TAYLOR COLLISON

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SomnoMed (SOM)

18 September 2024

Under new management

Speculative Investment

Recommendation: Outperform

Our View

We initiate coverage of SomnoMed, which manufactures and markets mandibular advancement splints (MAS) for treating obstructive sleep apnoea (OSA). We believe SOM represents an attractive investment opportunity following management changes and a recapitalisation earlier this year. We expect SOM to return to profitability in FY25 – key drivers of the improved performance include:

- Manufacturing capacity constraints that restricted sales growth in FY24 are being addressed (estimated $3m drag on EBITDA in FY24).
- Operating cost reductions to save $5m/year have been implemented.
- $20m capital raise in April has allowed its $11.5m debt to be repaid, reducing balance sheet risk and allowing $1.7m ongoing interest savings (SOM also incurred a $1m finance facility fee in FY24 that won't recur).

In addition to the positive earnings impact of the changes above, two potential catalysts in FY25 could provide further upside to our forecasts, namely:

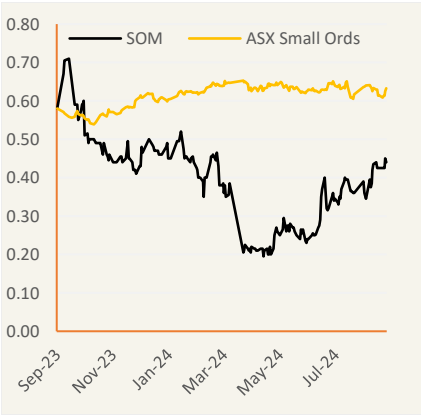
- Potential FDA clearance of the RestAssure device which has compliance and efficacy monitoring capability (FDA decision expected in October).
- PDAC review could potentially lead to improved Medicare reimbursement in the US for the company's lead product, the SomnoDent Avant.

SOM reported $91.7m of sales in FY24, so with $16.2m cash it is trading at 0.8x EV/sales. We value SOM at $0.67/sh based on our NPV model, or $0.66/sh fully diluted for options on issue. With a forecast return to profitable operations in FY25 and with the potential for additional upside catalysts to play out, we initiate coverage with an Outperform recommendation.

Summary (AUD)

Market Capitalisation	**$89M**
Share price	**$0.41**
52 week low	$0.19
52 week high	$0.55
Cash as at 30 June 2024	$16.2m

Share price graph (AUD)



Key Financials (AUD)

	FY24A	FY25E	FY26E
Revenue ($m)	91.7	100.9	111.0
R&D ($m)	(44.1)	(39.5)	(41.6)
SG&A ($m)	(13.5)	(14.7)	(15.7)
EBITDA ($m)	(2.5)	7.3	11.5
Reported NPAT ($m)	(12.2)	(0.1)	2.0
NPAT Adj. ($m)	(9.2)	(0.1)	2.0
EPS Adj. (c)	(7.7)	(0.0)	0.9
PE ratio (x)	n/a	n/a	43.5
DPS (c)	0.0	0.0	0.0
EV/Sales	0.8	0.7	0.7
EV/EBITDA (x)	n/a	10.0	6.4
EV/EBIT (x)	n/a	77.2	23.8

Key Points

FY24 Financial highlights

- FY24 revenue rose 9% to $91.7m, despite manufacturing capacity constraints. Revenue grew 5.5% on a constant currency basis.
- Underlying EBITDA, excluding $3m of costs associated with the cost reduction program, was ~$0.6m. Operating cash outflow $8.9m vs $3.9m outflow pcp. Underlying NPAT was a loss of $9.2m.
- RestAssure development costs (~$3.9m cash cost in FY24) will be much reduced (spend was $3.3m in FY23 and $7.8m in FY22).

We expect an FDA decision on RestAssure in early October

We expect the FDA to decide early October whether to clear SOM's RestAssure smart device for sale in the US. RestAssure will provide nightly patient usage and treatment effectiveness data, similar to the information that is available for patients who use CPAP machines. We expect the patient monitoring data will give sleep physicians more confidence to prescribe MAS therapy as an alternative to CPAP. While FDA clearance will be a key milestone, RestAssure will need to clear pricing and reimbursement hurdles before it can contribute meaningful extra revenue.

Management focused on driving efficiencies while containing costs

We are impressed by the new management team's emphasis on driving efficiencies by improving management systems and processes while maintaining ongoing cost discipline. We expect them to keep a lid on costs growth while investing in the manufacturing side of the business.

The team has made a promising start with the reduction in headcount in the regional SG&A functions, which are expected to save $5m in FY25. This represents a 10% reduction in total SG&A expenses.

Our conflicts of interests are disclosed on the last 2 pages of this report.

Somnomed - Summary of Forecasts — SOM $0.41

PROFIT & LOSS SUMMARY (A$m)

Year end June	FY23A	FY24A	FY25E	FY26E	FY27E
Sales	83.6	91.7	100.9	111.0	120.9
Other	0.0	0.0	0.0	0.0	0.0
Total Revenue	**83.6**	**91.7**	**100.9**	**111.0**	**120.9**
Growth (pcp)	14.8%	9.6%	10.1%	10.0%	9.0%
CoGS	(31.7)	(36.5)	(39.3)	(42.2)	(46.0)
Gross Profit Margin	62%	60%	61%	62%	62%
Regional SG&A expenses	(37.6)	(44.1)	(39.5)	(41.6)	(44.5)
Corporate & other expense	(12.2)	(13.5)	(14.7)	(15.7)	(16.8)
EBITDA	**2.1**	**(2.5)**	**7.3**	**11.5**	**13.7**
Dep'n/Amort'n	(6.5)	(5.7)	(6.4)	(8.4)	(8.9)
EBIT	(4.4)	(8.1)	1.0	3.1	4.8
Net Interest + Finance cost	(2.6)	(3.1)	0.0	0.1	0.2
Pre-Tax Profit	(7.0)	(11.3)	1.0	3.1	5.0
Tax Expense	(0.8)	(1.0)	(1.0)	(1.1)	(1.2)
NPAT Adj.	**(7.9)**	**(9.2)**	**(0.1)**	**2.0**	**3.8**
Growth (pcp)	n/a	n/a	n/a	n/a	85%
Adjustments	0.0	3.0	0.0	0.0	0.0
NPAT Reported	(7.9)	(12.2)	(0.1)	2.0	3.8

PER SHARE DATA

Year end June	FY23A	FY24A	FY25E	FY26E	FY27E
EPS (c) - Reported	**(10.0)**	**(10.1)**	**(0.0)**	**0.9**	**1.7**
Growth (pcp)	n/a	n/a	n/a	n/a	85%
EPS (c) - Adjusted	(10.0)	(7.7)	(0.0)	0.9	1.7
Growth (pcp)	n/a	n/a	n/a	n/a	85%
Dividend (c)	0.0	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0	0.0
Gross CF per share (c)	(4.9)	(5.2)	3.6	4.7	5.7
NTA per share (c)	4.4	11.4	10.9	11.5	12.8

KEY RATIOS

Year end June	FY23A	FY24A	FY25E	FY26E	FY27E
Net Debt : Equity (%)	52%	-21%	-29%	-43%	-58%
Net Debt: EBITDA (x)	5.5	3.8	(1.8)	(1.8)	(2.2)
Current ratio (x)	1.5	1.8	1.8	2.1	2.4
ROE (%)	-31%	-27%	0%	4%	8%
ROIC (%)	n/a	n/a	2%	8%	14%
Dividend Payout Ratio (%)	n/a	n/a	n/a	n/a	n/a

VALUATION MULTIPLES

Year end June	FY23A	FY24A	FY25E	FY26E	FY27E
PE Ratio (x)	**n/a**	**n/a**	**n/a**	**43.5**	**23.5**
Dividend Yield (%)	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
EV/Sales (x)	0.9	0.8	0.7	0.7	0.6
EV/EBITDA (x)	35.3	n/a	10.0	6.4	5.4
EV/EBIT (x)	n/a	n/a	77.2	23.8	15.4

BALANCE SHEET SUMMARY

Year end June	FY23A	FY24A	FY25E	FY26E	FY27E
Cash	12.0	16.2	20.0	27.1	36.3
Receivables	11.1	12.4	13.1	14.4	15.7
Inventories	4.1	6.3	6.1	6.7	7.3
Other	0.3	0.3	0.3	0.3	0.3
Total Current Assets	27.5	35.1	39.5	48.5	59.6
Inventories	0.0	0.0	0.0	0.0	0.0
Property Plant & Equip	6.2	5.8	4.9	1.4	(2.4)
Intangibles	19.0	20.3	21.4	22.4	23.5
Other	9.8	8.6	8.6	8.6	8.6
Total Non-Current Assets	35.0	34.7	34.9	32.4	29.7
TOTAL ASSETS	**62.5**	**69.8**	**74.4**	**80.9**	**89.3**
Accounts Payable	12.2	13.3	15.1	16.6	18.1
Borrowings	0.3	0.3	0.3	0.3	0.3
Lease Liabilities	2.3	2.3	2.3	2.3	2.3
Provisions	3.1	3.8	3.8	3.8	3.8
Other	0.5	0.2	0.2	0.2	0.2
Total Current Liab	18.4	19.9	21.8	23.3	24.8
Borrowings	16.4	0.7	0.7	0.7	0.7
Lease Liabilities	4.6	3.4	3.4	3.4	3.4
Provisions	0.8	0.7	0.7	0.7	0.7
Other	0.0	0.0	0.0	0.0	0.0
Total Non-Current Liab	21.7	4.8	4.8	4.8	4.8
TOTAL LIABILITIES	**40.1**	**24.8**	**26.6**	**28.1**	**29.6**
TOTAL EQUITY	**22.4**	**45.0**	**47.8**	**52.8**	**59.7**

CASH FLOW SUMMARY

Year end June	FY23A	FY24A	FY25E	FY26E	FY27E
EBIT (excl Abs/Extr)	**(4.4)**	**(8.1)**	**1.0**	**3.1**	**4.8**
Add: Dep'n & Amort'n	6.5	5.7	6.4	8.4	8.9
Change in Payables	(0.6)	1.1	1.8	1.5	1.5
Other non-cash items	(4.4)	(0.7)	(1.9)	(2.1)	(2.3)
Less: Tax paid	1.8	1.1	1.0	1.1	1.2
Net Interest	(1.8)	(1.9)	0.0	0.1	0.2
Change in Rec.	0.2	(1.2)	(0.8)	(1.3)	(1.3)
Change in Inv.	(1.0)	(2.2)	0.2	(0.6)	(0.6)
Gross Cashflows	(3.9)	(6.3)	7.7	10.1	12.4
Capex	(6.4)	(5.3)	(3.9)	(3.0)	(3.2)
Free Cashflows	(10.3)	(11.7)	3.8	7.1	9.2
Share Issue Proceeds	0.0	36.0	0.0	0.0	0.0
Other, incl. loans	6.6	(20.1)	0.0	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0	0.0
Net Cashflows	**(3.7)**	**4.2**	**3.8**	**7.1**	**9.2**
FX Effect on Cash	0.0	0.0	0.0	0.0	0.0

Overview

SomnoMed (SOM) markets mandibular advancement splints (MAS) for treating obstructive sleep apnoea (OSA). It is headquartered in Sydney and has a manufacturing plant in the Philippines (Manila).

OSA is a condition where the soft palate at the back of the mouth collapses and temporarily obstructs the airway. As the blood oxygen levels drop, an automatic reflex causes the individual to then wake up briefly (called an arousal or micro-awakening), which restarts their breathing. These breathing pauses, known as apnoeas, can happen many times a night.

People with OSA often suffer from daytime sleepiness and feel tired and unrefreshed after sleep.

As well as making you feel tired, untreated moderate to severe OSA increases the risk of other health problems, such as diabetes, high blood pressure and cardiovascular disease.

The most common treatment for moderate to severe OSA is a continuous positive airway pressure (CPAP) pump, which feeds pressurised air into a face mask to hold the patient's throat open while they sleep.

SOM's MAS therapy treats OSA by moving the lower jaw (mandible) forward, enlarging the airway and reducing the potential for the airway to collapse. MAS therapy is most commonly used to treat mild to moderate OSA and for patients with moderate to severe OSA who are unable to tolerate CPAP.

As Exhibit 1 shows, the stock has progressively sold off from a recent peak of $1.90 in October 2021 to $0.31 in February 2024.

Issues of concern for investors in this period included:

- Failure to demonstrate operational leverage despite revenue growth.
- Balance sheet risk created by the $16 million debt facility with Epsilon Direct Lending.
- Uncertainty around reimbursement in the US, including the failure of the SomnoDent Avant to receive full US Medicare reimbursement coding approval.
- The potential impact of the launch of SGLT2 drugs as effective treatments for obesity amid concerns that reductions in the obesity rate could reduce the overall prevalence of OSA and therefore the size of the market for OSA treatments.
- Cash burn from investment in development in the RestAssure smart MAS device to monitor compliance and efficacy (estimated investment ~$12m).
- Manufacturing capacity constraints that re-emerged in H1 FY24 which led to a backlog of unfilled orders for MAS devices.

Exhibit 1: SOM share price chart

Source: Taylor Collison research

On 22nd February this year CEO Neil Verdal-Austin resigned and was replaced by Non-Executive Directors Amrita Blickstead and Karen Borg as joint CEOs.

A review of operations by the new management team found that the company's manufacturing facility in the Philippines was not capable of manufacturing enough volume to satisfy the increasing demand for the Company's products.

On 9 April SOM announced that it would raise $22.6m via a 1 for 1.01 entitlement offer at $0.21 per share in order to:

- Pay out Epsilon Direct Lending Facility
- Fund a more aggressive cost reduction program that would save $5m in FY25
- Invest in manufacturing capacity initiatives

The cost reduction program was fully implemented by 30 June at a cost of $3.0m, primarily through headcount reductions in the regional sales and marketing and regional administration functions.

The share price has recovered from a low of $0.195 on 2 May to recently trade around ~$0.45/share, which gives SOM a current market capitalisation of approx. $97m.

Analysis of historical financials

Exhibit 2 shows that SOM has regularly delivered double digit revenue growth from the core MAS business. However over the past five years costs have grown faster than revenue. While group gross margin (including managed care revenue) has stayed steady at 58-60%, SG&A expenses have grown from 53% of revenue in the period FY19 (pre pandemic) to 59% of revenue in FY22-FY24.

In FY24 SOM generated 36% of revenue in the US, 57% in Europe and 7% in Asia Pacific. Sales of MAS devices, which comprise 80-85% of revenue, generate a high gross margin (69.1% gross margin in FY24).

Around 15-20% of revenue comes from managed care contracts (mainly in Europe) and sales of other products such as cleaning agents.

Under the managed care contracts SOM is paid a fee that covers the entire process of supplying and fitting the MAS device, including the associated dentist services. We estimate that SOM earns a gross margin of around 20% on the managed care and other revenue.

The above analysis leaves to one side SOM's disastrous foray into direct-to-patient sales in the US via its own sleep dentistry clinics under the Renew Sleep Solutions (RSS) umbrella in FY17. The RSS business was shut down in December 2018 with cumulative losses of over $30m.

In addition to bleeding cash, the direct competition from the RSS operations was affecting SOM's relationship with some of its independent dentist customers.

Exhibit 2: SOM Historical Financials (Core business excluding Renew Sleep Solutions)

Historic financials	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23	FY24
Sales revenue (A$m)	34.4	44.1	47.7	52.4	58.9	57.3	62.7	72.6	83.6	91.7
Sales growth (%pcp)	13.5%	28.2%	8.3%	9.7%	12.4%	-2.7%	9.4%	15.8%	15.2%	9.7%
Group gross margin (A$m)	19.5	25.3	27.8	31.9	34.6	33.1	37.7	44.3	51.9	55.1
Group gross margin (%)	58.6%	57.5%	58.4%	59.0%	59.0%	58.4%	60.2%	61.0%	62.1%	60.1%
Total SG&A expenses	(18.6)	(23.8)	(25.5)	(28.0)	(31.2)	(30.6)	(34.6)	(43.3)	(49.8)	(54.5)
SG&A % Sales	54.1%	54.1%	53.3%	53.4%	52.9%	53.3%	55.1%	59.6%	59.6%	59.4%
EBITDA adj.	0.9	1.5	2.4	3.9	4.9	2.5	3.2	1.0	2.1	0.6
EBITDA adj. % sales	2.5%	3.4%	5.0%	7.4%	8.4%	4.4%	5.0%	1.4%	2.5%	0.7%

Source: Taylor Collison research, Company accounts

We back SOM to outperform under the new management team

We are backing the ability of SOM's new management team to keep a lid on costs growth while investing in the manufacturing side of the business. The team has made a promising start with the reduction in headcount in the regional sales and marketing and regional administration functions, which are expected to save $5m in FY25. This is a 10% cut in total SG&A expenses.

We are encouraged by management's emphasis in our recent meetings on:

- Establishing a heightened focus on profitability within the sales channel; and on
- Driving efficiencies by improving management systems and processes while maintaining ongoing cost discipline.

This discipline includes a commitment that the launch of the RestAssure device (if approved) will be done in a measured way, with a beta launch in H2 FY25 and commercial sales not expected to commence until FY26.

While we acknowledge that some of the sales came from fulfilment of backlog orders, the fact that SOM reported 20% revenue growth in the first 2 months of FY25 gives us confidence that underlying demand in the market remains strong despite the longer order turnaround times that resulted from the manufacturing capacity constraints in FY24.

Our valuation of $0.67/share is based on the revenue growth prospects of the business as it currently stands. We assume that the focus on cost control will see operating costs grow 100-200 basis points below the rate of revenue growth, resulting in gradual improvement in EBITDA margins. We also assume that group gross margins, which were impacted by manufacturing constraints in FY24, recover to the 62% margin reported in FY23 by FY26.

We note that there are two potential catalysts that could lift revenue growth meaningfully above our base case forecasts, namely:

- PDAC review could potentially lead to Medicare reimbursement for SomnoDent Avant in the US.
- Potential FDA clearance of RestAssure device which has compliance and efficacy monitoring capability (FDA decision expected in October).

While we note that each of these factors has the potential to deliver a meaningful increase in revenue above our forecasts, given the uncertainties around each of them we have not attempted to quantify the potential revenue and earnings benefit.

PDAC review could lead to improved reimbursement in the US for the SomnoDent Avant

One potential catalyst that would see us upgrade our forecasts for SOM would be the granting of a favourable Medicare reimbursement code for the company's lead MAS device, the SomnoDent Avant, in the US.

Reimbursement in the US is heavily influenced by the decisions made by the Centers for Medicare and Medicaid Services (CMS). Medicare provides reimbursement for MAS devices which have been classified under the E0486 HCPCS[1] code but does not typically provide reimbursement for devices to which the alternative K1027 code applies. Many commercial insurers have coverage policies that are similar to the CMS rules.

The HCPCS codes for MAS devices are summarised in Exhibit 3.

Exhibit 3: HCPCS codes that apply to MAS devices in the US

HCPCS Code	Description
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment

Source: Taylor Collison research, United Healthcare, US Centers for Medicare & Medicaid Services

CMS only reimburses MAS devices under the E0486 HCPCS code if they have undergone Coding Verification Review by the Pricing, Data Analysis, and Coding (PDAC) Contractor.

MAS devices that are not approved to use the E0486 code can claim reimbursement under the K1027 code for a custom fabricated MAS device without a fixed mechanical hinge.

However, both Medicare and (to a lesser extent) commercial insurers are less likely to provide reimbursement for claims submitted under the K1027 code.

As Exhibit 3 shows, CMS ties reimbursement to a requirement that the MAS has a fixed hinge. This seems to be for historical reasons that have little to do with device efficacy. However, during our channel checks we learnt that a number of companies have attempted to get PDAC to relax the fixed hinge requirement over the years, but none has been successful.

SOM's Herbst Advance Elite and several of its older MAS devices have PDAC approval to use the E0486 code, but its lead product, the SomnoDent Avant does not. These two devices are shown in Exhibit 4.

[1] Healthcare Common Procedure Coding System

Exhibit 4: SomnoDent Avant (LHS) and SomnoDent Herbst Advance Elite (RHS)

Source: Taylor Collison research, Company website

SOM has made 2 applications to PDAC requesting CMS/Medicare reimbursement for the SomnoDent Avant device, but each of these applications has been rejected.

SOM is preparing to submit a further application to PDAC for approval to use the E0486 code for the SomnoDent Avant. It has altered its strategy and intends to emphasise that once the SomnoDent Avant is placed in the mouth its mechanical hinge is fixed in place. Even though the Avant hinges at the front of the upper plate rather than having a traditional hinge at the back, we believe that this argument is sound.

SOM has not yet submitted the revised application to PDAC as it wants to complete a thorough consultation process to refine the application in order to give itself the best chance of success.

We believe that this strategy has a much better chance of success than previous approaches, because it does not require PDAC to move away from its long held view that a fixed mechanical hinge is important.

While the outcome is still uncertain, we believe that the revised approach to PDAC has a realistic chance of success.

PDAC approval of the E0486 code for Avant would give SOM a competitive advantage and we would expect it to boost sales in the US.

RestAssure aims to fulfil an unmet need for clinician feedback on MAS effectiveness

We expect SOM to hear in early October whether the US FDA has cleared the company's RestAssure smart MAS device for sale in the US.

The RestAssure system includes a smart device with in-mouth sensors, cloud-based algorithms, a portal for physicians and dentists to review patient data, as well as the RestAssure patient app, as shown in Exhibit 5.

The aim in developing RestAssure was to build a connected device that provided nightly patient usage and treatment effectiveness data, in order to match the information that is available to clinicians for patients who use CPAP machines.

The expectation is that the availability of patient monitoring data from the RestAssure device may give sleep physicians more confidence to prescribe MAS therapy to OSA patients as an alternative to CPAP.

Rest Assure, if approved, has the potential to boost SOM's US sales in two ways, by:

- Growing the size of the total MAS market by increasing the willingness for sleep physicians to prescribe MAS therapy to OSA patients as an alternative to CPAP
- Taking market share from competing MAS products

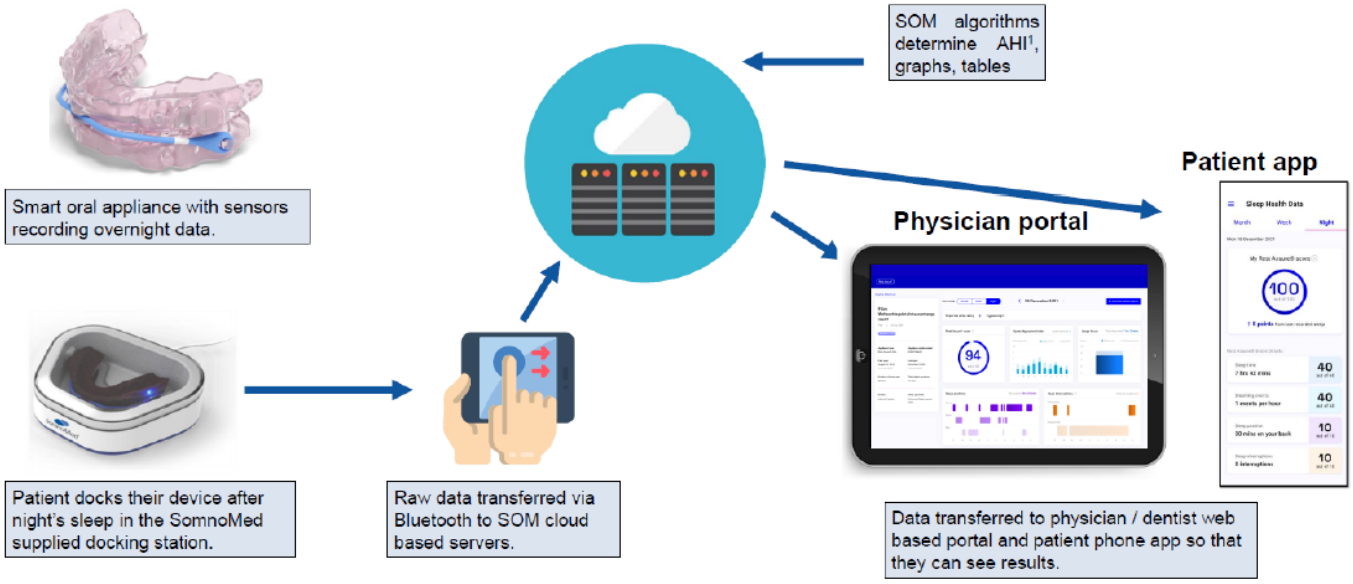
We estimate that SOM has invested approx. $12m in the RestAssure development program, which began in early 2020.

The company submitted a 510(k) application for FDA approval of RestAssure in October 2023. Earlier this month SOM submitted its response to the questions asked by FDA reviewers in its formal Additional Information request.

- The FDA's goal is to issue a final decision within 30 days of receiving the response to an Additional Information request regarding a 510(k) application, which the company submitted in early September.

- The FDA meets its review timeline goals for 510(k) applications 89% of the time, so we see a high likelihood of an FDA decision regarding RestAssure in early October. We note that SOM is expecting the FDA decision within 45 days of the recent submission (ie late October) vs our expectation of 30 days.

Exhibit 5: RestAssure smart oral appliance and cloud based infrastructure



Source: SomnoMed

While FDA clearance of RestAssure will be a key milestone for SOM, a number of additional hurdles will need to be cleared before it can contribute meaningful revenue.

SOM will need to either:

- Gain reimbursement coverage for RestAssure from CMS and/or commercial insurers in the US, preferably at a higher price than existing devices; or
- Convince Sleep Physicians and Sleep Dentists that the benefits of the treatment effectiveness data justifies asking patients to pay a higher out of pocket cost for the RestAssure device.

The management team has indicated that it intends to take a measured approach to the commercial launch of RestAssure (if approved).

It intends to commence with a beta product launch in H2 FY25 which will allow it to get feedback from sleep dentists, sleep physicians and health insurers. It does not expect commercial sales to commence until FY26.

The design of the RestAssure device is based on the company's Avant device that does not currently have CMS reimbursement, although the company is seeking to change that, as discussed above. If SOM does not receive a favourable ruling from PDAC regarding coverage of the Avant device, that may be an additional barrier to getting CMS reimbursement for the RestAssure device.

Financial forecasts and valuation

We initiate coverage of SOM with a valuation of $145m or $0.67 per share (undiluted), based on a discounted cash flow model, applying a 10% discount rate. We have extended our cash flow forecasts out to 2040 but do not include a terminal value. On a fully diluted basis our valuation is $0.66 per share, after taking into account the options on issue.

Key assumptions in our valuation model and financial forecasts include:

- Revenue grows by 10% to $101m in FY25
    - In subsequent years revenue grows by 10% in FY26 and 9% in FY27, with growth tapering to 7% from FY31 onwards.
- Regional SG&A expenses (excluding one-offs) decrease by $5m at the start of FY25 due to the headcount reductions implemented in FY24
    - Combined with 7% underlying cost growth this results in a $1.5m net decrease to $39.5m FY25.
- Corporate costs grow 8% in FY25 and 7% in FY26.
- Total SG&A expenses grow by 7% p.a. in FY27-FY28 and by 6% p.a. in subsequent years; this results in the growth in expenses being 100 basis points below revenue growth in most years.

Exhibit 6 shows our P&L forecasts for SOM. These base case forecasts reflect the business as it stands today and do not include any additional sales that might arise from a commercial launch of RestAssure (if approved) or from a potential favourable US reimbursement decision from PDAC regarding SomnoDent Avant.

Exhibit 6: Forecast P&L performance (A$m)

Financial forecasts	FY23a	FY24a	FY25f	FY26f	FY27f	FY28f	FY29f	FY30f
Sales revenue (A$m)	83.6	91.7	100.9	111.0	120.9	131.8	142.4	153.8
Sales growth (%pcp)	15.2%	9.7%	10.0%	10.0%	9.0%	9.0%	8.0%	8.0%
Group gross margin (A$m)	51.9	55.1	61.5	68.8	75.0	82.4	89.0	96.1
Group gross margin (%)	62.1%	60.1%	61.0%	62.0%	62.0%	62.5%	62.5%	62.5%
Regional SG&A expenses (A$M)	(37.6)	(41.0)	(39.5)	(41.6)	(44.5)	(47.6)	(50.4)	(53.5)
Corporate and other expenses (A$m)	(12.2)	(13.5)	(14.7)	(15.7)	(16.8)	(18.0)	(19.1)	(20.2)
Total SG&A expenses	(49.8)	(54.5)	(54.2)	(57.3)	(61.3)	(65.6)	(69.5)	(73.7)
SG&A % Sales	59.6%	59.4%	53.7%	51.6%	50.7%	49.8%	48.8%	47.9%
EBITDA adj.	2.1	0.6	7.3	11.5	13.7	16.8	19.5	22.4
EBITDA adj. % sales	2.5%	0.7%	7.3%	10.4%	11.3%	12.7%	13.7%	14.6%

Source: Taylor Collison research

Background – the Obstructive Sleep Apnoea market

OSA is a condition where the soft palate at the back of the mouth collapses and temporarily obstructs the airway. It is characterised by episodes of complete (apnoea) or partial collapse (hypopnea) of the upper airway, with an associated decrease in blood oxygen levels or arousal from sleep. These breathing pauses can happen many times a night.

OSA is estimated to affect over 100 million people in the developed countries and around 1 billion people worldwide.

People with OSA often suffer from daytime sleepiness and feel tired and unrefreshed after sleep.

As well as making you feel tired, untreated moderate to severe OSA increases the risk of other health problems, such as diabetes, high blood pressure and cardiovascular disease.

OSA is categorised as mild, moderate or severe based on the apnoea/hypopnea index (AHI), which is a measure of the number of apnoea or hypopnea events that occur per hour during sleep. The categories of OSA are:

- Mild AHI 5-15 events/hr
- Moderate AHI 15-30 events/hr
- Severe AHI >30 events/hr

The most common treatment for moderate to severe OSA is a continuous positive airway pressure (CPAP) pump, which feeds pressurised air into a face mask to hold the patient's throat open while they sleep.

MAS devices such as those sold by SOM treat OSA by moving the lower jaw (mandible) forward, enlarging the airway and reducing the potential for the airway to collapse. MAS therapy is most commonly used to treat mild to moderate OSA and for patients with moderate to severe OSA who are unable to tolerate CPAP.

CPAP is highly effective, but MAS devices are better tolerated

CPAP is highly effective if the patient can tolerate the mask and device, as the positive pressure can be increased (within limits) to reduce airway collapse until the AHI is in the normal range (< 5 events/hr). The downside to CPAP is that compliance is frequently poor. Many patients stop using CPAP after a few months, while others often only use the CPAP device for part of the night, due to the need to wear a mask connected to the CPAP machine.

For example, in a large Phase III CPAP trial, after 12 months the average CPAP usage was only 3.3 hours per night.

On the other hand, available data indicates that MAS device therapy has a lower average efficacy than CPAP, but it is better tolerated.

If treatment success is defined as a 50% reduction in AHI, with AHI reduced to <10 events/hr, studies have shown that around a third to one half of patients do not respond adequately to MAS therapy. However, the better compliance (greater number hours used per night) means that the net impact on the number of AHI events per night is often similar between CPAP and MAS therapy.

The effectiveness of MAS therapy can often be improved by combining it with other treatments such as a positional device to prevent the patient sleeping on their back (OSA is often worse when the patient sleeps on their back).

The fact that CPAP is highly effective if it is well tolerated means that in most markets, including the US, sleep physicians typically prescribe CPAP as first line therapy for patients with moderate or severe OSA.

MAS therapy is typically used in patients with moderate or severe OSA who fail CPAP (refuse or non-compliant), or in patients with mild OSA.

The positioning of MAS as a second line therapy is reinforced by the fact that many US health insurers require the patient to have had an unsuccessful CPAP trial before they will reimburse a MAS device.

Uptake of MAS devices is patchy, even among failed CPAP patients

While MAS therapy can be used as a first line therapy, particularly in patients with mild to moderate OSA, the main market opportunity in the US appears to be in failed CPAP patients.

However, even when focusing on failed CPAP patients, uptake of MAS devices in the US is patchy. Not all sleep physicians are willing to prescribe MAS therapy. Even if the sleep physician is willing to prescribe MAS therapy, a number of other factors need to be in place to support uptake, including:

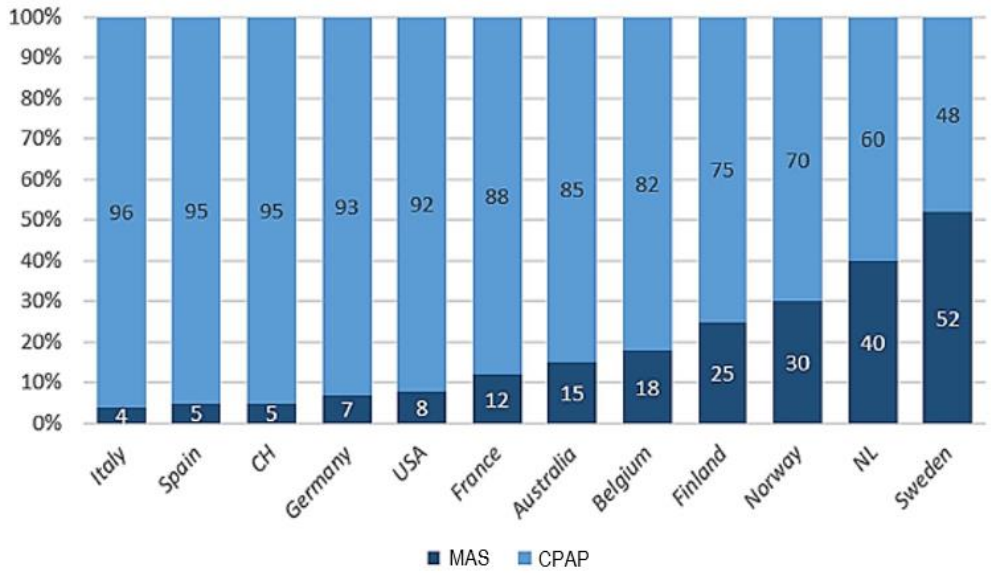
- Access to a suitably trained and qualified sleep dentist
- Adequate reimbursement in place
- Patient must have suitable dentition (missing teeth, decay or periodontal disease can make the patient unsuitable).

An industry player estimated that in the US 70% of treatments are paid for by private insurance, 25% are covered by Medicare and the remaining 5% are paid out of pocket by the patient. As a result, uptake of MAS therapy tends to be strongest in areas where a local health insurer has a favourable reimbursement policy.

CPAP dominates OSA therapy in most markets, but reimbursement policies can have a big impact

In 2019 SOM estimated that MAS penetration of the OSA market in the US was 8% vs 92% for CPAP (Exhibit 7). In countries such as the Netherlands and Sweden where reimbursement of MAS devices was more favourable, MAS penetration was 40-52%. We estimate that MAS penetration in the US still sits at around 8-10%.

Exhibit 7: Estimated MAS penetration in SomnoMed global markets



Source: Taylor Collison research, SOM presentation

The dominance of CPAP companies is more pronounced in terms of revenue generated. ResMed is by far the biggest player, capturing over 80% of sales in the sector.

Exhibit 8 shows that sales of the top two MAS companies are only 2% of the revenue generated by the top 2 CPAP companies.

Exhibit 8: Annual OSA segment revenue for leading CPAP and MAS companies

Company	Operating segment	Annual Global Sales (US$m)	US Sales estimate (US$m)
CPAP companies			
ResMed (RMD.AU)	Sleep apnoea and other chronic respiratory	4,100	2,700
Fisher and Paykel Healthcare (FPH.AU)	Homecare products	385	177
Philips Healthcare	Sleep and respiratory care	961	0
MAS companies			
SomnoMed (SOM.AU)		61	22
ProSomnus (delisted)*		28	21

*Source: Taylor Collison research. Note: *we assume that 75% of ProSomnus revenue is generated in North America, in line with the distribution of sales reps.*

In addition to SomnoMed and ProSomnus, another prominent MAS player in the US is Panthera Dental, which is headquartered in Quebec City, Canada, and has subsidiaries in the US, France and Germany. Panthera manufactures dental prostheses and implants, in addition to MAS devices. Panthera is privately owned, so its sales numbers are not available, but we understand that it has a smaller share of the US market than SOM and ProSomnus.

The MAS market is highly competitive, with a number of small dental laboratories also manufacturing devices. For example, there are 27 different companies that have devices that are verified by PDAC for use with the E0486 reimbursement code in the US.

The competitive nature of the MAS market is highlighted by the fact that ProSomnus entered Chapter 11 bankruptcy protection in May, after generating revenue of US$27.7 million, with a net loss of US$24.1 million, for the year ended December 31, 2023.

The fact that SOM has delivered consistent revenue growth in this competitive market highlights the quality of its products.

SomnoMed's products are milled from a single piece of hard, pre-cured dental acrylic, and finished with a flexible liner for improved comfort. The milled acrylic product is stronger and longer lasting than competing products, which are typically made from 3D printed nylon.

Risks

SOM is subject to the regulatory and competitive risks common to all life sciences companies. In our view the key risks include:

Competitive risk. The OSA therapy market is highly competitive. SOM currently faces competition from CPAP suppliers, other MAS device suppliers and surgical treatments for OSA. If new players or products enter the market or if pricing competition becomes more intense, SOM may not be able to generate revenue growth in line with our forecasts.

Reimbursement risk. We estimate that over 90% patients treated with MAS devices in the US receive reimbursement from either Medicare or commercial insurers. Unfavourable changes to reimbursement policies from any of these payers would have a negative impact on SOM's revenue.

Tender risk. In a number of European countries the provision of MAS therapy for OSA patients is subject to competitive tender. There is a risk that SOM may not be successful in winning new tenders or may not be successful in rolling over existing contracts when they are up for renewal.

SOM must control cost growth in order to deliver profitability. SOM has regularly delivered double digit revenue growth but over the past five years costs have grown faster than revenue. SOM has implemented headcount reductions to restore profitability. It is essential that the company maintains cost discipline in order to maintain and improve profit margins. If costs are allowed to grow faster than revenue, then SOM will not meet our forecasts and could report operating losses.

Anti-obesity drugs could reduce OSA prevalence. OSA is more common on obese people. The new class of SGLT2 anti-obesity drugs (eg Ozempic, Zepbound) have reported average weight loss of over 20% in clinical trials. Two recent trials of Zepbound reported ~50% reductions in AHI in patients with moderate to severe OSA. After 1 year, 48% and 60% of patients had only mild OSA or their OSA had resolved (the reports did not state how many of these patients had mild OSA vs those where the OSA had resolved (i.e. AHI <5 events/hr)). It is possible that the demand for MAS therapy could be reduced if there is widespread uptake of the new anti-obesity drugs, but it is not at all certain that this would be the case. It is even possible that by shifting more patients into the mild OSA category, the anti-obesity drugs could lead to increased demand for MAS devices.

Potential upside catalysts may not come to fruition. We have identified PDAC verification of the SomnoDent Avant device for Medicare reimbursement in the US and FDA approval of RestAssure as potential catalysts that could see SOM outperform our forecasts. If neither of these events comes to pass, then this would limit the potential for SOM to outperform our base case forecasts.

RestAssure might not generate meaningful revenue even if it wins FDA clearance. Successful commercialisation of RestAssure depends on the new device winning reimbursement at a higher price than the current SomnoDent Avant product. If SOM is not able to win reimbursement coverage for RestAssure from enough payers, there is a risk that the new device might not generate sufficient revenue to cover the sales and marketing expenses incurred to support the commercial launch.

Balance sheet risk. We expect SOM to be profitable and cash flow positive throughout the forecast period. We expect the $16.2m cash balance to be ample to support operations and planned capex. However, if SOM fails to restrict growth in operating expenses or if sales do not meet our expectations, then it may need to raise additional funds. There is no certainty that the funding will be available on acceptable terms if required.

Share Register

The top 3 shareholders plus management hold ~57% of ordinary shares in SOM.

Exhibit 9: The top 3 shareholders account for 55% of the register

Shareholder	%
TDM Growth Partners	31.3%
Australian Ethical Investment	15.8%
Fidelity International	8.2%
Board and Management	1.4%

Source: Taylor Collison research, SOM

Board and management

Guy Russo, Non-Executive Chairman – Guy Russo is an accomplished business leader with a strong commercial and customer-focussed background working in Australia and internationally. In addition to Chairman of SomnoMed he is Chairman of Guzman y Gomez Mexican Kitchen (GYG), Australia's fastest growing restaurant business. He is a non-executive Director of Scentre Group (ASX: SCG) which owns and operates Westfield Living Centres in Australia and New Zealand and Chairman of OneSky, an international charity for children living in poverty in Asia.

Previously, Guy has served as CEO, Wesfarmers Department Store Division (Kmart & Target); Managing Director, Kmart Australia & NZ; President, McDonald's Greater China; CEO McDonald's Australia Ltd and Chairman of Ronald McDonald House Children's Charities.

Amrita Blickstead, Director & Joint Chief Executive Officer – Amrita is an experienced Non-Executive Director and has extensive strategic, sales & marketing, and product development expertise. She has experience in retail, ecommerce, medical devices and has been an advocate for diversity & inclusion. Amrita is the former Chief Operating and Marketing Officer at eBay Australia & New Zealand and over her 10 year tenure led many different areas of the business across Strategy, Operations, Marketing, Sales, Loyalty, Advertising, Pricing, Consumer Selling, Cross Border Trade, Shipping and Small & Medium Business. Prior to eBay, Amrita established her career as a Management Consultant at Port Jackson Partners, and a Biomedical Engineer at Ventracor and Cochlear. Amrita is currently a Non-executive Director at Audinate as well as a non-profit Vision Beyond Aus.

Amrita holds a Master of Business Administration from Harvard Business School and a Bachelor of Mechanical (Biomedical) Engineering from the University of Sydney. Amrita won the Australian Financial Review BOSS Awards for Young Executive of the Year in 2019.

Karen Borg, Director & Joint Chief Executive Officer – Karen has held senior roles in FTSE 100-250 medical device, technology, consumer products and government services organisations. Karen was most recently the Chief Executive Officer for Catholic Healthcare Ltd and prior to this was the CEO of Healthdirect and the inaugural CEO of Jobs for NSW. She was also the former President (Asia Pacific & Middle East) of ResMed (ASX: RMD) and held several senior roles with Johnson & Johnson Medical Devices in Australia and the United States. Karen began her career in the fast-moving consumer goods sector and worked for Goodman Fielder, Nestle and Revlon in global business development and marketing.

Karen is on the Board of Optiscan Ltd (ASX: OIL) and was previously on the Board of The North Foundation and Interim Chair of the Australian Vaccine Research Alliance. She has a Bachelor of Arts from the University of Sydney.

Hamish Corlett, Non-Executive Director – Hamish is a founder and director of TDM Growth Partners, a leading private investment firm specializing in long term investments in high growth companies globally. TDM made its first investment in SomnoMed in April 2010 and has been a substantial shareholder in the Company since October 2012.

Prior to TDM, Hamish worked as an Investment Manager at Caledonia Investments, a global fund manager. Hamish also worked in London in an operating role for an ecommerce start up and in Sydney at Caliburn Partnership (now Greenhill) in corporate advisory. Hamish is also a Non-Executive Director QBiotics Group Limited.

Hamish holds a Bachelor of Commerce with Honours Class 1 (Accounting and Finance) from the University of Sydney and a Graduate Diploma of Counselling from the Australian College of Applied Psychologists.

Michael Gordon, Non-Executive Director – Michael is a Director of K Sleep Holdings Pty Limited ("Koala"), a direct to consumer household goods retailer. Michael was previously the CFO of Different Technologies, a property technology company, and before that Michael was CFO of Rokt, a high-growth marketing technology company with more than US$300m in revenue.

Prior to Rokt, Michael was the Group CFO and MD of Group Services for Greenlit Brands Pty Limited. Greenlit Brands grew from a turnover of A$250m (Freedom) to a A$2.4 billion vertically integrated retailer based in Australia and New Zealand and included the brands, Freedom, Snooze, Fantastic, Plush, OMF, Best & Less and Harris Scarfe. Prior to Greenlit Brands, Michael spent ten years with PricewaterhouseCoopers in South Africa, the United Kingdom and Australia specialising in the retail and pharmaceutical industries with experience in audit, taxation M&A and IPOs.

Michael is a Chartered Accountant and holds a Bachelor of Commerce and Bachelor of Accounting (University of Witwatersrand, South Africa).

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