

## New codes boost US opportunity

In November 2021, the Centers for Medicare and Medicaid Services (CMS) finalised the new Remote Therapeutic Monitoring (RTM) codes, effective 1 January 2022, which complement the Remote Physiological Monitoring (RPM) codes released in 2019. Collectively, the codes represent a significant improvement in reimbursement for providers of telehealth services in the US and should support the new physician driven ‘go-to-market’ strategy for wheezo.

## New CMS codes accelerate US launch

In March 2021, Respiri received 510 (K) clearance from the FDA for its wheezo device for use in any respiratory disorder where wheeze is deemed a symptom. With the codes now ratified, premarketing will commence in December 2021, 6 months ahead of schedule. Further, the company has indicated it is in discussions with potential US partners. These include telehealth/RPM firms and chronic care management providers.

## Potential partner for 4 markets in EU

Discussions with distributors are also now underway for proposed launch of wheezo into multiple markets in mainland Europe, with a focus of countries with favourable reimbursement policies.

## Multiple UK studies to validate wheezo

In the UK, several clinical trials are planned. These include a major 1,500-patient study in children evaluating the benefit of using wheezo in asthma management. The outcomes of this study in particular could potentially be used in a health economics submission for NHS reimbursement. Respiri is also currently in discussions with potential UK partners.

## Australian roll-out now more targeted

The roll-out of wheezo in Australia through community pharmacy channels was significantly hampered by COVID-19 during FY21 and the reliance of pharmacists to promote the product. As such, Respiri is now targeting pharmacies with a clear professional capacity to service their asthma patients. This will be supported by the Respiratory Physician led Remote Patient Monitoring Programme (R.A.M.P.) developed by the company which will be driven by medica specialists.

## Valuation

We have revisited our valuation of Respiri considering the slower than anticipated ramp up of sales in Australia due to the COVID-19 related disruptions. We derive an A\$17 cents per share valuation for Respiri, using DCF methodology and based on the roll-out of wheezo in Australia and US markets only at this point.

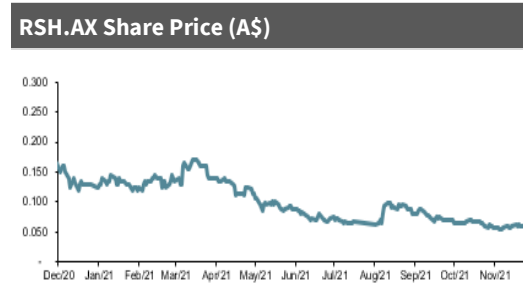


Respiri Limited is a commercial stage health-tech company developing mHealth and SaaS solutions for respiratory health management. It has proprietary technology and mobile health tools that specifically detect wheeze (an indicator of asthma, COPD, and respiratory disease more broadly) to provide an objective measure of airflow limitation. The company’s flagship ‘wheezo’ device and platform analyses breathing objectively, allowing for environmental factors; record, monitor and schedule medication including reminders; and share data with healthcare providers. Both CE (Conformite Europeene) mark and Therapeutic Goods administration (TGA) approval received.

Stock	RSH.ASX
Price	A\$0.06
Market cap	A\$44.1m
Valuation	A\$0.17

Company data	
Net cash	A\$5.9m (end Sep 2021)
Shares on issue	722.8m

Next steps	
4QCY21	US launch of wheezo
1QCY22	UK soft launch of wheezo
1HCY22	European partnership



Source:

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# Financials

## Exhibit 1: Financial summary

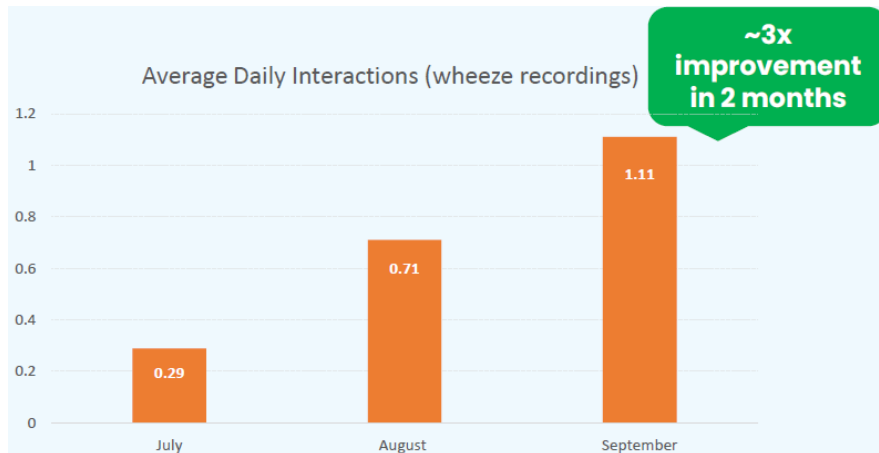
Respiri						RS-AU							
Year end 30 June, AUD unless otherwise noted													
<b>MARKET DATA</b>						<b>12-MONTH SHARE PRICE PERFORMANCE (A\$)</b>							
Price	\$	0.061											
52 week high / low	\$	0.06-0.24											
Valuation	\$	0.17											
Market capitalisation	\$m	44.1											
Shares on issue (basic)	m	722.8											
Options / rights	m	259.0											
Other equity	m	0.0											
Shares on issue (diluted)	m	981.8											
<b>INVESTMENT FUNDAMENTALS</b>						<b>PROFIT AND LOSS</b>							
Reported NPAT	\$m	FY19A	FY20A	FY21A	FY22E	FY23E	Revenue	\$m	FY19A	FY20A	FY21A	FY22E	FY23E
Underlying NPAT	\$m	(8.5)	(7.3)	(11.0)	(5.7)	(1.7)	Other income	\$m	1.0	2.2	1.3	2.5	9.4
Reported EPS (diluted)	¢	(169.0)	(127.0)	(158.0)	(79.3)	(22.9)	Total Revenue	\$m	1.0	2.2	1.4	3.1	9.8
Underlying EPS (diluted)	¢	(169.0)	(127.0)	(158.0)	(79.3)	(22.9)	Operating expenses	\$m	(12.4)	(6.6)	(5.9)	(6.7)	(5.9)
Growth	%	-24.9%	24.4%	-49.8%	-71.2%		EBITDA	\$m	(8.5)	(7.3)	(11.0)	(5.7)	(1.6)
Underlying PER	x	nm	nm	nm	nm	nm	Depreciation & Amortisation	\$m	0.0	0.0	0.1	0.0	0.0
Operating cash flow per share	¢	(1.3)	(0.8)	(1.0)	(1.0)	(0.5)	EBIT	\$m	(8.5)	(7.3)	(11.0)	(5.7)	(1.7)
Free cash flow per share	¢	(1.3)	(0.8)	(1.1)	(1.1)	(0.5)	Net interest	\$m	0.0	0.0	0.0	0.0	(0.0)
Price to free cash flow per share	x	nm	nm	nm	nm	nm	Pretax Profit	\$m	(8.5)	(7.3)	(11.0)	(5.7)	(1.7)
FCF Yield	%	nm	nm	nm	nm	nm	Tax expense	\$m	0.0	0.0	0.0	0.0	0.0
Dividend	¢	0.0	0.0	0.0	0.0	0.0	Reported NPAT	\$m	(8.5)	(7.3)	(11.0)	(5.7)	(1.7)
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%	Weighted average diluted shares	m	499.1	570.1	699.1	722.8	722.8
Yield	%	0.0%	0.0%	0.0%	0.0%	0.0%	<b>GROWTH PROFILE</b>						
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%	Revenue	%	FY19A	FY20A	FY21A	FY22E	FY23E
Enterprise value	\$m	44.6	41.3	36.1	43.7	47.7	Revenue	%	17.3	114.0	(34.9)	118.6	210.7
EV/EBITDA	x	(5.3)	(5.7)	(3.3)	(7.7)	(29.3)	EBITDA	%	173.6	(14.4)	51.2	(47.9)	(71.5)
EV/EBIT	x	(5.3)	(5.7)	(3.3)	(7.6)	(28.9)	EBIT	%	163.1	(14.4)	52.0	(48.1)	(71.2)
Price to book (NAV)	x	(20.5)	17.5	5.8	24.0	235.4	Reported NPAT	%	164.2	(14.3)	52.1	(48.1)	(71.2)
Price to NTA	x	(20.5)	17.5	5.8	24.0	235.4	DPS	%	nm	nm	nm	nm	nm
<b>KEY RATIOS</b>						<b>BALANCE SHEET</b>							
EBITDA margin	%	nm	nm	nm	nm	nm	Cash	\$m	FY19A	FY20A	FY21A	FY22E	FY23E
EBIT margin	%	nm	nm	nm	nm	nm	Receivables	\$m	0.3	3.6	8.0	0.3	(3.6)
NPAT margin	%	nm	nm	nm	nm	nm	Other	\$m	0.2	0.0	0.1	1.0	3.9
ROE	%	nm	nm	nm	nm	nm	Other	\$m	0.5	0.9	0.8	0.8	0.8
ROA	%	nm	nm	nm	nm	nm	Current assets	\$m	1.0	4.4	8.9	2.2	1.2
Net tangible assets per share	\$	(0.0)	0.0	0.0	0.0	0.0	PPE	\$m	0.0	0.2	0.2	0.2	0.4
Book value per share	\$	(0.0)	0.0	0.0	0.0	0.0	Intangible assets	\$m	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	\$m	0.5	(2.8)	(8.0)	(0.3)	3.6	Other	\$m	0.0	0.0	0.0	0.0	0.0
Interest cover/(EBIT/net interest)	x	nm	nm	nm	nm	nm	Non current assets	\$m	0.0	0.2	0.2	0.2	0.4
Gearing (net debt/EBITDA)	x	(0.1)	nm	nm	nm	(2.2)	Total assets	\$m	1.0	4.6	9.1	2.4	1.5
Leverage (net debt/(net debt + equity))	x	(0.5)	nm	nm	nm	1.0	Trade and other payables	\$m	1.8	1.1	1.3	0.3	1.1
<b>DUPONT ANALYSIS</b>						<b>Non current liabilities</b>							
Net Profit Margin	%	nm	nm	nm	nm	nm	Borrowings	\$m	0.8	0.7	0.0	0.0	0.0
Asset Turnover	x	0.0	0.0	0.0	1.0	6.3	Other	\$m	0.0	0.1	0.2	0.2	0.2
Return on Assets	%	nm	nm	nm	nm	nm	Current liabilities	\$m	2.6	2.0	1.5	0.5	1.3
Financial Leverage	x	(516.1)	287.5	0.0	0.0	0.0	Other financial liability	\$m	0.0	0.1	0.1	0.1	0.1
Return on Equity	%	nm	nm	nm	nm	nm	Other liability	\$m	0.0	0.0	0.0	0.0	0.0
<b>KEY PERFORMANCE INDICATORS</b>						<b>Non current liabilities</b>							
Wheezo	Key metrics	FY19A	FY20A	FY21A	FY22E	FY23E	Total liabilities	\$m	2.6	2.1	1.5	0.6	1.3
Australian	Doctors and Pharmacy volumes	nm	nm	nm	nm	nm	Net assets	\$m	(1.6)	2.5	7.6	1.8	0.2
United States	Partnering deals and product reach	nm	nm	nm	nm	nm	Share capital	\$m	106.0	113.7	127.1	127.1	127.1
United Kingdom	Clinical trials and reimbursement status	nm	nm	nm	nm	nm	Retained earnings	\$m	(109.2)	(115.3)	(126.3)	(132.1)	(133.7)
Europe	Partnering and access to reimbursed markets	nm	nm	nm	nm	nm	Other	\$m	1.6	4.1	6.8	6.8	6.8
<b>HALF YEARLY DATA</b>						<b>CASH FLOW</b>							
Total Revenue	\$m	2H20	1H21	2H21	1H22	2H22	Net loss for period	\$m	FY19A	FY20A	FY21A	FY22E	FY23E
Operating expenses	\$m	0.1	1.2	0.0	1.6	1.6	Depreciation & Amortization	\$m	(8.5)	(7.3)	(11.0)	(5.7)	(1.7)
EBITDA	\$m	(5.8)	(6.4)	(4.8)	(2.9)	(2.9)	Changes in working capital	\$m	0.0	0.0	0.1	0.0	0.0
EBIT	\$m	(5.8)	(6.4)	(4.8)	(2.9)	(2.9)	Other	\$m	0.3	(0.8)	0.0	0.0	0.0
PBT	\$m	(5.8)	(6.4)	(4.8)	(2.9)	(2.9)	Operating cash flow	\$m	1.8	3.4	3.6	(1.9)	(2.1)
Reported NPAT	\$m	(5.8)	(6.4)	(4.8)	(2.9)	(2.9)	Payments for PPE	\$m	(6.4)	(4.7)	(7.3)	(7.6)	(3.7)
						Other							
						Investing cash flow							
						Equity							
						Other							
						Financing cash flow							
						Cash year end							
						Free cash flow							

Source: Company reports, MST Access estimates

## AGM commentary - International strategy brought forward

At the recent AGM, Respiri CEO, Marjan Mikel, provided a comprehensive update and unveiled a more targeted physician driven commercialisation strategy to drive adoption of wheezo both domestically and in offshore markets. The revised domestic strategy is informed by the disappointing Australian launch of wheezo through community pharmacies during FY21 which commenced in October 2020 and was heavily hampered by COVID-19 related lockdowns. The new strategy uses positive findings of the medical specialist led Remote Patient Monitoring Programme (R.A.M.P.) showing increased patient engagement with the device when supported by the physician.

Exhibit 2: Remote Asthma Management Programme (RAMP) shows increased patient engagement



Source: Respiri

As such, Respiri is expanding its marketing focus to target both physicians specialising in asthma management and concentrating on select pharmacies with the capacity to service these patients.

The company will also use the new physician led strategic approach to capitalize on FDA 510(k) clearance and an improving reimbursement regime in the US with a premarketing to commence in December 2021.

Respiri also flagged a new wearable device designed for nocturnal asthma and exercise induced asthma monitoring named “Sorfe”.

### Remote Patient Monitoring codes; RPM and now RTM

The American Medical Association (AMA) maintains and develops the Current Procedural Terminology (CPT) code set. CPT<sup>1</sup> codes are descriptive terms used in reporting medical, surgical, and diagnostic procedures and services that are performed by physicians and other qualified healthcare professionals in the USA.

CPT codes form the basis for reimbursement, research, and tracking medical utilization. CPT codes have existed for numerous remote medical services, until recently, however codes to describe general remote monitoring of physiological data were only introduced in 2018. In 2020, in response to the COVID-19 pandemic the CMS broadened access to Medicare telehealth services so that beneficiaries could receive a wider range of services from their doctors without having to travel to a healthcare facility. This was actioned under the 1135 waiver authority and Coronavirus Preparedness and Response Supplemental Appropriations Act for the duration of the COVID-19 pandemic.

<sup>1</sup> CPT is the most widely utilized medical code set across the U.S. The CPT code set is not only used by clinicians for reporting purposes, but also by administrative personnel for claims processing and developing guidelines for medical care review

In November 2021, the Centers for Medicare and Medicaid Services (CMS) introduced five new CPT codes for devices allowing for prescribed payments relating to set up, supply and monitoring of devices for Remote Therapeutic Monitoring (RTM).

The establishment of these codes provides Respiri and its potential partners in the US market with an important commercial opportunity whereby the service providers using the wheezo and associated app can receive a reimbursement for the equipment used and the time spent for the patient care delivered remotely.

### Remote Physiological Monitoring (RPM)

RPM codes cover the collection and analysis of patient physiological data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition.

Exhibit 3: Remote Physiological Monitoring (RPM) codes (expanded in 2019)

CPT Code	Descriptor	Value USD
99453	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial set-up; and patient education on use of equipment	18.77
99454	Remote monitoring device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	62.44
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month.	51.61
99458	Patient Monitoring & Communication where patients receive an additional 20 mins (every 30 days)	42.22
99091	Physician/healthcare professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver (every 30 days)	59.19

Source: Respiri

### Remote Therapeutic Monitoring (RTM)

RTM is a family of five codes created by the CPT Editorial Panel in October 2020 and finalised by the CMS in November 2021. The RTM family expands Medicare reimbursement for remote monitoring specific to therapeutic areas and can include non-physiological measures. These codes also expand the classification of providers to include physical therapists, occupational therapists, speech language pathologists, clinical psychologists, and other practitioners than those currently permitted to bill RPM. The new codes cover three practice expense (PE)-only codes and two codes that include professional work (see Exhibit 4).

Exhibit 4: Remote Therapeutic Monitoring (RTM) codes finalised on 11 November 2021

CPT Code	Descriptor	Value USD
98975	Remote therapeutic monitoring (e.g. respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment	TBC
98976	Remote therapeutic monitoring (e.g. respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days	TBC
98977	Remote therapeutic monitoring (e.g. respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days	TBC
98980	Remote therapeutic monitoring treatment, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes	TBC
98981	Remote therapeutic monitoring treatment, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes	TBC

Source: [www.foley.com/en/insights/publications/2021/11/2022-remote-therapeutic-monitoring-cms-final-rule/Respiri](http://www.foley.com/en/insights/publications/2021/11/2022-remote-therapeutic-monitoring-cms-final-rule/Respiri)

## Valuation – Revised DCF valuation based on Australia and US only.

We have revisited our valuation of Respiri considering the slower than anticipated ramp up of sales in Australia given the COVID-19 related disruptions to community pharmacy workflows. We are however positive on the revised go-to-market strategy targeting specialist physicians and pharmacies with capacity and commitment to services asthma patients. Similarly, we think the company is well positioned with the wheezo device to gain traction in the US market, given the FDA clearance allowing marketing for a broad range of indications where wheeze can be established as a symptom and the more accommodative reimbursement effective January 2022, which should drive adoption within the scope of remote patient monitoring services. We derive an A\$17 cents per share valuation for Respiri, using DCF methodology. Key assumptions are shown in Exhibit 5.

Exhibit 5: Base Case DCF valuation and key metrics

	Jun-21	Jun-22	Jun-23	Jun-24	Jun-25	Jun-26
	2021	2022	2023	2024	2025	2026
EBIT	-11,041,699	-5,730,177	-1,651,173	14,171,366	26,869,589	22,438,951
Tax at standard rate	0%	0%	0%	0%	0%	0%
<b>Post-tax EBIT</b>	<b>-11,041,699</b>	<b>-5,730,177</b>	<b>-1,651,173</b>	<b>14,171,366</b>	<b>26,869,589</b>	<b>22,438,951</b>
Depreciation	79,601	21,928	25,765	47,799	124,659	226,691
Amortisation	0	0	0	0	0	0
<b>Post-tax cash flow</b>	<b>-10,962,098</b>	<b>-5,708,249</b>	<b>-1,625,407</b>	<b>14,219,166</b>	<b>26,994,249</b>	<b>22,665,642</b>
Less capex	-54,252	-50,348	-188,928	-616,949	-880,208	-625,439
Less change in working capital	107	-1,867	-2,093	-6,511	-5,250	1,779
Provisions/other	0	0	0	0	0	0
Acquisitions/disposals	0	0	0	0	0	0
<b>Free cash flow</b>	<b>-11,016,243</b>	<b>-5,760,464</b>	<b>-1,816,428</b>	<b>13,595,705</b>	<b>26,108,791</b>	<b>22,041,982</b>
Discount coefficient	0	1	2	3	4	5
<b>Discounted cash flow</b>	<b>-11,595,811</b>	<b>-5,390,234</b>	<b>-1,510,952</b>	<b>10,050,248</b>	<b>17,157,116</b>	<b>12,876,288</b>
Sum of discount streams	74,661,727					
Terminal growth	2.0%					
Future value into perpetuity	138,521,854					
NPV of terminal value	44,908,725					
PV of cash flows	119,570,451					
PLUS: Value of investments	0					
PLUS: Value of tax losses	0					
LESS: Minority interests	0					
LESS: Net debt	5,893,000	(end Sep 2021)				
<b>Equity value</b>	<b>125,463,451</b>					
Ordinary shares	<b>722,840,790</b>					
<b>Value per share (A\$)</b>	<b>0.17</b>					
<b>Discount Rate</b>	<b>12.5%</b>					

Source: MST Access

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