

KesApp Heal

Double trouble

- RAP announced that the FDA has not approved the de novo application for the ResApp-DX diagnostic and requires additional information that demonstrates the benefits outweigh the risks.
- The FDA announcement highlights the difficulties in obtaining clearance through the de novo pathway where no predicate device exists (510k pathway).
- Additionally, RAP announced Sanofi has let expire its option to enter in exclusive negotiations for its direct-to-consumer product. While optically this doesn't read well, partnerships with other suitors are now possible.
- We have withdrawn our US commercialisation assumptions from our forecasts until more clarity regarding the ongoing FDA discussions is provided.
- Our price target reduces to A\$0.09, reflecting a weaker commercial outlook and general market volatility. We downgrade our recommendation to Hold (from Speculative Buy).

ResApp Health

Current price: A\$0.09 Target price: ▼ A\$0.086 Previous target: A\$0.40 Up/downside: 1.2% Reuters: RAP.AX Bloomberg: RAP AU Market cap: US\$39m A\$59m

HOLD (previously SPECULATIVE BUY)

Average daily turnover: US\$0.5m A\$0.7m Current shares o/s 693.0m Free float: 74.1%

Key changes in this note

FY20F net loss up by A\$0.8m.

FY21F net loss up by A\$5m.

FY22F net profit down by A\$9.7m.



 Price performance
 1M
 3M
 12M

 Absolute (%)
 -30.6
 -34.6
 61.9

 Relative (%)
 -12.3
 -20.2
 69.0

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Analyst(s) own shares in the following stock(s) mentioned in this report:

- ResApp Health

FDA says no, but leaves door open

RAP announced that the FDA has declined its de novo application for the ResApp-DX diagnostic. The result comes as a surprise with solid clinical data to back up its claims, and highlights the difficulties in obtaining clearance for new technologies through this process where no predicate devices currently exist. While disappointing, RAP and its regulatory consultants will apply for an in-person meeting with the FDA review team to determine a path forward. The FDA's response doesn't appear to be a firm no and has left the door slightly ajar with the requirement for RAP to solidify its case that there is a clear balance of benefit to patients. It is plausible that the process from in-person meeting to clearance could take over 12 months. In either case, the market is likely to write off the potential value of the US opportunity for the time being which we view as reasonable.

Sanofi options exercise lapses

Separately, albeit more optically than fundamentally, Sanofi's option to enter into exclusive negotiations for a pilot phase for its direct-to-consumer application has lapsed without being exercised. While in concert with the negative FDA news it doesn't read positively, the news will now allow RAP to continue to advance discussions with a number of interested parties previously put on hold while this option was still on the table.

Changes to forecasts – market opportunity halves

Due to the potential change in commercial applicability of the cough diagnostic, we have pared back all US commercialisation assumptions (included in our addressable market share assumptions) which was 50% of our long-term forecasts.

Investment view - downgrade to Hold

Due to the above changes, our DCF valuation reduces to A\$0.18 (from A\$0.40). We have also applied a short-term 50% discount to valuation while current market conditions persist and is reflective of heightened volatility and investor caution towards early-stage companies. Our target price reduces to A\$0.09 (from A\$0.40). The downside risk is a delay in signing contracts in Europe and the upside risk is signing a new direct to consumer partner. We downgrade our recommendation to a Hold (from Speculative Buy).

Financial Summary	Jun-18A	Jun-19A	Jun-20F	Jun-21F	Jun-22F
Revenue (A\$m)	1.0	0.0	1.6	6.0	12.0
Operating EBITDA (A\$m)	-6.5	-7.0	-5.5	-1.3	4.5
Net Profit (A\$m)	-6.5	-7.2	-5.7	-1.5	4.4
Normalised EPS (A\$)	-0.01	-0.01	-0.01	-0.00	0.01
Normalised EPS Growth	(34.9%)	5.4%	(24.9%)	(75.1%)	(394.0%)
FD Normalised P/E (x)					14.77
DPS (A\$)	0.000	0.000	0.000	0.000	0.000
Dividend Yield	0.00%	0.00%	0.00%	0.00%	0.00%
Franking (%)	0	0	0	0	0
EV/EBITDA (x)	-8.57	-7.61	-9.67	-41.92	10.79
P/FCFE (x)	NA	NA	NA	NA	15.5
Net Gearing	(60.4%)	(94.8%)	(97.5%)	(95.7%)	(95.9%)
P/BV (x)	10.11	10.43	11.14	12.29	6.10
ROE	(77.4%)	(129.4%)	(101.8%)	(27.2%)	55.6%

SOURCE: MORGANS, COMPANY REPORTS

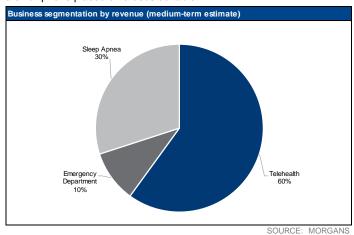


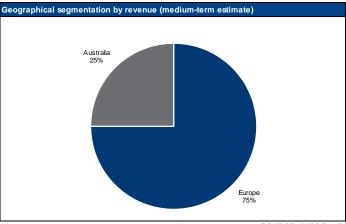
ResApp Health as at March 11, 2020

Market cap (A\$m):	59	Rating:	HOLD
Shares outstanding (m):	693.0	Price (A\$):	0.09
Free float (%):	74.1	Target price (A\$):	0.086
Website:	www.resapphealth.com.au	Upside/downside to target price (%):	1.2

Company description

ResApp Health Limited (RAP) is a digital health company developing smartphone applications for the diagnosis and management of respiratory disease. The technology is based on machine learning algorithms that use cough sounds to diagnose and measure the severity of respiratory conditions without the need for additional hardware. TECHNOLOGY: RAP was created to diagnose and measure the severity of a range of chronic and acute diseases such as pneumonia, asthma, bronchiolitis and chronic obstructive pulmonary disease (COPD) using this insight. ResApp has developed new machine-learning algorithms to measure the severity of OSA from a patient's overnight breathing and snoring sounds recorded using a smartphone placed on a bedside table.



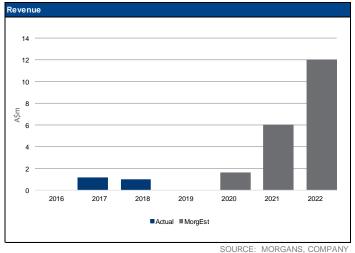


Assumptions	2018A	2019A	2020F	2021F	2022F
Clinical Revenue	2016A	2019A	20201	20216	20226
\$ Fee / test	5.0	5.0	5.0	5.0	5.0
Patient visits to ED/GP (m)	1,199	1,259	1.322	1,388	1.457
% present with respiratory	10%	10%	10%	10%	10%
Children/Adult split	25%	25%	35%	45%	45%
Total address market (m)	149.9	157.3	231.3	312.3	327.9
Market share	0.0%	0.0%	0.0%	0.0%	0.0%
Revenue- Clinical (US\$m)	0.0	0.0	0.0	0.0	0.0
Telehealth Revenue					
\$ Fee / test	4.0	4.0	4.0	4.0	4.0
# Providers	0	0	1	3	6
Avg consults p.a. / provider (m)	0	3	4	5	5
Patients presenting with problem	30%	30%	30%	30%	30%
Market addressable (childen/adults)	25%	25%	25%	25%	25%
Total address market (m)	0.00	0.00	0.30	1.13	2.25
Weighting within FY (%)	50%	100%	100%	100%	100%
Revenue- Telehealth (US\$m)	0.0	0.0	1.2	4.5	9.0
Revenue- Direct (US\$m)	0.0	0.0	0.0	0.0	0.0
Total revenue - ResApp (US\$m)	0.0	0.0	1.2	4.5	9.0
AUDUSD FX	0.75	0.75	0.75	0.75	0.75
Total revenue - ResApp (A\$m)	0.0	0.0	1.6	6.0	12.0

Milestone	table	
Timing	Milestone	Outcome
4QCY18	Top-line data from SMARTCOUGH-C-2	Mixed
2QCY19	File de novo premarket submission with FDA for lead pediatric product	Achieved
1QCY19	File for CE Mark in Europe for lead pediatric product	Achieved
1QCY19	SMARTCOUGH-C-2 Croup results	Insufficient data
2QCY19	Additional Australian adult study results	Achieved
3QCY19	CE Mark Clearance for pediatric application	Achieved
3QCY19	CE Mark Clearance for adult application	Achieved
4QCY19	Sleep Apnea study top-line readouts	Achieved
2QCY20	TGA clearance for Adult product	Achieved
2QCY20	FDA clearance for lead pediatric product	Failed
3QCY20	Lodgement of CE Mark submission for OSA	
3QCY20	Coviu integration	
3QCY20	Initial telehealth agreement EU	

SOURCE: MORGANS

SOURCE: MORGANS, COMPANY



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Key drivers / risks Key Drivers

providers and primary care physicians

Catalysts - FDA clearance and initial commercialisation.

Key risks:

Regulatory clearances yet to be received from FDA in the US (largest single potential revenue

Objective and repeatable - the trend towards medical diagnostics being both objective and repeatable.

Scalability - the low cost nature of the technology makes it easily scaleable for the tele-health

Clinical - a number of trials are yet to read out - poor results could impact the ability to commercialise the technology.

Funding risk - delays in receiving clearances could impact the commercialisation timelines resulting in further working capital being required.

FX risk - Main source of revenues are expected to be generated in overseas jurisdictions.

SOURCE: MORGANS, COMPANY



Income statement	FY18A	FY19A	FY20F	FY21F	FY22F	Valuation metrics						
						Share price (A\$)	0.085		Price Ta	arget (A\$)		\$0.086
Total revenue	1.0	0.0	1.6	6.0	12.0	DCF valuation inputs		г				
EBITDA	-6.5	-7.0	-5.5	-1.3	4.5	Rf	4.00%		10-year ra	te		4.009
Associate income	0.0	0.0	0.0	0.0	0.0	Rm-Rf	5.00%		Margin			2.09
Depreciation	0.0	0.0	0.0	0.0	0.0	Beta	1.70		Kd			4.209
EBITA	-6.6	-7.3	-5.8	-1.6	4.3	CAPM (Rf+Beta(Rm-Rf))	12.5%		Ke			12.59
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0	F '. (F/F) A	100.00/			flow (A\$m)	,	119.
EBIT	-6.6	-7.3	-5.8	-1.6	4.3	Equity (E/EV)	100.0%		-	erest (A\$m)	0.
Net interest expense	0.1	0.1	0.1	0.1	0.1	Debt (D/EV)	0.0%		Net debt (A			-5.
Pre-tax profit	-6.5 0.0	-7.2	-5.7	-1.5	4.4	Interest rate	4.20%		Investmen	,	۱۴۰۰۰)	0.
Income tax expense		0.0 -7.2	0.0	0.0	0.0	Tax rate (t) WACC	30.0%			ket value (A		125
After-tax profit	-6.5 0.0	0.0	-5.7 0.0	-1.5 0.0	4.4 0.0	WACC	12.5%			of shares	(111)	726. \$0.1 7
Minority interests NPAT	-6.5	-7.2	-5.7	-1.5	4.4				DCF	valuation		Φ 0.17
Significant items	0.0	0.0	0.0	0.0	0.0	Multiples		FY18A	FY19A	FY20F	FY21F	FY22
NPAT post abnormals	-6.5	-7.2	-5.7	-1.5	4.4	Enterprise value (A\$m)		65.2	67.2	67.2	66.7	71.
NFAT post abilioritials	-0.5	-1.2	-3.1	-1.3	4.4	EV/Sales (x)				42.0	11.1	6.
Cash flow statement	FY18A	FY19A	FY20F	FY21F	FY22F	EV/Sales (x) EV/EBITDA (x)		na -10.0	na -9.5	-12.1	-51.8	Ծ. 15.
EBITDA	-6.5	-7.0	-5.5	-1.3	4.5	EV/EBIT (x)		-10.0	-9.5 -9.2	-12.1	-31.6 -42.8	16.
Change in working capital	0.2	1.6	-5.5 -0.1	-1.3 -0.4	-0.5	PE (x)		-9.6 - 8.6	-9.2 -8.1	-11.6 -10.8	-42.0 -43.4	14.
Net interest (pd)/rec	0.2	0.1	0.1	0.1	0.1	PEG x)		-0.2	1.5	-0.4	-0.6	0.
Taxes paid	0.0	0.0	0.0	0.0	0.0	0 / /		-0.2	1.5	-U. -1	-0.0	0.
Other oper cash items	0.0	0.0	0.0	0.0	0.0							
Cash flow from ops (1)	-6.2	-5.3	-5.5	-1.5	4.1	Per share data		FY18A	FY19A	FY20F	FY21F	FY22
Capex (2)	0.0	0.0	0.0	0.0	0.0	No. shares		659.0	659.0	693.0	726.0	741.
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0	EPS (cps)		-1.0	-1.0	-0.8	-0.2	0.
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	Dividend per share (c)		0.0	0.0	0.0	0.0	0.
Cash flow from investing (3)	0.0	0.0	0.0	0.0	0.0	Dividend payout ratio (%)		0.0%	0.0%	0.0%	0.0%	0.09
Incr/(decr) in equity	0.0	7.5	5.8	1.2	1.2	Dividend yield (%)		0.0%	0.0%	0.0%	0.0%	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0	,,,,,				0.070	21272	
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0	Growth ratios		FY18A	FY19A	FY20F	FY21F	FY22
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0							
Other financing cash flow	0.0	0.0	0.0	0.0	0.0	Sales growth		na	na	na	275.0%	100.09
Cash flow from fin (5)	0.0	7.5	5.8	1.2	1.2	Operating cost growth		-32.6%	-6.0%	1.4%	2.2%	2.69
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0	EBITDA growth		34.9%	-8.5%	21.4%	76.7%	451.29
Inc/(decr) cash (1+3+5+6)	-6.2	2.1	0.3	-0.3	5.4	EBITA growth		35.3%	-10.4%	20.6%	73.2%	373.39
Equity FCF (1+2+4)	-6.2	-5.3	-5.5	-1.5	4.1	EBIT growth		35.3%	-10.4%	20.6%	73.2%	373.39
1- 9 - ()						NPAT growth		34.9%	-10.8%	21.3%	74.5%	399.99
Balance sheet	FY18A	FY19A	FY20F	FY21F	FY22F	Normalised EPS growth		34.9%	-5.4%	24.9%	75.0%	393.99
Cash & deposits	3.4	5.4	5.5	5.0	10.1	· ·						
Trade debtors	0.0	0.0	0.1	0.2	0.5	Operating performance		FY18A	FY19A	FY20F	FY21F	FY22
Inventory	0.0	0.0	0.1	0.3	0.6	Asset turnover (%)		2.7	0.0	4.9	19.0	28.
Other current assets	1.0	1.0	1.0	1.0	1.0	EBITDA margin (%)		na	na	-345.9	-21.5	37.
Goodwill	0.0	0.0	0.0	0.0	0.0	EBIT margin (%)		na	na	-362.7	-26.0	35.
Other intangible assets	2.0	1.8	1.5	1.2	0.9	Net profit margin (%)		na	na	-356.1	-24.2	36.
Fixed assets	0.0	0.0	0.0	0.0	0.0	Return on net assets (%)			-105.6	-20.5	-90.2	-119.
Investments	0.0	0.0	0.0	0.0	0.0	Net debt (A\$m)		-3.3	-5.4	-5.4	-4.9	-10.
Other assets	0.0	0.0	0.0	0.0	0.0	Net debt/equity (%)		-60.4	-94.8	-97.5	-95.7	-95.
Total assets	6.5	8.1	8.1	7.7	13.2	Net interest/EBIT cover (x)					
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	Invested capital		2.4	1.9	0.0	-0.1	-0.
Trade payables	8.0	2.3	2.3	2.4	2.5	ROIC (%)		-275.2	-376.1	-24191.5	1104.9	-8686.
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	Internal liquidity		FY18A	FY19A	FY20F	FY21F	FY22
Other term liabilities	0.1	0.1	0.1	0.1	0.1	Current ratio (x)		5.8	2.8	2.8	2.7	5.
Other liabilities	0.0	0.0	0.0	0.0	0.0	Receivables turnover (x)		15.7	0.0	48.7	38.4	32.
Total liabilities	1.0	2.5	2.5	2.6	2.6	Payables turnover (x)		11.0	4.6	3.1	3.1	3.
Share capital	21.8	29.3	35.1	36.3	37.5							
Other reserves	7.1	7.1	7.1	7.1	7.1							
Retained earnings	-23.3	-30.7	-36.6	-38.2	-34.1							
Other equity	0.0	0.0	0.0	0.0	0.0							
Total equity	5.5	5.7	5.5	5.1	10.5							
Minority interest	0.0	0.0	0.0	0.0	0.0							
Total shareholders' equity	5.5	5.7	5.5	5.1	10.5							
	6.5	8.1	8.1	7.7	13.2							
Total liabilities & SE	0.0											



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Regulatory disclosures

Analyst owns shares in the following mentioned company(ies): ResApp Health

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For a full explanation of the recommendation structure, refer to our website at morgans.com.au/research_disclaimer

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