EDISON

Respiri

H123 results

Strong momentum heading into FY24

Healthcare equipment

Respiri's H123 report summarised an eventful period, marked by commercial traction (six client wins; patient onboarding commenced at four centres) and recognition of the first remote patient monitoring (RPM) revenue from the Centers for Medicare & Medicaid Services (CMS). H123 revenues were A$0.6m (primarily R&D tax credits), lower than A$0.7m in H122, but we expect (wheezo-related) product sales to ramp up with increased patient onboarding and associated annuity income. The partnership-based US commercial strategy, along with tight checks on expenses, benefited operating performance, with the adjusted EBITDA loss improving 15% y-o-y to A$2.3m. The end-H123 cash balance of A$0.2m was bolstered by the A$1.9m post-period equity raise, which we estimate will provide runway into Q124. We adjust our estimates to reflect H123 performance and FX changes, which resulting in revising our valuation to A$165.5m or A$0.20/share (from A$189.1m or A$0.24/share previously).

Year end	Revenue (A$m)	EBITDA* (A$m)	PBT* (A$m)	EPS* (c)	P/revenue (x)	P/E (x)
06/21	1.4	(8.4)	(8.5)	(1.22)	28.2	N/A
06/22	0.8	(6.2)	(6.3)	(0.87)	52.4	N/A
06/23e	1.7	(4.2)	(4.2)	(0.51)	23.6	N/A
06/24e	5.9	(1.1)	(1.1)	(0.13)	6.9	N/A

Note: *EBITDA, PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. FY23 and FY24 EPS are adjusted for new shares.

Prelude to a busy period

With patient onboarding gaining speed towards the end of H123, we expect overall product revenue for the year to be back-end loaded with a sharper uptick from FY24 onwards, contingent on initial user feedback. The sales pipeline remains full, with 120+ leads and several discussions in advanced stages, according to management. We adjust our estimates (revenues and costs) based on the H123 results and near-term visibility, reducing FY23 and FY24 sales expectations while keeping peak sales potential unchanged. Our revised model now predicts that Respiri will turn EBITDA positive in FY25 (versus FY24 previously), in line with management's latest guidance.

New funding offers headroom to end FY23

Respiri's partner-based business model and cost optimisation efforts have allowed it to preserve cash (primarily through lower sales and marketing expenses), although external funding is still required. At our projected burn rates, the pro forma gross cash balance (A$2.2m) should fund operations into Q124, but we estimate the need to raise another A$2m in FY24 (subject to top-line contribution). We expect break-even at c 40,000 unit sales (device plus monthly fee) for wheezo (by FY25).

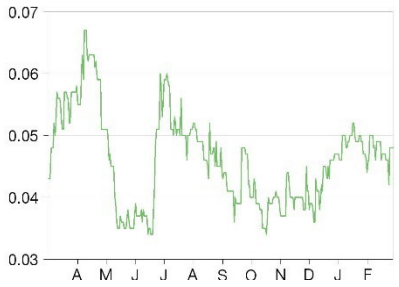
Valuation: A$165.5m or A$0.20 per share

We adjust our FY23 and FY24 estimates to reflect the latest FX rates, H123 performance and near-term operational visibility. Our revised valuation stands at A$165.5m or A$0.20/share (previously A$189.1m or A$0.24/share) including A$2.2m pro forma gross cash.

1 March 2023

Price	**A$0.048**
Market cap	**A$40m**
	US$0.67/A$
Pro forma gross cash (A$m) at 28 February 2023 (including gross proceeds of Jan/Feb raise)	2.2
Shares in issue (including 38.7m shares issued under Jan/Feb SPP)	842.4m
Free float	79.6%
Code	RSF, RSUF
Primary exchange	ASX
Secondary exchange	OTCQB

Share price performance



%	1m	3m	12m
Abs	2.1	26.3	14.3
Rel (local)	6.1	26.8	12.0
52-week high/low	A$0.07	A$0.03	

Business description

Respiri is an Australia-based medical device and SaaS company focused on respiratory health management through its integrated wheezo platform. The device is a breath sensor that works with the Respiri mobile applications to record data such as wheeze rates, breath recordings and other environmental factors and medication usage, which can be accessed by physicians in real time. wheezo received FDA clearance in March 2021 and was launched in the US in December 2021.

Next events

New client wins and patient onboarding	2023

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Edison profile page

US commercial strategy gaining traction

H123 was characterised by improving commercial traction in wheezo, Respiri's proprietary respiratory monitoring device, with multiple new contracts signed, taking the total client count to six at the end of the period. According to the latest available information, four of the six facilities have commenced patient enrolment, with 20 patients onboarded and a further 500 prospective patients identified. In our opinion, patient enrolment in the RPM programme marks an important step for the company, highlighting early acceptance from physicians/pulmonologists of the potential utility of the wheezo device for active, real-time monitoring of asthma/chronic obstructive pulmonary disease (COPD) patients. More importantly, Respiri has now recognised the initial receipt of claim inflows from the CMS (albeit not financially material at this stage), which provides early validation of the its US commercial strategy, in our opinion.

As a reminder, wheezo was launched in the US in December 2021, under a partner-based model (in collaboration with two telehealth providers, Access Telehealth and mTelehealth) to leverage the RPM reimbursement infrastructure in the country (currently mandated for reimbursement by the CMS in 28 of the 50 US states). Respiri's US revenue model is made up of two distinct revenue streams: device sales (US$50–60 per unit) and monthly service fees (US$10–20 per patient per month, based on the type of RPM services subscribed to; please refer to our initiation note for more details). All six new accounts have been contracted in collaboration with Access Telehealth and include the full suite of services (including real-time patient monitoring using Access Telehealth's platform, Remotli).

We note that the new accounts signed include a mix of large specialist hospitals and primary care facilities across six different US states, as well as diverse patient populations (ranging from paediatric to the elderly) and indications (asthma, COPD, cardiovascular disease patients with COPD comorbidities and other respiratory complications), highlighting the wide potential applicability and utility of wheezo in the RPM setting. Importantly, the specialist hospitals signed are part of large healthcare networks, which creates opportunities for Respiri to effect a broader roll-out provided early user feedback is positive. Below we provide a list of the current clients signed:

- **Michigan Children's Hospital:** first agreement signed in March 2022 with pilot programme assessing the wheezo platform (Respiri and partner Access Telehealth) concluded in February 2023. wheezo will now be included in the hospital's current standard of care for eligible asthma patients. We see this as a major opportunity for Respiri given that the paediatric population is likely to obtain the most utility from wheezo (as children are unable to self-monitor their asthma symptoms). Moreover, the Michigan Children's Hospital is part of the NYSE-listed Tenet Healthcare Corporation, which operates more than 60 hospitals and 110 outpatient centres across the US and recorded revenues of US$19.2bn in 2022. Successful uptake and feedback from the wheezo RPM programme at the hospital should facilitate a broader roll-out of the device to the group's entities.
- **Undisclosed North Carolina-based healthcare organisation focused on COPD:** initial agreement signed in August 2022 and patient onboarding commenced in January 2023. We note that the customer is part of a larger healthcare network focused on the region, which manages more than 60,000 inpatient admissions, 187,000 emergency department visits and 2,000,000 outpatient visits per year. According to Respiri, this translates to 25,000 emergency department visits and more than 250,000 outpatient visits for respiratory conditions, a number of which would likely be eligible for the wheezo RPM programme. We therefore believe a strong display of clinical utility from the initial patients could create an opportunity to accelerate adoption across the broader healthcare network and expand wheezo's market potential.

- **Minnesota Lung Center (MLC):** agreement signed in November 2022 for an initial three-month pilot study (subsequently reduced to two months) in patients with asthma and COPD. MLC is a leading private pulmonary practice based in Minneapolis focused on lung diseases, respiratory therapies and diagnostics. Notably, the centre employs nine pulmonologists (a general hospital would typically have two to three), which we believe provides Respiri with a greater opportunity to broaden awareness and showcase the utility of its flagship wheezo device to relevant stakeholders in the healthcare community. We see this deal as especially meaningful given MLC's core focus on respiratory diseases.
- **Arkansas Heart Hospital (AHH):** agreement signed in November 2022 for the full suite of RPM services, including Remotli, remote monitoring and patient engagement. AHH is one of the largest privately held cardiovascular disease (CVD) focused hospitals in the US and the wheezo programme was selected as an add-on to the current standard of care for CVD patients who also suffer from COPD. According to a scientific journal published in 2018, the prevalence of COPD ranges between 13% and 39% in heart failure patients and between 10 and 15% in cases of atrial fibrillation. Moreover, one-third of patients with ischemic heart disease are believed to also suffer from COPD.
- **Medical Center of Conyers (family practice):** agreement signed in December 2022, making it the first private practice to be signed by Respiri and involves managing patients suffering from asthma and COPD. First patients have been onboarded.
- **Hand Family Healthcare (primary care practice):** agreement signed in December 2022. Hand Family Healthcare caters for a large rural population that lacks easy proximity to large speciality hospitals, making primary care facilities critically important to healthcare management. With its ease of use and RPM feature, we believe wheezo is well suited for such centres and their patient populations.

Opportunities beyond wheezo and the US

While the near-term priorities for Respiri continue to centre around wheezo's US roll-out, we see incremental opportunity in the medium term from commercial operations in other geographies (particularly the UK) and launch of the company's wearable device, Sorfe. The wearable device is being designed as a continuous monitoring means of capturing physiological data to assess asthma/COPD symptoms. Unlike wheezo, which monitors breathing sounds when placed against the trachea, Sorfe will be a wearable (to be worn on the chest) to support continual monitoring, which could help track the treatment regime and pre-empt the chance of exacerbation. Sorfe will be focused on tracking and monitoring nocturnal asthma symptoms and hospital transition care (for recently discharged patients) and is being positioned as an extension to wheezo. Development work on the device is progressing, with the first version of the algorithm developed to process physiological data and calculate the parameters used in continuous overnight monitoring of asthma/COPD symptoms successfully. Respiri is currently working on refining the product to allow real-time display of physiological data. Management expects to commence preliminary clinical studies with Sorfe in March/April 2023 with the target of obtaining FDA clearance by FY24. The company is also targeting launch for wheezo in the UK in FY24, which should further support top-line growth. Note that our model currently does not incorporate Sorfe and geographies other than the US and subsequent inclusion of these therefore presents upside opportunities to our valuation.

Financials: Cost optimisation efforts bearing fruit

Respiri reported H123 revenues of A$597k (A$659k in H122), which includes A$587k in R&D tax credit and grants received from the Australian government, A$8.4k in wheezo device sales and A$1.4k in subscription sales and RPM fees. With patient onboarding gaining speed, we estimate

that product sales figures will increase in the coming quarters, although we now assume a comparatively slower ramp-up in FY23 and FY24, based on the H123 results and near-term sales visibility. Our model new assumes sales of A$1.7m and A$5.9m in FY23 and FY24, respectively, versus A$5.0m and A$8.1m previously. However, our long-term outlook and peak sales expectations are unchanged.

Respiri's efforts to achieve a slimmer cost base were reflected in the operating results for the period, particularly in materially lower selling and marketing expenses (A$81k in H123 versus A$524k in H122), courtesy of the partnered RPM model it applies in the US, with the telehealth partner shouldering the majority of the sales and marketing efforts, with some support from Respiri. R&D expenses were also below our estimates, coming in at A$330k in H123, a y-o-y decline of 44%. This was partially offset by higher employee-related expenses (A$1.7m versus A$1.5m in H122). Overall, the H123 reported operating loss declined by 15% y-o-y to A$2.6m. We have made adjustments to our expense forecasts (reducing R&D and SG&A estimates and increasing payroll-related costs) based on the H123 figures. Our revised EBITDA estimates for FY23 and FY24 are a loss of A$4.2m and A$1.1m, respectively, versus a loss of A$2.3m in FY23 and profit of A$0.4m in FY24, previously.

The period-end cash balance stood at A$0.2m, which was bolstered by the January/February 2023 equity issue (38.7m shares at A$0.05/share), raising A$1.9m in gross proceeds. Based on our cash burn projections, we estimate the need to raise another A$2m in FY24 to reach profitability in FY25, provided sales targets are achieved. Our model incorporates the additional funding as illustrative debt but, assuming the funds are raised through an equity issue (at the current trading price of A$0.05/share), Respiri will need to issue another 40m shares, resulting in our per-share valuation readjusting to A$0.19/share. Overall, based on our revised assumptions, we expect the company to become EBITDA positive in FY25 versus our previous estimate of FY24.

Valuation

We value Respiri using a risk-adjusted NPV methodology based on the epidemiology-based approach to estimate the market opportunity. Given the very early stage of commercialisation, we continue to assume a peak penetration rate of 2% of the addressable population. Please refer to our initiation note for details on our model assumptions. Following the aforementioned changes to our estimates, updated FX rates and pro forma net cash position, our overall valuation readjusts to A$165.5m (A$189.1m previously). In addition, the per-share valuation is affected by a higher share count following the January/February equity issue, resetting at A$0.20/share from A$0.24/share previously.

Exhibit 1: Respiri risk-adjusted NPV

Product	Indication	Geography	Clinical stage	Launch	Peak	Peak sales (US$m)	NPV (A$m)	Probability	rNPV (A$m)	rNPV/ share* (A$)
Wheezo	Asthma and COPD	United States	FDA 510 (k) clearance	2022	2035	108.4	163.3	100%	163.3	0.19
Pro forma net cash (including Jan/Feb 2023 share placement)							2.2	100%	2.2	0.00
Valuation							**165.5**		**165.5**	**0.20**

Source: Edison Investment Research. Note: *Shares outstanding = 842.4m (including 38.7m from the January/February placement).

Exhibit 2: Financial summary

A$'000s	2021	2022	2023e	2024e
Year-end June	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	1,436	772	1,712	5,872
Cost of Sales	(1,263)	(259)	(134)	(541)
Gross Profit	173	513	1,578	5,331
R&D expenses	(1,387)	(1,463)	(878)	(1,094)
Sales & marketing expenses	(2,185)	(917)	(229)	(809)
General & corporate expenses	(5,032)	(4,371)	(4,630)	(4,508)
EBITDA	(8,432)	(6,238)	(4,159)	(1,079)
Depreciation	(80)	(82)	(40)	(26)
Amortisation	0	0	0	0
Operating Profit (before amort. and except.)	(8,512)	(6,320)	(4,199)	(1,105)
Intangible Amortisation	0	0	0	0
Share-based payments	(2,530)	(311)	(289)	(303)
Exceptionals	0	0	0	0
Operating Profit	(11,042)	(6,631)	(4,487)	(1,409)
Net Interest	1	7	2	1
Profit Before Tax (norm)	(8,510)	(6,313)	(4,197)	(1,105)
Profit Before Tax (reported)	(11,040)	(6,624)	(4,485)	(1,408)
Tax	0	0	0	0
Profit After Tax (norm)	(8,510)	(6,313)	(4,197)	(1,105)
Profit After Tax (reported)	(11,040)	(6,624)	(4,485)	(1,408)
Average Number of Shares Outstanding (m)	699.1	728.6	823.1	842.4
EPS - normalised fully diluted (c)	(1.22)	(0.87)	(0.51)	(0.13)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	162	83	60	51
Intangible Assets	0	0	0	0
Tangible Assets	162	83	60	51
Investments	0	0	0	0
Current Assets	8,945	4,123	2,788	3,466
Stocks	537	2,651	2,262	2,520
Debtors	136	50	112	383
Cash	7,973	1,217	210	359
Other	299	204	204	204
Current Liabilities	(1,467)	(1,198)	(871)	(948)
Creditors	(1,295)	(790)	(674)	(751)
Short term borrowings	0	0	0	0
Other current liabilities	(172)	(408)	(198)	(198)
Long Term Liabilities	(71)	0	0	(2,000)
Long term borrowings	0	0	0	(2,000)
Other long term liabilities	(71)	0	0	0
Net Assets	7,570	3,008	1,976	568
CASH FLOW				
Operating Cash Flow	(7,339)	(8,478)	(4,444)	(1,834)
Net Interest	1	7	2	1
Tax	0	0	0	0
Capex	(54)	(2)	(17)	(18)
Acquisitions/disposals	0	0	0	0
Financing	12,533	1,639	3,454	0
Dividends	0	0	0	0
Net Cash Flow	5,141	(6,834)	(1,005)	(1,851)
Opening net debt/(cash)	(2,835)	(7,973)	(1,217)	(210)
Other	(3)	78	(2)	(1)
Closing net debt/(cash)	(7,973)	(1,217)	(210)	1,641

Source: Company accounts, Edison Investment Research

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