical literature supporting the case for oral appliance therapy in sleep apnoea, as an alternative to CPAP. The outlook for European growth in FY14 remains strong. We note further plans in Asia, specifically South Korea.
- **Contemplating upside to FY14 forecasts** – we have already factored a conservative US growth scenario in FY14, but continuing progress with G2 and the introduction of a mid-price product (Herbst) could attract additional volume.
- **Potential catalysts** – the US medical strategy could deliver earlier catalysts than pure volume gains. We think SomnoMed is well placed to develop the managed care facet of its US business. Acquisition opportunities in the US include further diagnostics and compliance tools to help embed oral appliances in the diagnostic/treatment algorithms for obstructive sleep apnoea.

Risks & Catalysts

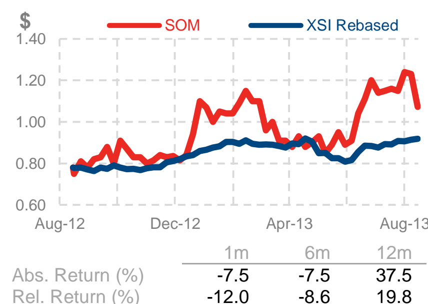
- **Upside risks.** An expected recovery in US volume growth; sustained high growth in Europe; market development initiatives in new countries (France, Germany, Korea); clinical data; and acquisitions in the USA or Europe.
- **Downside risks.** Delays in developing the US medical market for oral appliances; delays in reaching a reliable EPS growth profile; increased competition; and lack of liquidity.

12m Target Price (AUD)	$1.34
Share Price @ 09-Sep-13 (AUD)	$1.13
Fcst 12m Capital Return	18.8%
Fcst 12m Dividend Yield	0.0%
12m Total S'holder Return	**18.8%**

Shane Storey
shane.storey@wilsonhtm.com.au
Tel. +61 7 3212 1351

Daniel Sciberras
daniel.sciberras@wilsonhtm.com.au
Tel. +61 7 3212 1022

12m Share Price Performance



	1m	6m	12m
Abs. Return (%)	-7.5	-7.5	37.5
Rel. Return (%)	-12.0	-8.6	19.8

WHTM Return Re-investment Matrix

Return	Cash Generator	Champion
High	Cash Generator	Champion
Low	Challenged	**Potential**
Re-Investment	Low	High

WHTM Risk Assessment

	Low	Med	High	Spec
Share Price Risk			■	
Business Risk		■		

Year-end June (AUD)	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT Rep ($m)	0.7	0.7	0.7	2.7	4.1
NPAT Norm ($m)	0.8	0.7	0.7	2.7	4.1
Consensus NPAT ($m)			1.0	1.9	
EPS Norm (cps)	1.4	1.5	1.7	6.2	9.5
EPS Growth (%)	-25	7	11	273	53
P/E Norm (x)	80.8	75.6	68.1	18.2	12.0
EV / EBITDA (x)	55.1	68.0	34.4	14.0	9.8
FCF Yield (%)	0.2	0.8	0.2	4.8	7.7
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Dividend Yield (%)	0.0	0.0	0.0	0.0	0.0
Franking (%)	0	0	0	0	0

Mkt Cap: $47m **Enterprise Value:** $51m **Shares:** 43m **Sold Short:** %

Key Changes		02-Sep	After	Var %
NPAT:	**FY14**	1.1	0.7	-32.0%
Norm	**FY15**	2.6	2.7	4.7%
($m)	**FY16**	3.6	4.1	12.4%
EPS:	**FY14**	2.4	1.7	-32.0%
Norm	**FY15**	5.9	6.2	4.7%
(cps)	**FY16**	8.4	9.5	12.4%
DPS:	**FY14**	0.0	0.0	0.0%
(cps)	**FY15**	0.0	0.0	0.0%
	FY16	0.0	0.0	0.0%
Price Target:		**1.19**	**1.34**	**12.7%**
Rec:		**BUY**	**BUY**	

ASX 300 wgt: n/a **Median T'over/Day:** $0.0m

Issued by Wilson HTM Ltd ABN 68 010 529 665 - Australian Financial Services Licence No 238375, a participant of ASX Group and should be read in conjunction with the disclosures and disclaimer in this report. Important disclosures regarding companies that are subject of this report and an explanation of recommendations can be found at the end of this document.

PRICE TARGET

	Valuation	Price Target
WACC (%)		14.0
Terminal growth (%)		3.0
NPV Forecast FCF		29.4
NPV Perpetuity (A$M)		25.1
Net Debt /(Cash) (A$M)		4.2
Valuation (A$M)		58.7
TOTAL ($ / Share)	**1.16**	**1.34**

INTERIMS ($m)

Half Yr (AUD)	Dec 12	Jun 13	Dec 13	Jun 14
	1H A	2H A	1H E	2H E
Sales	9.0	9.5	10.8	12.0
EBITDA	0.6	0.2	0.4	1.1
EBIT	0.4	-0.1	0.1	0.7
Net Profit	**0.3**	**0.4**	**0.1**	**0.6**
Norm. EPS	**0.5**	**1.0**	**0.2**	**1.4**
EBIT/Sales	3.9	-1.2	1.2	6.2
Dividend (c)	0.0	0.0	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0

FINANCIAL STABILITY

Year-end June (AUD)	FY13A	FY14E	FY15E
Net Debt	-4.2	-4.0	-6.0
Net Debt / Equity (%)	<0	<0	<0
Net Debt / EV (%)	**<0**	**<0**	**<0**
Current Ratio (x)	3.7	3.7	3.8
Interest Cover (x)	<0	<0	<0
Adj. Cash Int. Cover (x)	**1.2**	**<0**	**<0**
Debt / CashFlow (x)	0.0	0.0	0.0
Net Debt (cash) / share	<0	<0	<0
NTA / share ($)	0.2	0.2	0.3
Book Value / share ($)	0.3	0.3	0.3
Payout Ratio (%)	0	0	0
Adj. Payout Ratio (%)	0	0	0

EPS RECONCILIATION ($m)

	FY13A		FY14E	
	Rep.	Norm.	Rep.	Norm.
Sales Revenue	18	18	23	23
EBIT	0.2	0.2	0.9	0.9
Net Profit	**0.7**	**0.7**	**0.7**	**0.7**
Notional Earn.	0.0	0.0	0.0	0.0
Pref./Conv. Div.	0.0	0.0	0.0	0.0
Profit for EPS	**0.7**	**0.7**	**0.7**	**0.7**
Diluted Shrs(m)	47	47	43	43
Diluted EPS (c)	**1.5**	**1.5**	**1.7**	**1.7**

RETURNS

	FY13A	FY14E	FY15E	FY16E
ROE (%)	6.8	6.0	19.7	24.0
ROIC (%)	2.6	7.9	24.1	33.3
Incremental ROE	-2.1	0.9	115.4	41.6
Incremental ROIC	-8.1	34.7	181.9	140.0

KEY ASSUMPTIONS

Year-end June (AUD)	FY09A	FY10A	FY11A	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue Growth (%)	111.5	38.5	15.1	23.6	21.3	23.3	20.2	19.3
EBIT Growth (%)	-33.4	-103.9	720.1	-15.5	-55.4	268.0	237.9	50.1
NPAT Growth (%)	-35.2	-148.3	-4.9	-4.7	-7.2	2.0	273.0	52.6
EPS Growth (%)	**-50.2**	**-146.8**	**-11.6**	**-25.2**	**6.9**	**11.1**	**273.0**	**52.6**
EBIT / Sales (%)	-25.6	0.7	5.1	3.5	1.3	3.8	10.8	13.6
Tax Rate (%)	0.9	-586.9	-10.7	-18.8	-123.7	21.6	10.8	9.4
ROA (%)	**-30.0**	**1.1**	**7.8**	**4.4**	**1.5**	**5.1**	**14.4**	**17.3**
ROE (%)	**-34.0**	**17.0**	**13.5**	**8.7**	**6.4**	**6.2**	**18.7**	**22.2**

PROFIT & LOSS ($m)

Year-end June (AUD)	FY09A	FY10A	FY11A	FY12A	FY13A	FY14E	FY15E	FY16E
Sales Revenue	7.7	10.7	12.3	15.2	18.5	22.8	27.4	32.7
EBITDA	-1.7	0.2	0.8	0.9	0.7	1.5	3.6	5.2
Depn & Amort	0.3	0.2	0.2	0.4	0.5	0.6	0.7	0.7
EBIT	**-2.0**	**0.0**	**0.6**	**0.5**	**0.2**	**0.9**	**3.0**	**4.4**
Net Interest Expense	-0.2	-0.1	-0.1	-0.1	-0.1	0.0	0.0	-0.1
Tax	0.0	-0.7	-0.1	-0.1	-0.4	0.2	0.3	0.4
Minorities / pref divs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Equity accounted NPAT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Profit pre Sig. Items	**-1.8**	**0.8**	**0.7**	**0.7**	**0.7**	**0.7**	**2.7**	**4.1**
Abn's / Ext's / Signif.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Reported Net Profit	**-1.8**	**0.8**	**0.7**	**0.7**	**0.7**	**0.7**	**2.7**	**4.1**

CASHFLOW ($m)

Year-end June (AUD)	FY09A	FY10A	FY11A	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA	-1.7	0.2	0.8	0.9	0.7	1.5	3.6	5.2
Interest & Tax	0.2	0.1	0.1	0.1	0.0	-0.2	-0.3	-0.4
Working Cap / Other	0.2	0.2	-1.2	-0.7	-0.2	-0.7	-0.4	-0.4
Operating Cash Flow	**-1.3**	**0.5**	**-0.3**	**0.3**	**0.6**	**0.7**	**2.9**	**4.4**
Maintenance Capex	0.0	-0.5	-0.3	-0.2	-0.2	-0.6	-0.7	-0.8
Free Cash Flow	**-1.4**	**-0.1**	**-0.6**	**0.1**	**0.4**	**0.1**	**2.2**	**3.6**
Dividends Paid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Growth Capex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Invest. / Disposals	0.0	0.0	-0.1	-0.3	-0.5	-0.3	-0.3	-0.3
Other Inv. Flows	0.0	0.0	0.2	-0.3	-0.1	0.0	0.0	0.0
Cash Flow Pre Financing	**-1.4**	**-0.1**	**-0.5**	**-0.5**	**-0.2**	**-0.2**	**2.0**	**3.3**
Funded by Equity	0.0	0.4	0.3	0.1	0.5	0.0	0.0	0.0
Funded by Debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Funded by Cash	1.4	-0.4	0.2	0.3	-0.3	0.2	-2.0	-3.3

BALANCE SHEET SUMMARY ($m)

Year-end June (AUD)	FY09A	FY10A	FY11A	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	4.0	4.3	3.9	3.5	4.2	4.0	6.0	9.3
Current Receivables	1.4	1.6	2.2	3.7	4.4	4.9	5.9	6.9
Current Inventories	0.1	0.2	0.2	0.5	0.9	1.2	1.5	1.7
Net PPE	0.2	0.6	1.1	1.1	1.2	1.1	1.0	1.0
Investments	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Intangibles / Capitalised	0.3	1.0	1.2	2.7	5.3	5.6	6.0	6.4
Other	0.0	0.1	0.1	0.5	0.2	0.2	0.2	0.2
Total Assets	**6.0**	**7.8**	**8.7**	**12.0**	**16.1**	**17.0**	**20.6**	**25.6**
Current Payables	1.5	1.9	2.2	2.4	3.5	3.6	4.4	5.2
Total Debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Liabilities	0.2	0.3	0.3	0.4	1.0	1.1	1.2	1.4
Total Liabilities	**1.7**	**2.2**	**2.5**	**2.8**	**4.5**	**4.7**	**5.6**	**6.5**
Minorities / Convertibles	0.0	0.0	0.0	0.5	0.6	0.6	0.6	0.6
Shareholder Equity	**4.3**	**5.7**	**6.2**	**9.2**	**11.6**	**12.3**	**15.0**	**19.1**
Total Funds Employed	**4.3**	**5.7**	**6.2**	**9.2**	**11.6**	**12.3**	**15.0**	**19.1**

SomnoMed Limited (SOM)

CHANGES TO FORECASTS

We have made some minor adjustments to our forecasts following the detail of SomnoMed's Appendix 4E disclosure and discussions with management.

Line by line:

Volume outlook – no changes. Looking for 10% growth in the USA, 25% growth in Europe and 10% in rest of world (RoW) to 41,100 SomnoDent devices.

Revenue – small upgrade to FY15 (other products). We are currently working at AUDUSD = 0.95 and AUDEUR = 0.71 with no changes in device average selling prices (ASPs).

Gross margins – we have improved the outlook for gross margins by c.200 bps compared with our previous forecasts but similar to the FY13 reported 67%. SomnoMed plans to build in additional efficiencies – particularly with the semi-automation of the models used to make the SomnoDent devices. These improvements should more than offset any dilution from introducing lower price point products in the US market this year.

Operating expenses and EBITDA – we have increased our forecast expenses to recognise the ongoing investments in US "medical initiatives".

Tax – we expect a tax expense this year of c.$200K compared with FY13's c.$400K net tax benefit.

TABLE 1: CHANGES TO FORECASTS FY14-15E (ABSOLUTE CHANGES SPECIFIED)

		Previous	Current	abs change
FY14E	Volume ('000s)	41.1	41.1	0.0
	Sales revenue (A$M)	22.8	22.8	0.0
	EBITDA (A$M)	1.9	1.5	-0.5
	EBIT (A$M)	1.4	0.9	-0.5
	NPAT (A$M)	1.2	0.7	-0.5
	EPS (cps)	3.1	1.7	-1.5
FY15E	Volume ('000s)	47.9	47.9	0.0
	Sales revenue (A$M)	26.1	27.4	1.3
	EBITDA (A$M)	3.3	3.6	0.3
	EBIT (A$M)	2.8	3.0	0.2
	NPAT (A$M)	2.4	2.7	0.3
	EPS (cps)	6.0	6.2	0.2

Source: WHTM Research

TABLE 2: FINANCIAL SUMMARY FOR SOMNOMED FY13-16E

Forecast detail - Income	FY13A	FY14E	FY15E	FY16E
Volumes				
USA	20,307	22,338	25,019	28,963
Europe	11,164	13,955	17,444	20,525
ROW	4,369	4,825	5,395	5,935
Total	35,841	41,119	47,858	55,423
volume growth	*16%*	*15%*	*16%*	*16%*
FX settings				
AUDEUR	0.79	0.71	0.69	0.67
AUDUSD	1.03	0.95	0.93	0.90
Sales revenue (A$M)	**18.5**	**22.8**	**27.4**	**32.7**
Gross profit (A$M)	12.3	15.3	18.4	21.9
gross margin	*67%*	*67%*	*67%*	*67%*
Operating expenses (A$M)				
SG&A	(10.1)	(12.4)	(13.3)	(15.2)
R&D, other	(1.4)	(1.4)	(1.4)	(1.5)
EBITDA (A$M)	**0.8**	**1.5**	**3.6**	**5.2**
EBITDA margin	*4%*	*6%*	*13%*	*16%*
PBT (A$M)	0.3	0.9	3.0	4.5
Tax	(0.4)	0.2	0.3	0.4
NPAT (A$M)	**0.7**	**0.7**	**2.7**	**4.1**

Source: SomnoMed, WHTM Research

KEY THEMES FOR FY14

1. US business finds a new footing

- **Volume growth recovery** – in the short term we expect to see further evidence that the disruptions felt in the first three periods of FY13 are behind the company. There was good evidence of a partial restoration of US trading conditions over Q4FY13, over and above what we would normally expect to see, given Q4's relative seasonal strength. The weaker performances in FY13 ought to also provide somewhat easier comparable periods in FY14. Our forecast of 10% US volume growth could be surpassed.
- **FY14 also introduces mid-priced options to US market** – in May SomnoMed received approval from the US Food & Drug Administration (FDA) for its SomnoMed Herbst device which will soon be introduced at a lower price point than the SomnoDent/G2 range (c.US$300-350 versus US$550+ for the G2). The Herbst is also an intraoral device intended for the treatment of mild to moderate obstructive sleep apnoea, but employs a different adjustment mechanism. The Herbst coupling (Figure 1) was originally conceived for making orthodontic adjustments to resolve overbites and to treat temporomandibular joint disorders/pain. Other Herbst-style oral appliances are widely available but only SomnoMed's features the proprietary "Flex" material of construction. We expect a launch towards the end of the American summer.

FIGURE 1: SOMOMED HERBST (LHS) AND THE TOP OF RANGE SOMNODENT G2

Source: SomnoMed

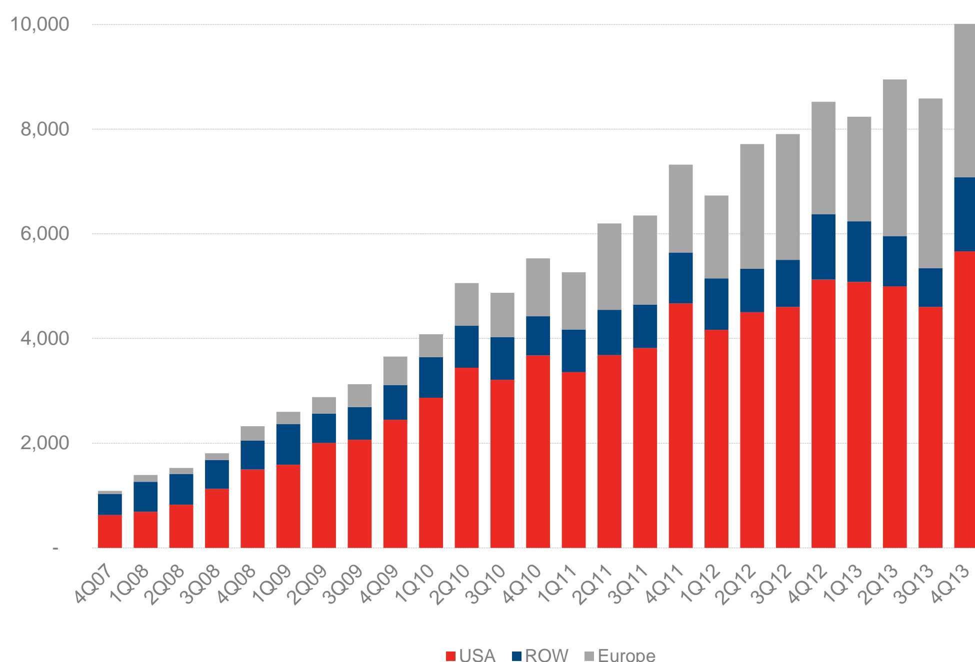
Herbst offers new volume opportunities – this new product opens up an opportunity to take volume in the mid-price segment of the appliance market where SomnoMed, hitherto, has had no business. We think the product could be more attractive to segments of the patient population covered by Medicare (aged 65 and over) or by other private plans whose coverage does not stretch to a G2 fitting.

Medical initiatives ongoing – in FY13 SomnoMed recruited an advisory board and executive team to drive education initiatives designed to familiarise sleep physicians with oral appliances as an alternative to continuous positive airway pressure (CPAP) therapy. More directly, we understand that there is now a small sales force dedicated to detailing sleep physicians, face to face. Combining the SomnoDent devices with diagnostic equipment (MATRx) and compliance monitoring (DentiTrac) capabilities is also an important step. It will take time for these measures to translate into incremental volumes, but the work done to ensure the oral appliance prescribing pathway is as equivalent as possible to CPAP should be helpful.

Managed care progress – we think that managed care is the future of how SomnoDent will be accessed and paid for in the USA. SomnoDent has been available through the Health Maintenance Organisation (HMO) Kaiser Permanente for some years now, and has won wider recognition in its multidisciplinary approach to managing sleep apnoea. We think it is likely that other HMOs will also value SomnoMed's offering as recognition of oral appliance therapy broadens. SomnoMed does appear to be well positioned to work with HMOs, with the ability to offer an approved device of the requisite quality, access to a network of fitting dentists and importantly a fixed price.

Acquisitions – we think SomnoMed could make acquisitions in the USA over the next two years, but of a different style to the European deals we have seen in recent times. In Europe, SomnoMed's acquisitions have been of distribution partners. The key benefits have been those of owning the marketing channel from a tactical perspective, and that of denying competitors access. SomnoMed's US channels are already direct (in the main), so acquisition opportunities are likely to be more horizontal than vertical. We think SomnoMed is more likely to consider adding further technological assets, such as diagnostics, compliance or even reimbursement tools that further embed oral appliances in the diagnostic/treatment algorithms for obstructive sleep apnoea.

FIGURE 2: ESTIMATED GEOGRAPHIC SOMNODENT UNIT SALES FY08-13



Source: WHTM Research

2. European growth to continue in FY14

SomnoMed is leveraging its distribution network and channel expertise to expand its addressable markets in Europe. We estimated 36% volume growth in Europe over FY13 to c.11,100 units, driven mainly by Netherlands and the Nordics. We are forecasting 25% growth in FY14, but understand this is slightly below SomnoMed's internal targets. Europe too is seasonally weak in Q1FY (summer holidays) but we understand that FY14 is tracking better than company expectations, albeit it is early days.

The SomnoDent product is still relatively new in France, where SomnoMed competes with ResMed's Narval CC device, among others. French reimbursement set a lower list price for SomnoDent (about 10% less expensive than Narval CC). The combination of attractive relative pricing and product features has fostered good acceptance in the French market thus far, which we think can grow into a premier market for SomnoMed. As noted previously, recent sales and marketing hires in Germany produced a meaningful improvement in the fourth quarter of FY13, but reimbursement remains relatively difficult to access from German statutory and private payors.

3. Korea a new direction for the RoW business

SomnoMed plans to go direct in Korea now that the South Korean FDA (KFDA) has granted regulatory clearances which should allow SomnoMed to ship product into that country from manufacturing facilities outside the country. Korea is only a small market at the moment (200-250 devices, annually) but we expect that can improve now that the regulatory regime is changing. Following the regulatory changes, the KFDA only recognises two oral appliances – SomnoDent and another locally manufactured device. We are forecasting c.10% RoW aggregate volume growth in FY14.

4. Medical evidence development ongoing

SomnoMed has funded recent clinical R&D at hospitals in Sydney (see WHTM Research, *SomnoDent versus CPAP*, published Mar-13), Antwerp and Berlin. The level of external, independent validation continues to improve, with more clinical trials reporting efficacy, compliance and outcomes data for oral appliances, in comparison to CPAP. There is a lack of American studies at this point, although we understand that SomnoMed plans to sponsor clinical work in that country, potentially starting this year. We provide a mini-review of recent RCTs involving oral appliances and CPAP in Appendix 1.

VALUATION: DISCOUNTED CASH FLOW (DCF)

We value SomnoMed using DCF. Having re-assessed the outlook for the forecast period our valuation has increased from $1.17 to $1.34 per share, reflecting a “roll forward” change only.

TABLE 4: DCF VALUATION SUMMARY FOR SOMNOMED

DCF Parameters			
WACC	14.0%	Tax rate	27%
Risk-free rate	6.0%	Terminal growth rate	3.0%
Risk premium	6.0%	Forecast horizon	FY23
Equity beta	1.33		
DCF Valuation			
PV of future cash flows ($M)	24		
PV of terminal value ($M)	34		
Value of operating assets ($M)	58		
Less net debt (cash)	-	Share count	43.4
Equity value ($M)	**58**	**Value/share ($)**	**1.34**

Source: WHTM Research

RECOMMENDATION, RISKS TO OUR VIEW

We upgrade our investment rating to BUY (previously Hold). Although FY14 will be as much an “investing year” for SomnoMed as FY13 was, SomnoMed is simultaneously leveraging its existing distribution network and channel expertise to expand its addressable market. The medical initiatives are necessary foundations for its US business to generate sustainable earnings growth by extending well beyond the dental channel. Treatment penetration in the USA remains low (3-5%) but we think it is likely to improve as the evidence gaps close, and as sleep physicians become more confident in prescribing oral appliance therapy. The key question is whether US sleep physicians will accept the argument that despite a weaker impact on the hard measurements of sleep apnoea, overall treatment acceptance/compliance outweighs that, so the overall performance is non-inferior to CPAP.

Randomised controlled trials comparing oral appliances and CPAP – a mini-review

There remains an evidence gap for sleep physicians to overcome, in prescribing oral appliances in preference to CPAP

Bridging the evidence gaps – large randomised trials have proven that CPAP provides improvements in sleepiness symptoms, blood pressure, arterial stiffness[1] and reduces the risk of both fatal and non-fatal cardiovascular events[2]. CPAP remains the first choice therapy, and keeps the upper airway open during sleep. However, this treatment can be difficult for some patients to tolerate and comply with on a long-term basis. Oral appliances (OA) including SomnoMed's SomnoDent device, are designed to keep the upper airway open by either advancing the lower jaw forward and/or by keeping the mouth open during sleep. There is increasing evidence suggesting that oral appliances (OA) including SomnoMed's SomnoDent improves subjective sleepiness and sleep disordered breathing compared with controls (devices that do not draw the lower jaw forward at all)[3].

A Cochrane Review in 2009[4] found that OA should not be considered as first choice therapy for obstructive sleep apnoea (OSA), where symptoms and sleep disruption are severe. There has not yet been a sufficient amount of randomised controlled trials (RCTs) that examine the efficacy of OA compared with CPAP in terms of symptoms and quality of life.

Not enough head-to-head trials have been completed comparing OA with CPAP

The medical literature comparing CPAP and OA at an early stage – there has been approximately 15 RCTs that reach an adequate level of evidence (9 included over page in Table 3). Most of them employ a crossover design, where both CPAP and OA are used by the same patient with appropriate "wash out" periods between treatments. Only four studies were "parallel" designs, where patients are randomised to receive one treatment and not the other (higher quality trials). Most of the trials compared CPAP and OA for their ability to reduce Apnoea-Hypopnoea Index (AHI)[5] and improve sleep measures such as Epworth Sleepiness Scores[6]. The trials used a range of different OAs – not limited to SomnoMed's devices.

OA emerging as a viable alternative but evidence gaps include compliance monitoring and long-term outcomes

RCTs favour CPAP on OSA endpoints but OA shows overall equivalence – across all RCTs, CPAP appears to be more effective in suppressing apnoea/hypopnea. CPAP and OA seem to be equivalent on measures of sleepiness and quality of life. Both forms of treatment reliably improve aspects of blood pressure, but there are no significant differences between therapies. Most studies record a subjective patient preference for OA over CPAP and report better compliance – spending more hours per night on therapy. One of the key drawbacks from all RCTs to date is the lack of an objective way of measuring compliance with OA therapy – but this should be addressed in future studies now that SomnoDent devices will incorporate Braebon's Dentitrac chips.

[1] Kohler, M. *et al.* (2011) *Effects of continuous positive airway pressure therapy withdrawal in patients with obstructive sleep apnea: a randomised controlled trial* Am. J. Crit. Care 184: 1192 – 1199.
[2] Marin, J. *et al.* (2005) *Long term cardiovascular outcomes in men with obstructive sleep apnea-hypopnea with or without treatment with continuous positive airway pressure: an observational study* The Lancet 365: 1046 – 1053.
[3] Gotsopoulos, H. *et al.* (2002) *Oral appliance therapy improves symptoms in obstructive sleep apnea*. American Journal of Respiratory Critical Care Medicine 166:743.
[4] Lim, J. *et al.* (2009) *Oral appliances for obstructive sleep apnoea (Review)* The Cochrane Library 2009, Issue 3.
[5] The AHI measurement is an indicator of sleep apnoea severity. Apneas (pauses in breathing) must last for at least 10 seconds and are associated with a decrease in blood oxygenation. Hypopneas are periods of abnormally shallow breathing. Combining these two events gives an overall sleep apnea severity score. The AHI, as with the separate apnea and hypopnea indices, are presented as the number of events per hour of sleep. AHI values are typically categorized as 5–15/hr = mild; 15–30/hr = moderate; and > 30/h = severe.
[6] Epworth Sleepiness Score is currently the most widely used assessment of subjective sleepiness and apnoea hypopnoea index is the most widely used assessment of sleep disordered breathing from overnight monitoring.

A 2013 RCT was the first to suggest long-term equivalence (CPAP vs OA) on a hard cardiovascular endpoint (mortality)

Most recent RCT the best yet, with 6+ year cardiovascular outcomes – investigators have recently published the first head-to-head RCT looking at cardiovascular death as an outcome[7]. This relatively large study followed patients for a median of 6.5 years, and found that both CPAP and OA had comparable improvements in cardiovascular mortality – risks not dissimilar to subjects without sleep apnoea. As expected, CPAP outperformed OA with its ability to improve AHI. Poor cardiovascular outcomes may be limited to patients with untreated, severe sleep apnoea (AHI > 30/hr)[2].

Establishing "non-inferiority" to CPAP is the key to lifting US treatment penetration

Is it enough to change US clinical practice? – the key question is whether sleep physicians and other clinicians become more willing to accept that these broader benefits (sleepiness scores, blood pressure, quality of life, treatment preference/compliance) are clinically meaningful; and outweigh the "hard numbers" that characterise a patient's apnoea (AHI). No oral appliance can reduce a patient's AHI as well as CPAP will, generally speaking. Clinical trials suggest that whatever oral appliances lack with respect to AHI suppression, their overall effectiveness is comparable as patients are more likely to adhere to the therapy.

[7] Anandam, A. *et al.* (2013) *Cardiovascula mortality in obstructive sleep apnoea treated with continuous positive airway pressure or oral appliance: an observational study* Respirology Jun 3. doi: 10.1111/resp.12140. [Epub ahead of print]

TABLE 3: SELECTED RANDOMISED CONTROLLED TRIALS COMPARING CPAP AND ORAL APPLIANCE IN THE TREATMENT OF OBSTRUCTOIVE SLEEP APNEA

Author	n	Interventions	Outcomes	Results
Anandam, A. *et al.* (2013)[7]	457	Control; CPAP; OA (parallel)	Cardiovascular death	CPAP & OA deaths similar to non-apnoeic controls; No difference in death rates (CPAP vs OA); Treatment compliance better for OA (6.5h vs 5.8h); Residual AHI better for CPAP (4.5/h vs 16.3/h).
Phillips, C. *et al.*(2013)[8]	126	CPAP, OA (crossover)	Blood pressure	OA non-inferior to CPAP on blood pressure; CPAP resolved more cases of apnoea (77% vs 40%) Treatment compliance better for OA (6.5h vs 5.2h); Treatment preference favours OA (51% vs 23%).
Doff, M. H. *et al.* (2013)[9]	103	Cohort study following previous RCT	AHI, sleep scores	No difference in treating apnoea at 2 years; CPAP superior for severe apnoea; CPAP superior for AHI reduction.
Lam, B. *et al.* (2007)[10]	101	CPAP, OA	AHI, sleep scores	CPAP and OA lowered morning blood pressure; CPAP superior on AHI and sleepiness measures.
Barnes, M. *et al.* (2004)[11]	114	CPAP, OA (3 mths each, crossover)	Sleep outcomes Blood pressure	Equivalence in outcomes; both effectively apnoea; Neither improved neurobehavioral outcomes.
Randerath, W. *et al.* (2002)[12]	20	CPAP, OA (6 wks each, crossover)	AHI	Residual AHI better for CPAP (3.5/h vs 10.5/h); Preference/compliance better for OA (no data).
Tan, Y. K. *et al.* (2002)[13]	24	CPAP, OA (2 mths each, crossover)	AHI, sleep scores	Residual AHI better for CPAP (3.1/h vs 8.0/h); Preference/compliance better for OA (no data); Treatments equivalent on sleep scores.
Engleman, H. M. *et al.* (2002)[14]	48	CPAP, OA (8 wks each, crossover)	AHI, sleep scores	Residual AHI better for CPAP (8/h vs 15/h); CPAP superior on Epworth scores.
Ferguson, K. A. *et al.* (1997)[15]	24	CPAP, OA (4 mths each, crossover)	AHI	Residual AHI better for CPAP (4.2/h vs 13.6/h). CPAP resolved more cases of apnoea (70% vs 55%)

Source: WHTM Research

[8] Phillips, C. L. et al. (2013) *Health outcomes of CPAP versus oral appliance treatment for obstructive sleep anpea: a randomised controlled trial* Am J Respir Crit Care Med Feb 14 [Epub ahead of print].
[9] Doff, M. H. *et al.* (2013) *Oral appliance versus continuous positive airway pressure in obstructive sleep apnea syndrome: a 2-year follow-up*. Sleep. 2013 Sep 1;36(9):1289-96. doi: 10.5665/sleep.2948
[10] Lam, B. *et al.* (2007) *Randomised study of three non-surgical treatments in mild to moderate obstructive sleep apnoea*. Thorax 62(4):354–9.
[11] Barnes, M. *et al.* (2004) *Efficacy of positive airway pressure and oral appliance in mild to moderate obstructive sleep apnea*. American Journal of Respiratory and Critical Care Medicine 170(6):656–64
[12] Randerath, W. *et al.* (2002) *An individually adjustable oral appliance vs continuous positive airway pressure in mild-to-moderate obstructive sleep apnea syndrome* Chest 122: 569 – 575.
[13] Tan, Y. K. *et al.* (2002) *Mandibular advancement splints and continuous positive airway pressure in patients with obstructive sleep apnoea. European Journal of Orthodontics* 2002;24:239–49.
[14] Engleman, H. M. *et al.* (2002) *Randomized crossover trial of two treatment for sleep apnea/hypopnea syndrome.* American Journal of Respiratory & Critical Care Medicine 166:855–9.
[15] Ferguson, K. A. *et al.* (1997) *A short term controlled trial of an adjustable oral appliance for the treatment of mild to moderate obstructive sleep apnoea*. Thorax 52:362–8.

RETURN RE-INVESTMENT MATRIX

Return	Low Re-investment	High Re-investment
High	Cash Generator	Champion
Low	Challenged	**Potential**

Return: Lead product launched (SomnoDent) in all major markets. Enjoys the leadership position in this emerging category of treatments for obstructive sleep apnoea.

Re-investment: Opportunities grow the global market by fostering links between medical and dental aspects of sleep apnoea. Increase awareness of alternatives to CPAP.

RISK MEASURES

	Low	Med	High	Spec
Share Price Risk			■	
Business Risk		■		

Share price risk: SOM liquidity is low, posing high risks.

Business risk: Small company with limited resources addressing a global opportunity. Competition increasing could grow market; could take market. These risks are mitigated by having a well-co-ordinated infrastructure for product manufacturing and supply.

BUSINESS DESCRIPTION

SomnoMed develops, manufactures and sells oral appliance devices for the treatment of obstructive sleep apnoea (OSA), snoring and bruxism. The company has developed a global infrastructure to address the OSA market, with the majority of its sales derived from the US and Europe.

INVESTMENT THESIS

Our thesis on SomnoMed is that an increasing number of OSA patients will choose an oral appliance in preference to continuous positive air pressure (CPAP) devices given increasing awareness and improving reimbursement arrangements. SomnoMed currently enjoys a leadership position in this market. We see ResMed's (RMD) recent entry into this market as validation of our investment thesis. We expect that the medically oriented diagnosis and referral channels for OSA will embrace oral appliances as an alternative for OSA patients who refuse treatment with CPAP.

REVENUE DRIVERS

- Growth rates. In recent years the company has sustained consistent 20-30% unit sales growth pcp comps. We think this can increase to 35% or higher as the company taps the medically diagnosed OSA referral channels
- Regulatory and/or reimbursement approvals of new products, new territories

BALANCE SHEET

- SOM had c.$4.2M cash as at end-FY13

MARGIN DRIVERS

- Making a high (c.70%) gross margin on its oral appliances
- We expect SG&A expense to increase modestly as the company develops and grows its market
- Low level of R&D expenditure

BOARD

- Dr Peter Neustadt (Executive Chairman)
- Ms Lee Ausburn (Non-Executive Director)
- Mr Robert Scherini (Non-Executive Director)

KEY ISSUES / CATALYSTS

- Upside risks:
  - Quarterly cash flow indicates SomnoMed's sales growth progress
  - Product launches
  - Progress developing links to medical diagnosis channels

MANAGEMENT

- Dr Peter Neustadt (Executive Chairman)
- Neil Verdal-Austin (CFO)
- Kien T. Nguyen (President, North America)
- Dr Jagdeep Bijwadia (Chief Medical Officer)
- Stacey Gilbert, VP Managed Care

RISK TO VIEW

- Downside risks:
  - Relatively limited capital for business development investment
  - Emerging competition
  - If successful, could face scale-up and logistics challenges when demand increases
  - Reimbursement in US is improving, but still needs to develop and broaden

CONTACT DETAILS

Address: Level 3, 20 Clarke St, Crows Nest, NSW 2065 Australia
Phone: +612 9467 0400
Website: www.somnomed.com.au

Head of Research

Jacqueline Fernley	(02) 8247 6661
Industrials	
James Ferrier	(03) 9640 3827
Ivor Ries	(03) 9640 3863
Andrew Dalziel	(07) 3212 1946
Stewart Oldfield	(03) 9640 3818
Chris Gibson	(03) 9640 3828
Daniel Wan	(02) 8247 6694
Healthcare and Biotechnology	
Shane Storey	(07) 3212 1351
Daniel Sciberras	(07) 3212 1022
Resources	
Cameron Judd	(03) 9640 3864
Phillip Chippindale	(02) 8247 3149
Liam Schofield	(02) 8247 3173
Nathan Szeitli	(03) 9640 3806
Quantitative Strategy/TAA	
Damien Klassen	(02) 8247 3101

Head of Institutional Sales

Duncan Gamble	(02) 8247 6629
Sydney	
Jonathan Scales	(02) 8247 6613
Richard Moulder	(02) 8247 6603
Michael Pegum	(02) 8247 6602
Anthony Wilson	(02) 8247 3113
Melbourne	
David Permezel	(03) 9640 3885
Adam Dellaway	(03) 9640 3824

Wealth Management Research

Peter McManus	(02) 8247 3186
John Lockton	(02) 8247 3118

Email: firstname.lastname@wilsonhtm.com.au

National Offices

Brisbane	Ph: (07) 3212 1333
Sydney	Ph: (02) 8247 6600
Melbourne	Ph: (03) 9640 3888
Gold Coast	Ph: (07) 5509 5500
Dalby	Ph: (07) 4660 8000
Hervey Bay	Ph: (07) 4197 1600

Our web site: www.wilsonhtm.com.au

Return Reinvestment Matrix and Risk Measures

Definitions at http://www.wilsonhtm.com.au/Disclosures

Recommendation Structure and Other Definitions

Definitions at http://www.wilsonhtm.com.au/Disclosures

Disclaimer

Whilst Wilson HTM Ltd believes the information contained in this communication is based on reliable information, no warranty is given as to its accuracy and persons relying on this information do so at their own risk. To the extent permitted by law Wilson HTM Ltd disclaims all liability to any person relying on the information contained in this communication in respect of any loss or damage (including consequential loss or damage) however caused, which may be suffered or arise directly or indirectly in respect of such information. Any projections contained in this communication are estimates only. Such projections are subject to market influences and contingent upon matters outside the control of Wilson HTM Ltd and therefore may not be realised in the future.

The advice contained in this document is general advice. It has been prepared without taking account of any person's objectives, financial situation or needs and because of that, any person should, before acting on the advice, consider the appropriateness of the advice, having regard to the client's objectives, financial situation and needs. Those acting upon such information without first consulting one of Wilson HTM Ltd investment advisors do so entirely at their own risk. This report does not constitute an offer or invitation to purchase any securities and should not be relied upon in connection with any contract or commitment whatsoever. If the advice relates to the acquisition, or possible acquisition, of a particular financial product – the client should obtain a Product Disclosure Statement relating to the product and consider the Statement before making any decision about whether to acquire the product. This communication is not to be disclosed in whole or part or used by any other party without Wilson HTM Ltd's prior written consent.

Disclosure of Interest. SomnoMed Limited

The Directors of Wilson HTM Ltd advise that at the date of this report they and their associates have relevant interests in SomnoMed Limited. They also advise that Wilson HTM Ltd and Wilson HTM Corporate Finance Ltd A.B.N. 65 057 547 323 and their associates have received and may receive commissions or fees from SomnoMed Limited in relation to advice or dealings in securities. Some or all of Wilson HTM Ltd authorised representatives may be remunerated wholly or partly by way of commission.

In producing research reports, members of Wilson HTM Ltd Research may attend site visits and other meetings hosted by the issuers the subject of its research reports. In some instances the costs of such site visits or meetings may be met in part or in whole by the issuers concerned if Wilson HTM Ltd considers it is appropriate and reasonable in the specific circumstances relating to the site visit or meeting.

Please see disclosures at http://www.wilsonhtm.com.au/Disclosures. Disclosures applicable to companies included in this report can be found in the latest relevant published research.