Wheezo receives FDA clearance in the US

Respiri has received 510(k) clearance from the US Food and Drug Administration (FDA) for its wheezo device, thereby allowing the company to market and sell wheezo as a class II medical device, along with the wheezo associated App in the US market.

Broad indication and regulatory approval for sale with or without prescription expands channel options and US market opportunity

The FDA approval covers the broad use of wheezo in detecting and recording abnormal breath sounds at the windpipe reported as WheezeRate in adults and children (2 years and older). As such, Respiri is approved for use beyond asthma to any respiratory disorder where wheeze is deemed a symptom. This broad indication expands strategic options for partnering with disease management service providers. and adds to company target appeal given consolidation in the US telehealth market over the past 12 months. Importantly, clearance as a class II medical device raises the prospect that the wheezo and SaaS offering could be eligible for reimbursement under current remote patient monitoring CPT codes thereby increasing incentives for physicians to adopt. Further, wheezo's regulatory approval is OTC (over the counter) means the device can be sold to patients with or without a prescription (in pharmacy and online).

Targeting US market launch in 3Q CY22

Respiri believes the United States SAAS opportunity represents around $360 to $480 per annum per patient in the US (5 times the revenue opportunity in Australia). Notwithstanding current partner Cipla's first right of refusal to distribute wheezo in the US, Respiri has indicated it is in discussions with several potential commercial partners in the US. Subject to partnering and reimbursement status of the wheezo being ratified, Respiri anticipates a physician driven model for roll out in the US could commence in 3QCY22. The launch of its respiratory physician led telehealth and remote patient management program in Australia will form the basis of the US model.

Key appointments to support late 2021 UK market launch

Respiri has strengthened its advisory panel with the appointment of Dr Andrew Weekes, medical director of GSK Australia, and Dr Mark Levy, a member of GINA (Global Initiative for Asthma). Both add significant expertise to support entry into the UK market in late 2021.

Valuation

Our valuation of Respiri remains unchanged at A$0.37/share. Our base case assumes - commercial roll-out with distribution partner Cipla in Australia and New Zealand in FY21, and incorporates a probability-weighted adjustment (we have applied 60%) of Cipla extending its agreement with Respiri for commercial roll-out into the United Kingdom, France, Germany and Italy in FY22. The US market has not been included in our base-case valuation given the absence of a distribution partner at time of writing, and the longer-term timeframe on this potential market launch. Nonetheless, we think the US market opportunity represents substantial upside to our base case valuation.

RESPIRI

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. The wheezo has received FDA clearance. Both CE (Conformite Europeene) mark and Therapeutic Goods administration (TGA) approval also received.

Stock	RSH
Price	A$0.16
Market cap	A$116m
Valuation	A$0.37 per share

Next steps	
2Q CY21	Australian pharmacy sales update

RSH share price (one year, A$)

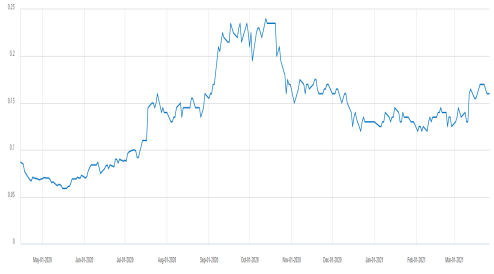

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Exhibit 1 – Summary financial statements

Financial Summary (AUD 000's)	FY19a	FY20a	FY21e	FY22e	FY23e	FY24e
PROFIT & LOSS						
Total Revenue	1,031	2,207	8,664	28,425	79,309	93,901
Operating Costs	-9,501	-9,458	-9,706	-20,049	-37,061	-37,827
EBITDA	-8,475	-7,252	-1,043	8,376	42,248	56,074
EBIT	-8,480	-7,263	-1,056	8,359	42,222	56,031
Tax	0	0	0	0	0	0
NPAT (Reported)	-8,475	-7,261	-1,049	8,370	42,253	56,088
NPAT (Underlying)	-8,475	-7,261	-1,049	8,370	42,253	56,088
Minority Interest	0	0	0	0	0	0
Shares Outstanding (m)	525.9	716.9	716.9	716.9	716.9	716.9
EPS (Underlying) cps	-1.70	-1.27	-0.15	1.17	5.89	7.82
Dividend per share (cps)	0	0	0	0	0	0
BALANCE SHEET						
Current Assets	1,003	4,431	15,865	24,222	66,402	122,370
Cash	307	3,552	14,986	23,343	65,524	121,491
Receivables	162	8	8	8	8	8
Inventory	0	309	309	309	309	309
Other Assets	535	561	561	561	561	561
Non-Current Assets	11	188	204	218	290	411
PP&E	10	188	204	218	290	411
Goodwill	0	0	0	0	0	0
Other Non-current Assets	1	0	0	0	0	0
Current Liabilities	2,576	1,996	1,996	1,996	1,996	1,996
Payables	1,757	1,131	1,131	1,131	1,131	1,131
Short Term Debt	806	717	717	717	717	717
Provisions & Tax	0	0	0	0	0	0
Other financial liabilities	13	148	148	148	148	148
Non-Current Liabilities	0	128	128	128	128	128
Long Term Debt	0	0	0	0	0	0
Provisions	0	0	0	0	0	0
Other financial liabilities	0	128	128	128	128	128
Net Assets	-1,563	2,495	13,946	22,316	64,568	120,656
Share Capital	106,043	113,695	126,195	126,195	126,195	126,195
Reserves	1,590	4,106	4,106	4,106	4,106	4,106
Retained Earnings	-109,197	-115,306	-116,355	-107,985	-65,733	-9,644
Minority Interests	0	0	0	0	0	0
Total Equity	-1,563	2,495	13,946	22,316	64,568	120,656
CASH FLOW						
Operating Cash Flow	-6,411	-4,688	-1,036	8,386	42,279	56,131
Working Capital Change	-576	-1,101	807	0	0	0
Maintenance Capex	-3	-13	-30	-30	-98	-163
Expansion Capex	0	0	0	0	0	0
Acquisitions	0	0	0	0	0	0
Investing Cash Flow	-3	-13	-30	-30	-98	-163
Equity Issued	3,750	8,532	12,500	0	0	0
Debt Issued	800	0	0	0	0	0
Dividends	0	0	0	0	0	0
Financing Cash Flow	4,332	7,959	12,500	0	0	0
Change in Cash Balance	-2,083	3,259	11,434	8,356	42,181	55,967

Source: Respiri, MST Access.

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