WILSONS

Equity Research

Date
23 February 2022

Theme
Financial Results

Company
SomnoMed (SOM)

O/W: CPAP had better watch out!

We upgrade our rating on SomnoMed to OVERWEIGHT maintaining our $2.40/sh price target. SomnoMed's unveiling of their new technology-enabled oral appliance, Rest Assure®, gives us confidence in the growth outlook for the US business which has been underpenetrated in the past. The ability for SOM to provide daily efficacy, in addition to compliance data, will finally allow for objective comparisons of treatment effectiveness between CPAP and OAT in mild-moderate sleep apnoea patients and a way for clinicians to track their patients care longitudinally. This has been a significant historical barrier to OAT adoption. ResMed's first connected CPAP solution (AS10) won them significant, durable market share – we see this as SOM's opportunity. Further, we expect clinical study data will support clinical guideline changes along with reimbursement support, in time. We model significant contributions from 2H24e with plenty of supporting SP catalysts in the coming 12 months including data publication and regulatory approval/s.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$2.40**
Share price @ 22-Feb-22 (AUD)	$1.85
Forecast 12-mth capital return	29.7%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**29.7%**
Market cap	$153m
Enterprise value	$142m
Shares on issue	83m
Sold short	0.0%
ASX 300 weight	n/a
Median turnover/day	$0.0m

Key points

Earnings call takeaways. Revenue: $33.9M (+10% v pcp) pre-announced. Underlying EBITDA of $0.2M in line with expectations. Gross profit added 300bps vs pcp to 62% reflecting further digital manufacturing/scale efficiencies. NPAT normalised loss of $2.9M slightly behind expectations. Geographies: USA responsible for 1H22 growth (+25% v pcp) with EU (+5%) and APAC (-5%) battling COVID disruptions. Trading: 2H22 YTD has seen positive EU/APAC recovery + good US sales continuing. Guidance: FY22 guidance maintained (≥15% revenue growth; breakeven EBITDA; $8M R&D investment). Management bullish on outlook for 2H22. Balance sheet: $17.6M cash with €3M undrawn debt facility available.

New connected device. SomnoMed have provided further details on their new technology-enabled oral appliance, Rest Assure® with on-board patient monitoring and cloud-connected data feedback. This is truly transformational to OAT in sleep apnoea – for the first time, patients and clinicians have on-demand access to compliance and efficacy data on a nightly basis. This connectivity and data feedback was revolutionary to RMD's CPAP business – we assess this can be as impactful to OAT adoption, particularly in USA, with up to 1% of CPAP OSA market share on offer in our view (+27k devices/yr).

Model changes. Modest changes to near term forecasts reflect remodelling of segmental (US/EU/APAC) margins. Small base effect re % changes to NPAT/EPS. We had already factored in US growth acceleration in anticipation of Rest Assure® at end FY21.

Valuation. Our DCF valuation of $2.40/share remains which reflects a 16% growth story for US business driven by Rest Assure® adoption. We model a scenario with upside to $2.85/sh provided Rest Assure® could capture 1% of US OSA market share in time.

Risks and catalysts on p.12 of this report

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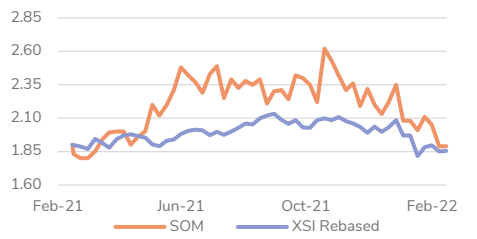
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-11.7	-20.9	-0.5
Rel return (%)	-10.3	-9.9	1.8

Earnings forecasts

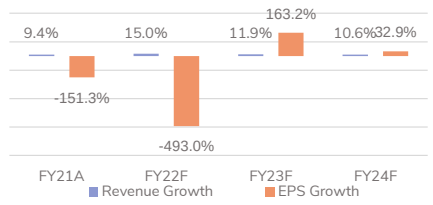
Year-end June (AUD)	FY20A	FY21A	FY22F	FY23F	FY24F
NPAT rep ($m)	-1.1	-1.1	-5.0	2.9	3.9
NPAT norm ($m)	-0.2	-0.8	-4.6	2.9	3.9
Consensus NPAT ($m)			-3.3	3.1	4.4
EPS norm (cps)	-0.3	-0.8	-5.0	3.2	4.2
EPS growth (%)	-102.6	-151.3	-493.0	163.2	32.9
P/E norm (x)	-549.4	-218.6	-36.9	58.3	43.9
EV/EBITDA (x)	30.2	36.4	446.0	17.0	12.8
FCF yield (%)	2.2	0.4	-3.0	1.1	2.1
DPS (cps)	0.0	-0.1	0.0	0.0	0.0
Dividend yield (%)	0.0	-0.1	0.0	0.0	0.0
Franking (%)	0	0	0	0	0

Source: Company data, Wilsons estimates, Refinitiv

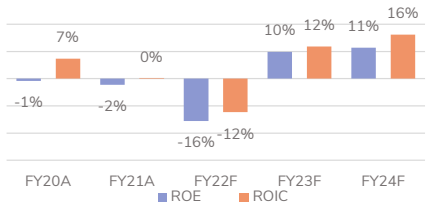
Key changes

		25-Aug	After	Var %
NPAT:	FY22F	-3.7	-4.6	N/A
norm	FY23F	3.9	2.9	-27.4%
($m)	FY24F	4.2	3.9	-7.0%
EPS:	FY22F	-4.1	-5.0	N/A
norm	FY23F	4.4	3.2	-27.4%
(cps)	FY24F	4.6	4.2	-8.3%
DPS:	FY22F	0.0	0.0	0.0%
(cps)	FY23F	0.0	0.0	0.0%
	FY24F	0.0	0.0	0.0%
Price target:		2.40	2.40	0.0%
Rating:		M/W	O/W	

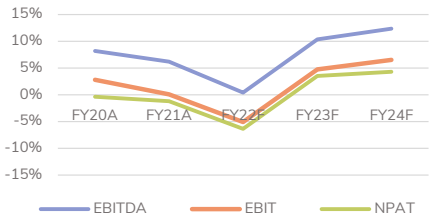
Growth rates



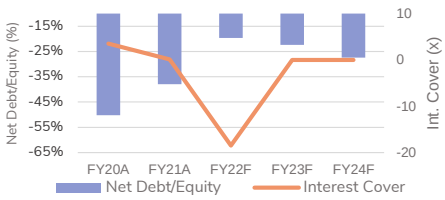
Returns



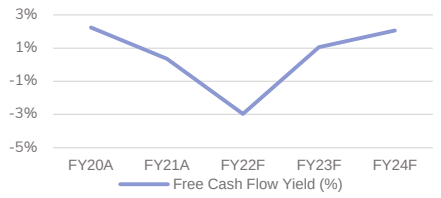
Margin trends



Solvency



Free cash flow yield



Interims ($m)

	1H21A	2H21A	1H22A	2H22E
Sales revenue	30.8	31.9	33.9	38.2
EBITDA	3.2	0.7	0.2	0.1
EBIT	1.3	-1.3	-1.7	-2.0
Net profit	**0.8**	**-1.6**	**-2.5**	**-2.1**
Norm EPS	**0.6**	**-1.7**	**-3.8**	**-2.2**
EBIT/sales (%)	4.4	-4.0	-5.0	-5.2
Dividend (c)	0.0	-0.1	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0
Payout ratio (%)	0.0	5.8	0.0	0.0
Adj payout (%)	0.0	0.0	0.0	0.0

Key assumptions

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
Revenue Growth (%)	11.9	29.0	-7.4	-2.8	9.4	15.0	11.9	10.6
EBIT Growth (%)	-747.2	178.2	-131.9	-37.9	-96.4	-6,381.8	-205.2	51.6
NPAT Growth (%)	-1,534.2	202.3	-203.7	-102.9	256.5	507.8	-162.4	34.7
EPS Growth (%)	**-1,476.9**	**191.8**	**-199.2**	**-102.6**	**151.3**	**493.0**	**-163.2**	**32.9**
EBIT / Sales (%)	-5.9	-12.8	4.4	2.8	0.1	-5.1	4.8	6.6
Tax Rate (%)	-14.3	-19.8	24.6	102.8	-85.8	-18.6	0.0	0.0
ROA (%)	**-7.1**	**-19.8**	**6.0**	**2.8**	**0.1**	**-6.4**	**6.5**	**9.3**
ROE (%)	-7.4	-25.6	33.1	-0.7	-2.4	-14.6	8.5	10.5
SomnoMed EBITDA ($m)	1.3	3.9	4.9	4.7	3.9	0.3	8.4	11.1
RSS EBITDA ($m)	-4.1	-10.4	-10.2	0.0	0.0	0.0	0.0	0.0

Financial ratios

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
PE (x)	-42.9	-14.7	14.8	-561.3	-223.4	-37.7	59.6	44.8
EV/EBITDA (x)	-83.7	-21.9	28.9	30.2	36.4	446.0	17.0	12.8
Dividend yield (%)	0.0	0.0	0.0	0.0	-0.1	0.0	0.0	0.0
FCF yield (%)	-3.3	-7.5	-5.1	2.2	0.4	-3.0	1.1	2.1
Payout ratio (%)	0.0	0.0	0.0	0.0	12.0	0.0	0.0	0.0
Adj payout (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Profit and loss ($m)

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
Sales revenue	49.3	63.6	58.9	57.3	62.7	72.1	80.7	89.2
EBITDA	-1.7	-6.5	4.9	4.7	3.9	0.3	8.4	11.1
Depn & amort	1.2	1.7	2.3	3.1	3.8	4.0	4.5	5.2
EBIT	**-2.9**	**-8.2**	**2.6**	**1.6**	**0.1**	**-3.7**	**3.9**	**5.9**
Net interest expense	-0.1	0.0	0.0	0.5	0.5	0.2	0.0	0.0
Tax	0.4	1.6	0.6	1.2	0.3	0.7	0.0	0.0
Minorities/pref divs	-0.8	-2.1	0.0	0.0	0.0	0.0	1.0	2.0
Equity accounted NPAT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (pre-sig items)	**-2.4**	**-7.7**	**2.0**	**0.0**	**-0.8**	**-4.6**	**2.9**	**3.9**
Abns/exts/signif	-1.0	-0.9	-18.4	-1.1	-0.3	-0.4	0.0	0.0
Reported net profit	**-3.3**	**-8.6**	**-16.4**	**-1.1**	**-1.1**	**-5.0**	**2.9**	**3.9**

Cash flow ($m)

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
EBITDA	-1.7	-6.5	4.9	4.7	3.9	0.3	8.4	11.1
Interest & tax	-1.2	-0.6	-1.0	-1.4	-1.1	-0.4	0.0	0.0
Working cap/other	0.2	-2.4	-10.5	1.9	-0.1	-2.0	-2.3	-2.7
Operating cash flow	**-2.7**	**-9.5**	**-6.5**	**5.2**	**2.7**	**-2.0**	**6.1**	**8.4**
Maintenance capex	-2.4	-2.0	-1.3	-1.8	-2.2	-2.5	-4.5	-5.2
Free cash flow	**-5.1**	**-11.5**	**-7.9**	**3.4**	**0.6**	**-4.5**	**1.6**	**3.2**
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	-2.0	-2.5	0.0	0.0
Invest/disposals	-0.3	-0.2	-0.3	-0.4	0.0	0.0	0.0	0.0
Oth investing/finance flows	-0.1	-0.6	-0.6	-2.2	-2.7	-0.8	0.0	0.0
Cash flow pre-financing	**-5.5**	**-12.3**	**-8.8**	**0.9**	**-4.1**	**-7.8**	**1.6**	**3.2**
Funded by equity	2.4	11.2	0.0	16.9	0.4	0.0	0.0	0.0
Funded by debt	0.0	0.0	3.0	4.5	-4.8	0.0	0.0	0.0
Funded by cash	3.1	1.1	5.8	-22.2	8.5	7.8	-1.6	-3.2

Balance sheet summary ($m)

	FY17A	FY18A	FY19A	FY20A	FY21A	FY22F	FY23F	FY24F
Cash	14.2	13.4	7.7	30.2	21.1	13.5	15.1	18.2
Current receivables	10.2	13.6	10.6	7.6	10.6	11.3	13.2	15.5
Current inventories	1.9	2.0	1.9	2.2	2.3	3.0	3.6	4.2
Net PPE	4.5	6.6	3.2	10.2	4.7	4.5	4.5	4.5
Intangibles/capitalised	10.4	10.1	11.2	11.0	17.2	13.9	14.6	15.4
Total assets	**41.2**	**45.7**	**34.8**	**61.7**	**56.2**	**51.6**	**56.5**	**63.3**
Current payables	8.0	8.4	8.1	8.6	10.6	11.5	12.5	13.5
Total debt	0.0	1.4	3.6	13.2	8.9	8.2	8.2	8.2
Total liabilities	**10.3**	**12.9**	**16.9**	**27.9**	**24.0**	**24.6**	**25.7**	**26.7**
Shareholder equity	**31.0**	**32.8**	**17.8**	**33.8**	**32.2**	**27.0**	**30.8**	**36.6**
Total funds employed	**31.0**	**34.2**	**21.4**	**47.0**	**41.1**	**35.2**	**39.0**	**44.8**

1H22 Result review

1H22 result snapshot. SomnoMed released 1H22 results which were in line with expectations, following their pre-announced 2Q trading update in January. Core revenue of $33.9M was 10% up on pcp but below our initial forecasts (-5%) driven by strong US sales rebound. Gross margin expansion of 300bps vs pcp to 62%. Underlying EBITDA of $0.2M loss (-94% v pcp), slightly ahead of expectations (WILSe: $0.1M loss) and FY22 guidance – reflects investment in newly announced product platform, Rest Assure®. NPAT loss of $3.0M for period ahead of our $2.0M loss estimates. OCF of $0.01M was ahead of expectations. Cash balance of $17.6M at end of period with ~$5M (€3M) of undrawn debt facility available.

FY22 outlook maintained with ≥15% revenue growth and breakeven EBITDA guided. This revenue guidance implies ≥20% growth v pcp in 2H22e. SOM also called out $8.0M in cash investment (R&D) to support Rest Assure® device development ($3.0M of this expensed in 1H22).

Table 1. SomnoMed's 1H22 results vs pcp and our estimates

(AUD$m)	1H21a	1H22a	%chg	Forecast	%chg	Var (abs$)	%var
USA	9.5	11.9	25%	11.9	25%	-	0%
Europe	18.6	19.5	5%	19.5	5%	-	0%
APAC	2.7	2.6	-5%	2.6	-5%	-	0%
Core revenue	**30.8**	**33.9**	10%	**33.9**	10%	-	0%
COGS	12.7	13.0	2%	14.0	10%	1.0	-7%
Gross profit	18.1	20.9	16%	19.9	10%	(1.0)	5%
Segment profit	**5.8**	**5.7**	**-2%**	**5.9**	**2%**	**0.2**	**-4%**
Net corporate, R&D, other	2.7	5.5	107%	5.8			-5%
Underlying EBITDA	**3.2**	**0.2**	-94%	**0.1**	**-96%**	**(0.1)**	**76%**
Interest, other	0.2	0.2	nm	-	nm	(0.2)	nm
Tax	0.3	0.6	nm	0.1	nm	(0.5)	nm
Reported NPAT	0.6	(3.0)	nm	(2.0)	nm	1.0	nm
NPAT (normalised)	**0.8**	**(2.9)**	**nm**	**(2.0)**	**nm**	**1.0**	**nm**
Reported EPS (cps)	0.6	(3.8)	nm	(2.2)	nm	1.5	70%
Operating cash flow	**3.3**	**0.01**	-100%	**(1.6)**	-148%	**(1.6)**	

% of net revenue	1H21a	1H22a	Wilsons
Gross margin	58.7%	61.7%	58.7%
Segment profit margin	18.9%	16.9%	17.5%
EBITDA profit margin	10.3%	0.6%	0.3%

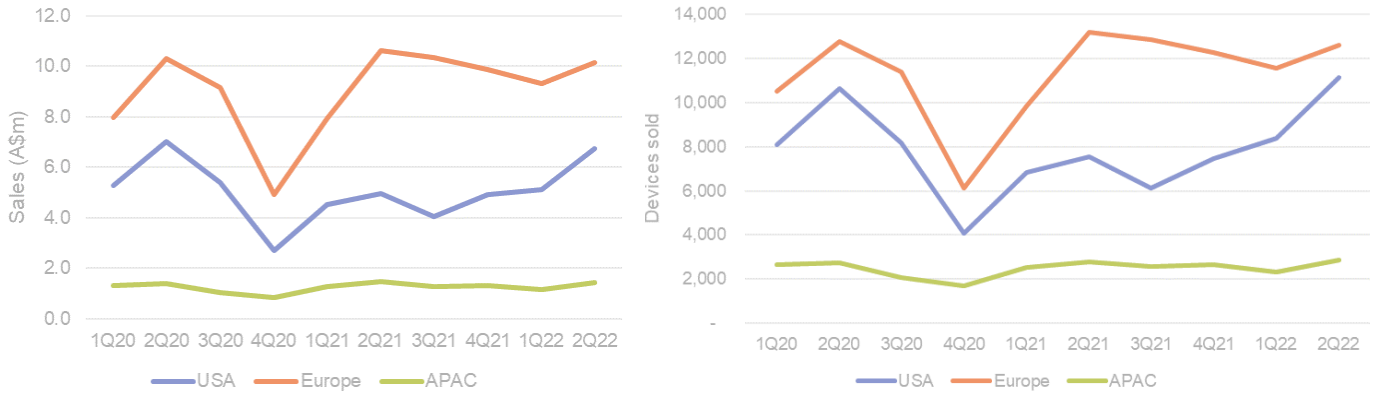
FY22 guidance	
Revenue	≥15% revenue growth
Underlying EBITDA	~$0
R&D expense (new product)	$8M ($5M for 2H22)

Source: SOM, Wilsons

Result commentary

US market has returned to growth following a slow 2H21 recovery. We note the US market in particular had a strong 1H following a slow period of recovery (2H21) (See **Figure 1**). EU and APAC regions were more stable in 1H22 reflecting recovery back to pre-COVID levels (~1H20). The US market performance was called out as being responsible for revenue growth in this period (USA +25% v pcp) with Europe (+5% v pcp) and APAC (-5% v pcp) minor contributors.

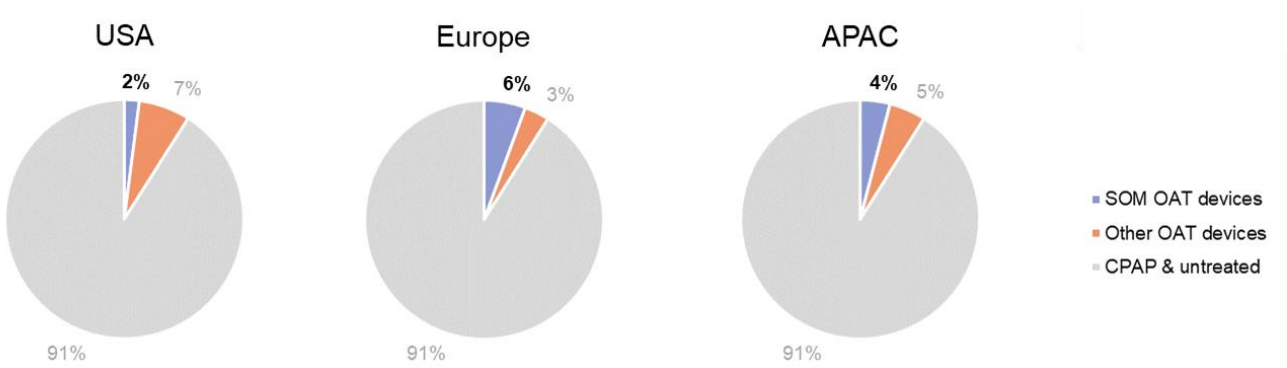
Figure 1. SOM quarterly revenue and device sales estimates by geographical segment (FY20-1H22)



Source: SOM, Wilsons

Market share reminder and growth runway. As a reminder, the US is the market in which SomnoMed's is least penetrated (~20-25% of OAT market) and offers the biggest growth opportunity for the business. European and APAC are both markets where SomnoMed is the dominant oral appliance with 60-65% and 40-50% share of the OAT market, respectively. Importantly – OAT only accounts for 8-10% of OSA market share globally, with CPAP the dominant therapy choice. Changing this market share equation even by 1%, with >500M mild OSA patients as an addressable market, moves the needle considerably for SOM's business prospects. **Figure 2** below highlights the considerable OSA market share still available to OAT, and SomnoMed in particular, as a treatment modality across all jurisdictions.

Figure 2. SOM's estimated total OSA market share by jurisdiction



Source: Wilsons estimates, SOM.

Gross margin expansion. SomnoMed added 300bps to gross margin during the 1H22 period (62% vs 59% in pcp). We suspect this continues to reflect product sales mix shifts with digitally manufactured devices (i.e. SomnoDent Avant®) comprising more of the total sales volume as well as volume leverage efficiency. We expect this remains attainable for existing marketed products however anticipate a lowered GM on the new Rest Assure® device/s given the additional onboard technology capabilities. We note that the docking/charging station will have a different accounting treatment to the in-mouth device, as flagged by management, with future COGS to reflect only the in-mouth components. GM discovery post Rest Assure® launch in ~2H23e will be anticipated.

Outlook

Changes to forecasts

We have made minor changes only to revenue and cost base assumptions across the near term forecast period (FY22-24e) detailed in **Table 2** below (delta for all changes <$3M in quantum). These reflect changes to our modelling structure with new revised segment level margin expectations and growth rates. As a reminder, at the FY21 result we upgraded our growth expectations and cost base to accommodate the new technology investment that was earmarked, which has now been unveiled (Rest Assure), hence no significant changes to our model at this time. We have reaffirmed forecast expectations (**Table 3**) given the additional new product information and market opportunity provided.

Table 2. Changes to our SOM forecasts (FY22-24e)

		FY22e	FY23e	FY24e
Revenue - previous	$m	73.4	82.9	92.5
Revenue - new	**$m**	**72.1**	**80.7**	**89.2**
- Change	*%*	*-2%*	*-3%*	*-4%*
Cost base - previous	$m	71.5	71.8	79.6
Cost base - new	**$m**	**71.8**	**72.3**	**78.2**
- Change	*%*	*1%*	*1%*	*-2%*
EBITDA - previous	$m	0.2	8.9	10.5
EBITDA - new	**$m**	**0.3**	**8.4**	**11.1**
- Change	*%*	*47%*	*-6%*	*5%*

Source: Wilsons

Revised forecasts

Table 3. Revised SomnoMed forecasts FY22-25e

	1H	*2H*	**FY21a**	*1H*	*2H*	**FY22e**	1H23	2H23	**FY23e**	**FY24e**	**FY25e**
SomnoMed core revenue ($m)	30.8	31.9	**62.7**	33.9	38.2	**72.1**	38.0	42.7	**80.7**	**89.2**	**100.5**
USA	9.5	9.0	**18.5**	11.9	13.2	**25.1**	13.5	14.9	**28.4**	**31.5**	**37.3**
EMEA	18.6	20.2	**38.8**	19.5	22.1	**41.5**	21.8	24.7	**46.5**	**51.6**	**56.8**
AsiaPac	2.7	2.6	**5.3**	2.6	3.0	**5.6**	2.7	3.1	**5.8**	**6.1**	**6.4**
Segment profits	5.8	5.1	**10.9**	5.7	5.9	**11.6**	7.0	7.5	**14.5**	**18.0**	**20.8**
USA	1.6	0.5	**2.1**	1.2	1.0	**2.2**	2.1	2.0	**4.2**	**5.2**	**7.2**
EMEA	3.8	4.7	**8.5**	4.1	4.8	**8.9**	4.4	5.3	**9.7**	**12.2**	**13.0**
AsiaPac	0.4	(0.1)	**0.3**	0.4	0.1	**0.5**	0.4	0.2	**0.6**	**0.6**	**0.7**
Corporate, R&D, other	(2.7)	(4.3)	**(7.0)**	(5.5)	(5.7)	**(11.3)**	(3.0)	(3.1)	**(6.1)**	**(6.9)**	**(8.0)**
EBITDA ($m)	3.2	0.7	**3.9**	0.2	0.1	0.3	4.0	4.4	**8.4**	**11.1**	**12.8**
- EBITDA margin	*10.3%*	*2.3%*	***6.2%***	*0.6%*	*0.3%*	***0.4%***	*10.5%*	*10.2%*	***10.4%***	***12.4%***	***12.7%***
- USA revenue growth	*-23%*	*11%*	***-9.3%***	*25%*	*47%*	***35.6%***	*13%*	*13%*	***13.2%***	***11.0%***	***18.4%***
- EMEA revenue growth	*2%*	*43%*	***19.9%***	*5%*	*9%*	***6.9%***	*12%*	*12%*	***12.0%***	***11.0%***	***10.0%***
- AsiaPac revenue growth	*-2%*	*39%*	***15.0%***	*-2%*	*12%*	***5.2%***	*5%*	*5%*	***5.0%***	***5.0%***	***5.0%***
- USA segment margin	*17.1%*	*5.4%*	***11.4%***	*10.5%*	*7.5%*	***8.9%***	*16.0%*	*13.6%*	***14.7%***	***16.4%***	***19.2%***
- EMEA segment margin	*20.3%*	*23.2%*	***21.8%***	*21.0%*	*21.8%*	***21.4%***	*20.3%*	*21.5%*	***20.9%***	***23.7%***	***22.8%***
- AsiaPac segment margin	*16.8%*	*-4.4%*	***6.3%***	*14.9%*	*2.4%*	***8.2%***	*16.1%*	*5.1%*	***10.3%***	***9.4%***	***10.2%***

Source: SOM, Wilsons.

Valuation

Assessing DCF implications

We value SomnoMed using DCF analysis with most inputs (rates, beta) consistent with the rest of our small-midcap medical device coverage. The single most important driver of DCF is the long-run volume growth outlook for oral appliance therapy (OAT) in the USA. The European business has performed consistently for many years, given favourable reimbursement and clinical practice attitudes towards OAT. The Asia Pacific business is similarly stable, albeit a lower growth market. Segment operating profitability for these two businesses are also relatively predictable. By contrast, OAT is vastly underpenetrated in the USA with less than 10% overall share of the obstructive sleep apnoea (OSA) market (the category dominated by CPAP therapy). A summary of our valuation model is provided below in **Table 4**.

Table 4. Base case DCF framework for Somnomed.

	FY22	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30
EBIT	-3.9	2.1	2.6	6.4	4.1	8.7	13.0	16.8	19.7
D&A	4.1	4.5	5.2	5.9	6.3	6.7	7.1	7.5	7.9
Chng W/Cap	-2.3	-2.2	-2.7	-3.0	-3.2	-3.5	-3.5	-3.5	-3.5
Capex, acquisitions	-3.1	-3.4	-3.9	-4.4	-4.7	-5.0	-5.3	-5.6	-5.9
FCFF	-5.1	1.0	1.2	4.9	2.5	6.9	11.3	15.2	18.2
risk-adjusted FCFF	**-5.1**	**1.0**	**1.2**	**4.9**	**2.5**	**6.9**	**11.3**	**15.2**	**18.2**
Cumulative WACC	1.1	1.2	1.3	1.4	1.5	1.7	1.8	2.0	
PV of FCFFs	**-4.7**	**0.8**	**0.9**	**3.5**	**1.6**	**4.1**	**6.2**	**7.6**	
Terminal Value									*331*

DCF parameters		**DCF valuation**	
WACC	9.0%	Forecast horizon	FY30
Risk-free rate	3.0%	Terminal growth rate	3.5%
Equity risk premium	6.0%	PV of FCFs	20.0
Equity beta	1.0	PV of Terminal Value	166.0
Cost of equity	9.0%	Enterprise value	186.0
Cost of debt	n/a	Cash	12.6
		Equity value	198.63
		SOI	82.76
		Valuation	**2.40**

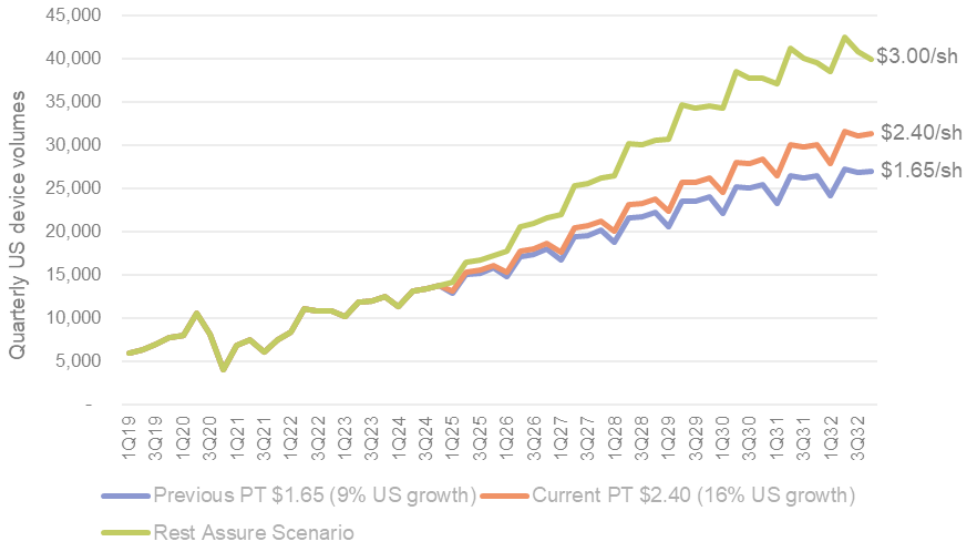
Source: Wilsons

Three valuation scenarios

As a reminder, we upgraded our SOM price target from $1.65/sh to $2.40/sh at the company's FY21 result, in anticipation of the Rest Assure® platform. Prior to the upgrade we had assumed USA growth in line with recent performance, assuming ~12.5% CAGR over the forecast period before moderating linearly into mid-high single digits. Essentially the prior forecast held SomnoMed's US growth broadly in line with the broader OSA market (historically a 6-8% annual growth market in terms of diagnosis volumes).

Our August upgrade to $2.40 per share anticipated an acceleration of US volume growth. After an initial launch period of routine growth, we factored an acceleration to 18% for three years (FY25-27e) before moderating over subsequent years. **Figure 3** overleaf shows the long-term difference in US volumes that result from these three scenarios. The benefit to valuation stems primarily from volume translating into a greater degree of fixed cost leverage and margin expansion in the US business. US segment operating margin has traditionally lagged that of Europe (15% versus 22% respectively in our FY23-24e forecasts). We assess that could quickly reverse if the Rest Assure campaign has the desired effect in the USA. In assessing valuation upside, note that in all scenarios we have limited the US segment profitability margin to 30%.

Figure 3. SomnoMed US device volume impacts based on three valuation scenarios outlined



Source: Wilsons.

Upside to $3.00/sh from taking share in USA from CPAP. We estimate 2.7M OSA diagnoses lead to treatment each year in the USA. Acknowledging errors in the calculation we estimate that each 1% of the US OSA market represents approximately 25,000 – 30,000 patients (**Table 5**).

Our forecasts currently estimate ~46,600 US device sales for FY23e, prior to the full launch of Rest Assure. To double US volume by the end of FY27e would imply an acceleration in growth to >20%. Under this scenario we assess potential valuation upside of 25% to $3.00 per share. We have not assessed the valuation impact of gross margin efficiencies, increased working capital or capex investments required to lift the scale of the US business in this way, however note that SomnoMed are already investing in additional milling machines/space to double their existing manufacturing capacity.

Table 5. Estimates of what 1% of OSA market constitutes in patient terms

FY21 Resmed flow generator sales (US$m)	863
% sales related to OSA	*85%*
ResMed OSA sales (US$m)	734
ResMed US OSA market share	*58%*
Total US CPAP sales market (US$m)	1,265
ASP (US$/machine)	500
Annual US CPAP machine sales	2,529,483
CPAP share of OSA market	*93%*
Total OSA patient market	2,719,874
Each 1% of OSA share (patients)	**27,199**

Source: RMD, Wilsons

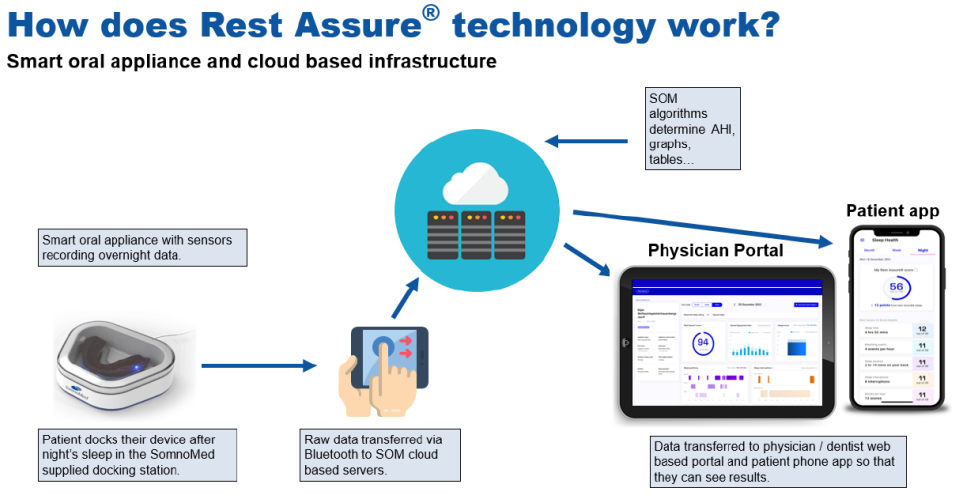
Rest Assure®

First connected oral appliance for sleep apnoea. SomnoMed plans to introduce a new technology-enabled oral appliance, Rest Assure® - the first and only oral appliance for obstructive sleep apnoea (OSA) treatment that has on-board capabilities to measure both compliance (wear time) and efficacy (surrogate AHIs) during the night and feed that data back to both the patient and their treating clinician via the cloud. We have previously postulated that SomnoMed's 'transformation technology' could be something of this nature, making use of and extending the Bluetooth-enabled chip and sensors that have resided within SomnoDent devices since 2015. We assess this new offering has the ability to revolutionise SomnoMed's USA business in particular, where traction with sleep physicians has been challenging given the lack of feedback they receive once a patient is prescribed to a dentist for oral appliance therapy (OAT) fitting. Rest Assure® fills this important void.

Range includes two devices – maintains choice for customer base. The new Rest Assure® range will include two devices, the Avant and Elite (both digitally manufactured) to cater to patients' existing needs for fit/feel as well as price-point (**Figure 4**). The device will also accompanied by a small docking & charging station that sits on the patient's bedside. The patient places the device within the docking station each morning at which time the device downloads the previous night's data via WiFi. The patient is then able to view their sleep data (<10 mins) on the phone App which is also sent to the physician web portal for their review/filing (**Figure 5**).

Patient and clinician portals have a ResMedian feel. The first glimpses of the new Rest Assure® clinician portal and patient phone App have an uncanny resemblance to ResMed's MyAir™ (patient) and AirView™ (provider) portals, which we expect is not by coincidence (**Figure 6**). Sleep physicians have become accustomed to navigating and using ResMed's AirView™ to manage their CPAP patients and therefore attempts by SomnoMed to make their new connected offering similar in functionality and feel will likely be met with gratitude from said physicians that are not required to learn how to use yet another portal/software. We expect this should help remove an incremental barrier to adoption. Similar to ResMed's MyAir™ offering, SOM's Rest Assure® patient app will attempt to coach patients into better sleep habits by providing feedback on five domains (adherence, efficacy, sleep position, treatment interruptions, respiratory rate) and providing a sleep score out of 100 each day to track progress.

Figure 5. The cloud-based infrastructure supporting SOM's new Rest Assure® technology



Source: SOM.

Regulatory approvals expected ~3Q FY23. SomnoMed anticipate to file for regulatory approvals (FDA 510(k) & European CE mark) later this year for Rest Assure, with approvals expected 3Q (Jan-March) FY23 followed by 4Q FY23 first sales. The company has completed two clinical studies with the new device platform, with a third study (validation/usability study) ongoing (expected to finish next month), the results of which will be presented at the World Sleep Congress in Rome (11 – 16 March 2022). Based on this timeline we model first meaningful Rest Assure® contributions from 2H24e.

Figure 4. New Rest Assure® platform

Source: SomnoMed

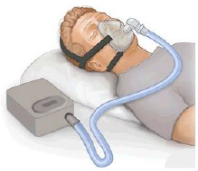
Figure 6. ResMed's AirView™ patient data management portal

Source: ResMed.

Efficacy measurement via mandibular movement sensor. SomnoMed's new device is able to measure efficacy via a movement sensor that has been fitted within the device. The Apnoea Hypoxia Index (AHI) is the scale used in OSA to determine the number of apneas (periods where breathing stops) per hour of sleep and is the gold standard efficacy measure in OSA treatment clinicians track. The Rest Assure® device is able to calculate AHIs via an algorithm which is based on specific patterns of jaw movement. It has been adapted using an FDA-approved diagnostic sleep test, the Sunrise® test, using this mandibular movement sequence to evaluate apnoea events. This data, combined with thermal sensor data as to when the device is within the patient's mouth (for compliance), will then be used to generate SomnoMed's 'Effectiveness' scores that are reported each day after use.

Data outputs align with CPAP outputs to allow for more direct therapy comparisons. Importantly SomnoMed have designed the Rest Assure® outputs to align to key measures generated by connected CPAP devices which allows clinicians to more directly compare the two therapy modalities. It is well known that CPAP efficacy is outstanding (unbeatable) but that as a therapy it suffers from suboptimal patient compliance thus lowering its overall effectiveness. OAT measures lower on the absolute efficacy scale however data shows patient compliance is far superior to CPAP, meaning in mild-moderate OSA patients, CPAP may be the inferior therapy choice. Allowing prescribing sleep physicians to compare data outputs between modalities is bound to lead to more informed therapy decisions (and could drive stronger clinical support for OAT in 1st line OSA). **Table 6** highlights the data measures provided by Rest Assure® and the alignment to standard CPAP data measures.

Table 6. Rest Assure® data readouts versus standard CPAP data measures used by clinicians

	Usage (adherence)	Efficacy	Sleep Position - Prone / Supine	Treatment Interruptions	Respiratory Rate
CPAP 	Time the device is connected to patient (software algorithm detects breathing)	Surrogate AHI from ventilation, validated by comparing to diagnostic sleep test	Not provided	Mask removal	Breathing algorithm
Rest Assure® 	Remove from dock, temperature sensor detects device in mouth, other sensors activated	Surrogate AHI, validated by comparing to diagnostic sleep test (validation study in progress)	Determined by sensors in device	Patient moving into a vertical position (sitting or standing up), removing the device from mouth	Jaw movement algorithm

Source: SomnoMed

We would anticipate SOM may undertake or support further clinical trials to put Rest Assure® head to head with CPAP in mild OSA patients to definitively evaluate if OAT is a superior therapy in this patient subgroup. Data such as this could be used to support US reimbursement changes.

Clinical data focuses on usability, reliability and validation. SomnoMed have shared snippets of data from two of their three clinical studies conducted with the new Rest Assure® device/s. The Algorithm derivation study focused on correlation between Rest Assure® AHI algorithm scores and NOX AHI scores (NOX being the best-in-class at home sleep test), resulting in an 80% correlation to the NOX test. The second study compared these two outputs (NOX AHI & surrogate AHI) in 31 patients (~400hrs of patient sleep) to show reliability of the data. The third ongoing study (n=30 patients, 480hrs sleep) focuses algorithm validation (vs NOX outputs) in addition to usability and comfort data that will be used to support marketing approval applications.

Compliance + Efficacy together is the key. We understand SomnoMed's intellectual property centres around the combination of measuring BOTH compliance and efficacy within the same device at the same time, in order to produce a quantitative measure of effectiveness through their "Effectiveness Equation". As a reminder, this is not SOM's first attempt at data tracking, with past attempts including the DentriTrac system (**Figure 7**), that could measure the period of time the device was being worn using a thermal sensor (i.e. in the mouth). The missing piece was efficacy. We understand SOM have provisional patents protecting this new device platform that focus on the dual data measurement aspect within a singular device.

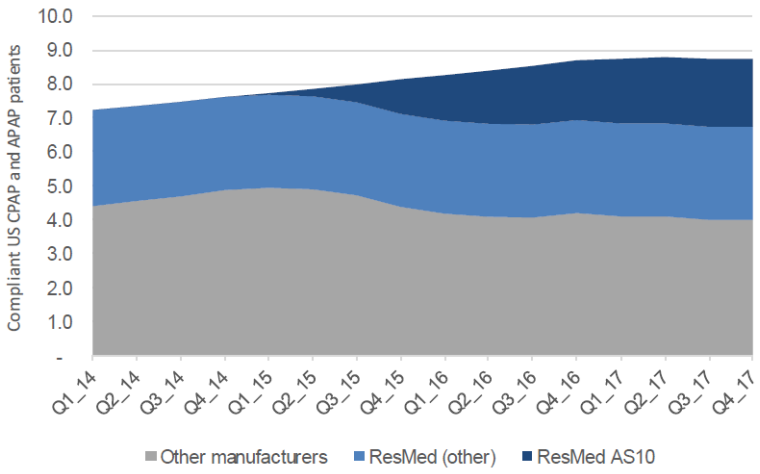
Figure 7. Previous data tracking attempts, e.g. DentiTrac™ system, were missing all important efficacy data.

Source: SomnoMed

Impact on SomnoMed's business

Rest Assure® could be SOM's AirSense10 moment? The launch of ResMed's AirSense10 (AS10) CPAP device transformed ResMed's CPAP business in terms of durable market share gains over competitors. AS10 was the first cloud-connected device that RMD launched which included the AirView™ system back in 2014, which allowed both patients and clinicians to have daily feedback of a patient's CPAP compliance and efficacy. The introduction of AS10 saw RMD take ~16% market share from competitors over the proceeding 18-month period post-launch (**Figure 8**) and continues to be a driving force in their market gains and new patient/physician adoption. We assess Rest Assure could provide this same tailwind for SomnoMed, particularly in the US market, where sleep physician uptake is low/challenging. This would cement them not only as the dominant OSA oral appliance provider, but also taking incremental market share from CPAP patients with mild-moderate OSA (where CPAP is likely overkill and compliance challenges equate to likely under-treatment).

Figure 8. The impact of ResMed's first connected device launch (AS10) to their CPAP market share was significant



Source: ResMed, Wilsons.

Could this change US reimbursement for OAT? At present oral appliance therapy (OAT) is only reimbursed as a 2nd line treatment in US patients that have already tried and failed CPAP. This opposes the European situation where OAT is reimbursed as an equal 1st line OSA therapy to CPAP, or is in fact the preferred 1st line therapy over CPAP in mild to moderate OSA cases. The ability for SomnoMed to be able to provide objective efficacy and compliance data to CMS (and insurers) could change the way in which OAT is viewed from a cost perspective (i.e. if data shows mild-moderate OSA patients are being adequately treated with OAT as 1st line therapy therefore removing considerate costs associated with trial of CPAP to the healthcare system). We expect private insurance payers would embrace an opportunity to reduce costs and may therefore support changes to OAT reimbursement. Of course, we do not expect this to be an immediate outcome, but over time, we can see it developing into a critical piece in growing SOM's US business scale and prominence.

SomnoMed's internal modelling aims to win 1-3% of CPAP market share. As a reference point, a 1% gain in CPAP market share represents an approximate doubling in SOM's existing OAT business. SomnoMed anticipate Rest Assure can provide a platform to expand their business 3-4 fold by taking market share away from CPAP (in the mild-moderate OSA patient segment). We assess this scenario with Rest Assure taking ~1% of OSA market share earlier in our note which sees valuation upside if executed (p. 7).

Provides upgrade opportunity across SomnoDent range. We anticipate the new Rest Assure device will drive an upgrade cycle for a large majority of SomnoMed's resident SomnoDent devices, with physicians wanting the ability to monitor their patients remotely with clinical efficacy data. The challenge being for SomnoMed, they are not able to contact patients directly and will instead approach this marketing campaign through their dental networks (which has worked well in the past for them with new product launches).

Future investment will be required in software & data engineers; Planet Innovation involvement positive. Establishment of a connected care business from scratch is no easy feat. SomnoMed revealed they have been working with Planet Innovation on development of Rest Assure, utilising their inhouse software and data expertise on a contractual basis over the past 12-24months. We remind readers that Planet Innovation have pedigree in new medtech development counting RMD, COH, NAN, and Cook Medical as prior partners among many others. SOM will need to invest here to ensure their new connected care offering is good/well supported and continues to develop. We would expect elevated salary expenditure to come on board closer to launch as they build in-house data engineering and software expertise, as opposed to contracting via third parties.

Marketing and sales teams already in place to support launch. We do not anticipate significant additional investment will be required on the sales and marketing front to support Rest Assure® launches. SomnoMed have just invested in building out their sales and marketing capabilities across all geographies in preparation for Rest Assure. This is alongside a customer service support team that will interface with Rest Assure patients regarding product use/queries.

Capex not a significant line item. SomnoMed are contracting out manufacture of both the onboard sensors/chips as well as the docking station device for the new Rest Assure platform to third-party CDMOs and will continue to manufacture only the in-mouth milled device in their Manila facility. The new Rest Assure components will be sent to SOM for final assembly and QA/QC before being dispatched to customers. As such we do not anticipate significant Capex investment to rebuild manufacturing lines and note the expansion of their existing Manila facility already underway to increase capacity.

Unlikely to introduce a new SaaS revenue stream – opportunities down the line. It is unclear if there is a way for SomnoMed to monetise the new connected component of the Rest Assure® platform, however it seems doubtful. Unlike in the case of CPAP, were DMEs are the cost beneficiaries of a connected solution (and therefore willing to pay a SaaS revenue), oral appliance distribution is managed via dentists who have no direct incentive to ensure patient compliance. This brings into question who would be the payer of a SaaS offering in this instance, where the benefit is clear to the clinician but is not attached to reimbursement or time efficiencies yet to justify purchase of a SaaS product. Further bolt on technology pieces could however change this (i.e. from a billing perspective – akin to ResMed's Brightree), which were noted by management as definite long-term strategy items being the focus of their newly appointed Global Head of Strategy.

SomnoMed (SOM)

Business description

SomnoMed Limited (SOM) develops, manufactures and sells oral appliance devices for the treatment of obstructive sleep apnoea (OSA). 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

We upgrade our rating on SomnoMed to OVERWEIGHT maintaining our $2.40/sh price target. SomnoMed's unveiling of their new technology-enabled oral appliance, Rest Assure®, gives us confidence in the growth outlook for the US business which has been underpenetrated in the past. The ability for SOM to provide daily efficacy, in addition to compliance data, will finally allow for objective comparisons of treatment effectiveness between CPAP and OAT in mild-moderate sleep apnoea patients and a way for clinicians to track their patients care longitudinally. This has been a significant historical barrier to OAT adoption. ResMed's first connected CPAP solution (AS10) won them significant, durable market share – we see this as SOM's opportunity. Further, we expect clinical study data will support clinical guideline changes along with reimbursement support, in time. We model significant contributions from 2H24e with plenty of supporting SP catalysts in the coming 12 months including data publication and regulatory approval/s to support our OVERWEIGHT call.

Revenue drivers

Growth rates.

Regulatory and/or reimbursement approvals of new products, new territories.

Balance sheet

Cash of $17.6M as of end 1H22.

$5M undrawn debt facility available.

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

R&D expenditure

Increased adoption of digitally manufactured devices and sales mix skew

Board

Guy Russo (Non-Executive Chairman)

Neil Verdal-Austin (Managing Director)

Hamish Corlett (Non-Executive Director)

Amrita Blickstead (Non-Executive Director)

Michael Gordon (Non-Executive Director)

Hilton Bret (Non-Executive Director)

Karen Borg (Non-Executive Director)

Key issues/catalysts

Upside risks:

Quarterly cash flow indicates SomnoMed's sales growth progress

Product launches (Rest Assure®)

Progress developing links to medical diagnosis channels

Management

Neil Verdal-Austin (CEO)

Hervé Fiévet (CFO)

Mark Harding (SVP Global Marketing/R&D)

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 the USA is improving, but still needs to develop and broaden

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